at least January 1, 2003, any changes in medicaid regulations that modify the medicaid upper payment limit for non-State Government-owned or operated hospitals.

S. 1749

At the request of Mr. KENNEDY, the names of the Senator from New Mexico (Mr. BINGAMAN), the Senator from New York (Mr. SCHUMER), the Senator from Nebraska (Mr. HAGEL), and the Senator from Nevada (Mr. REID) were added as cosponsors of S. 1749 , a bill to enhance the border security of the United States, and for other purposes.

S. 1757

At the request of Mr. CRAIG, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. 1757, a bill to authorize an additional permanent judgeship in the district of Idaho, and for other purposes.

S.J. RES. 12

At the request of Mr. SMITH of New Hampshire, the name of the Senator from Maine (Ms. SNOWE) was added as a cosponsor of S.J. Res. 12, a joint resolution granting the consent of Congress to the International Emergency Management Assistance Memorandum of Understanding.

AMENDMENT NO. 2152

At the request of Mr. DEWINE, the name of the Senator from Hawaii (Mr. INOUYE) was added as a cosponsor of amendment No. 2152 intended to be proposed to H.R. 3090, a bill to provide tax incentives for economic recovery.

AMENDMENT NO. 2157

At the request of Mr. MCCAIN, the name of the Senator from Vermont (Mr. JEFFORDS) was added as a cosponsor of amendment No. 2157 intended to be proposed to H.R. 3090, a bill to provide tax incentives for economic recovery.

AMENDMENT NO. 2202

At the request of Mr. CONRAD, his name was added as a cosponsor of amendment No. 2202.

STATEMENTS ON INTRODUCED BILLS AND JOINTS RESOLUTIONS

By Mr. THOMAS (for himself and Mrs. LINCOLN):

S. 1760. A bill to amend title XVIII of the Social Security Act to provide for the coverage of marriage and family therapist services and mental health counselor services under part B of the Medicare Program, and for other purposes; to the Committee on Finance.

Mr. THOMAS. Mr. President, I am pleased to rise today to introduce the Seniors Mental Health Access Improvement Act of 2001 with my distinguished colleague from Arkansas, Mrs. LINCOLN. Specifically, the Seniors Mental Health Access Improvement Act of 2001 permits mental health counselors and marriage and family therapists to bill Medicare for their services. This will result in an increased choice of providers for seniors and enhance their ability to access mental health services in their communities.

This legislation is especially crucial to rural seniors who are often forced to travel long distances to utilize the services of mental health providers currently recognized by the Medicare program. Rural communities have difficulty recruiting and retaining providers, especially mental health providers. In many small towns a mental health counselor or a marriage and family therapist is the only mental health care provider in the area. Medicare law, as it exists today, compounds the situation because only psychiatrists, clinical psychologists, clinical social workers and clinical nurse specialists are able to bill Medicare for their services.

It is time the Medicare program recognized the qualifications of mental health counselors and marriage and family therapists as well as the critical role they play in the mental health care infrastructure. These providers go through rigorous training, similar to the curriculum of masters level social workers, and yet are excluded from the Medicare program.

Particularly troubling to me is the fact that seniors have disproportionally higher rates of depression and suicide than other populations. Additionally, 75 percent of the 518 nationally designated Mental Health Professional Shortage Areas are located in rural areas and one-fifth of all rural counties have no mental health services of any kind. Frontier counties have even more drastic numbers as 95 percent do not have a psychiatrist, 68 percent do not have a psychologist and 78 percent do not have a social worker. It is quite obvious we have an enormous task ahead of us to reduce these staggering statistics. Providing mental health counselors and marriage and family therapists the ability to bill Medicare for their services is a key part of the solution.

Virtually all of my State of Wyoming is a mental health professional shortage area and will greatly benefit from this legislation. Wyoming has 169 psychologists, 121 psychiatrists, and 247 social workers for a total of 537 Medicare eligible mental health providers. Enactment of the Seniors Mental Health Access Improvement Act of 2001 will double the number of mental health providers available to seniors in my State with the addition of 517 mental health counselors and 55 marriage and family therapists currently licensed in the State.

In crafting this legislation Senator LINCOLN and I worked with numerous outside organizations with an interest in this issue. As a result of this collaboration, the ''Seniors Mental Health Access Improvement Act of 2001'' is strongly supported by the American Counseling Association, the Wyoming Counseling Association, the American Mental Health Counselors Association, the Arkansas Mental Health Counselors Association, the American Association for Marriage and Family Therapy, the Wyoming and Arkansas Chapters of the Association for Marriage and Family Therapy, the California Association of Marriage and Family Therapists, and the National Rural Health Association.

I believe this legislation is critically important to the health and well-being of our Nation's Seniors and I strongly urge all my colleagues to become a cosponsor.

Mr. President, I ask unanimous consent that the text of the bill and letters of endorsement from supporting organizations be printed in the RECORD.

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

S. 1760

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 ''Seniors Mental Health Access Improvement Act of 2001''.

SEC. 2. COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES UNDER PART B OF THE MEDICARE PROGRAM.

(a) COVERAGE OF SERVICES.—

(1) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by sections 102(a) and 105(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–468 and 2763A–471), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended—

(A) in subparagraph (U), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (V)(iii), by inserting ''and'' after the semicolon at the end; and

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

''(W) marriage and family therapist services (as defined in subsection (ww)(1)) and mental health counselor services (as defined in subsection (ww)(3));''.

(2) DEFINITIONS.—Section 1861 of such Act (42 U.S.C. 1395x), as amended by sections 102(b) and 105(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–468 and 2763A–471), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended by adding at the end the following new subsection:

''Marriage and Family Therapist Services; Marriage and Family Therapist; Mental Health Counselor Services; Mental Health Counselor

''(ww)(1) The term 'marriage and family therapist services' means services performed by a marriage and family therapist (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses, which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

''(2) The term 'marriage and family therapist' means an individual who—

''(A) possesses a master's or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

''(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

''(C) in the case of an individual performing services in a State that provides for licensure or certification of marriage and family therapists, is licensed or certified as a marriage and family therapist in such State.

''(3) The term 'mental health counselor services' means services performed by a mental health counselor (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

''(4) The term 'mental health counselor' means an individual who—

''(A) possesses a master's or doctor's degree in mental health counseling or a related field;

''(B) after obtaining such a degree has performed at least 2 years of supervised mental health counselor practice; and

''(C) in the case of an individual performing services in a State that provides for licensure or certification of mental health counselors or professional counselors, is licensed or certified as a mental health counselor or professional counselor in such State.''.

(3) PROVISION FOR PAYMENT UNDER PART B.—Section 1832(a)(2)(B) of such Act (42 U.S.C. 1395k(a)(2)(B)) is amended by adding at the end the following new clause:

''(v) marriage and family therapist services and mental health counselor services;''.

(4) AMOUNT OF PAYMENT.—Section 1833(a)(1) of such Act (42 U.S.C. 1395*l*(a)(1)), as amended by sections 105(c) and 223(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–472 and 2763A–489), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended—

(A) by striking ''and (U)'' and inserting ''(U)''; and

(B) by inserting before the semicolon at the end the following: '', and (V) with respect to marriage and family therapist services and mental health counselor services under section 1861(s)(2)(W), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under clause (L)''.

(5) EXCLUSION OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)) is amended—

(A) in paragraph (2)(A)(i)(II), by striking ''clauses (ii) and (iii)'' and inserting ''clauses (ii) through (iv)''; and

(B) by adding at the end of paragraph (2)(A) the following new clause:

''(iv) EXCLUSION OF CERTAIN MENTAL HEALTH SERVICES.—Services described in this clause are marriage and family therapist services (as defined in section 1861(ww)(1)) and mental health counselor services (as defined in section 1861(ww)(3)).''.

(6) INCLUSION OF MARRIAGE AND FAMILY THERAPISTS AND MENTAL HEALTH COUNSELORS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) of such Act (42 U.S.C. 1395u(b)(18)(C)), as amended by section 105(d) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–472), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended by adding at the end the following new clauses:

''(vii) A marriage and family therapist (as defined in section 1861(ww)(2)).

''(viii) A mental health counselor (as defined in section 1861(ww)(4)).''.

(b) COVERAGE OF CERTAIN MENTAL HEALTH SERVICES PROVIDED IN CERTAIN SETTINGS.—

(1) RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1861(aa)(1)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(1)(B)) is amended by inserting '', by a marriage and family therapist (as defined in subsection (ww)(2)), by a mental health counselor (as defined in subsection (ww)(4)),'' after ''by a clinical psychologist (as defined by the Secretary)''.

(2) HOSPICE PROGRAMS.—Section 1861(dd)(2)(B)(i)(III) of such Act (42 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by inserting ''or a marriage and family therapist (as defined in subsection (ww)(2))'' after ''social worker''.

(c) AUTHORIZATION OF MARRIAGE AND FAMILY THERAPISTS TO DEVELOP DISCHARGE PLANS FOR POST-HOSPITAL SERVICES.—Section 1861(ee)(2)(G) of the Social Security Act (42 U.S.C. 1395x(ee)(2)(G)) is amended by inserting ''marriage and family therapist (as defined in subsection (ww)(2)),'' after ''social worker,''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to services furnished on or after January 1, 2002.

AMERICAN COUNSELING ASSOCIATION,
Alexandria, VA, November 27, 2001.

Hon. CRAIG THOMAS,
U.S. Senate,
Washington, DC.

DEAR SENATOR THOMAS: I am writing on behalf of the American Counseling Association, which with over 53,000 members is the nation's largest non-profit membership organization representing state-licensed professional mental health counselors, to express our strong support for your legislation, the ''Seniors Mental Health Access Improvement Act of 2001''. We applaud your leadership in introducing this legislation.

Medicare's mental health benefit currently excludes two core mental health professions: licensed professional counselors and licensed marriage and family therapists. Statistics such as those included in the attached fact sheet show that Medicare beneficiaries are not getting the mental health treatment they need. Lack of access to providers is one of the primary factors involved.

As with other areas of health care, accessing mental health services is especially problematic in rural areas. In many underserved communities, licensed professional counselors are the only mental health specialists available. We feel strongly that proposals to improve rural Medicare beneficiaries' access to mental health care must include expanding the pool of covered providers. However, access to providers is not only a rural issue. An article cited on the enclosed fact sheet, recently published by the American Psychiatric Association, states that ''the supply of both specialists and resources cannot meet current or future demands'' for mental health treatment of older Americans.

Coverage of licensed professional counselors under Medicare is a common-sense step toward ensuring that all beneficiaries get the help they need. There are over 81,000 professional counselors licensed as master's level mental health professionals in Wyoming and 44 other states across the country. These providers meet education, training, and examination requirements on par with those of clinical social workers, who have been covered under Medicare for over ten years.

Thank you for your leadership in introducing this important legislation. We look forward to working with you to gain its enactment, and I urge you and your staff to call on us if we can be of any assistance.

Sincerely,

JANE GOODMAN,
President.

AMERICAN COUNSELING ASSOCIATION,
Alexandria, VA, November 27, 2001.

Hon. BLANCHE L. LINCOLN,
U.S. Senate,
Washington, DC.

DEAR SENATOR LINCOLN: I am writing on behalf of the American Counseling Association, which with over 53,000 members is the nation's largest non-profit membership organization representing state-licensed professional mental health counselors, to express our strong support for your legislation, the ''Seniors Mental Health Access Improvement Act of 2001''. We applaud your leadership in introducing this legislation.

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As with other areas of health care, accessing mental health services is especially problematic in rural areas. In many underserved communities, licensed professional counselors are the only mental health specialists available. We feel strongly that proposals to improve rural Medicare beneficiaries' access to mental health care must include expanding the pool of covered providers. However, access to providers is not only a rural issue. An article cited on the enclosed fact sheet, recently published by the American Psychiatric Association, states that ''the supply of both specialists and resources cannot meet current or future demands'' for mental health treatment of older Americans.

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Thank you for your leadership in introducing this important legislation. We look forward to working with you to gain its enactment, and I urge you and your staff to call on us if we can be of any assistance.

Sincerely,

JANE GOODMAN,
President.

WYOMING COUNSELING ASSOCIATION,
November 27, 2001.

Hon. CRAIG THOMAS,
U.S. Senate,
Washington, DC

DEAR SENATOR THOMAS: The Wyoming Counseling Association is pleased to convey its strong support of your legislation, the ''Seniors Mental Health Access Improvement Act of 2001''. We are proud of your leadership on mental health issues, as evidenced by your introduction of this and other legislation, and your support of S. 543, the ''Mental Health Equitable Treatment Act of 2001''.

Wyoming's residents often have only limited—if any—access to mental health professionals. There simply aren't enough providers. Given this fact, it makes no sense to continue to exclude licensed professional counselors from Medicare coverage, when similarly-trained providers are covered. In many parts of the state, licensed professional counselors are the only mental health specialists around.

We believe that establishing Medicare coverage of licensed professional counselors is a cost-effective means of improving the health and well-being of enrollees. The more than 500 professional counselors licensed in Wyoming should be allowed to help meet their mental health needs. It should jolt Congress into action to know that older Americans are the demographic group in the U.S. most at risk of committing suicide. This must be remedied.

Please let us know if there is anything we can do to assist you on mental health issues, and thank you again for your leadership, initiative, and hard work.

Sincerely,

KAREN ROBERTSON,
President.
DR. DAVID L. BECK,
Past-President.
LESLEY TRAVERS,
President-elect.

AMERICAN MENTAL HEALTH COUNSELORS ASSOCIATION,
Alexandria, VA, November 27, 2001.

Hon. CRAIG THOMAS,
U.S. Senate, Hart Senate Office Building, Washington, DC

DEAR SENATOR THOMAS: I am writing on behalf of the American Mental Health Counselors Association (AMHCA) to express our strong support for the Seniors Mental Health Access Improvement Act, legislation to expand access to mental health providers in the Medicare program. As president of AMHCA and a Licensed Mental Health Counselor (LMHC), I commend you and Senator Lincoln for introducing this important legislation.

AMHCA is the nation's largest professional organization exclusively representing the mental health counseling profession. Our members practice in a variety of settings, including hospitals, community mental health centers, managed behavioral health care organizations, employee assistance plans, substance abuse treatment centers, and private practice. Currently, there are more than 80,000 licensed or certified professional counselors practicing in the United States, including many in rural areas where access to mental health care is often scarce.

As you know, Medicare covers the services of independently practicing psychiatrists, clinical psychologists, clinical social workers, and clinical nurse specialists, but does not recognize mental health counselors or marriage and family therapists as separately reimbursable mental health providers. Specifically, the Seniors Mental Health Access Improvement Act would correct this inequity by including mental health counselors and marriage and family therapists among the list of providers who can deliver mental health services to Medicare beneficiaries, provided they are legally authorized to deliver such care under state law. Enactment of this provision would increase access to and the availability of mental health services to Medicare beneficiaries, particularly for those seniors who reside in rural and underserved areas. The inclusion of mental health counselors and marriage and family therapists as Medicare providers would also afford beneficiaries greater choice among qualified providers.

Again, thank you for the leadership you have shown in introducing this legislation and for your commitment to ensuring greater access for seniors affected by mental illness. If I can be of assistance to you as you work towards the enactment of the Seniors Mental Health Access Improvement Act, please feel free to contact me. Beth Powell, AMHCA's Director of Public Policy and Professional Issues, is also available to assist you and your staff.

Sincerely,

MIDGE WILLIAMS,
President.

AMERICAN MENTAL HEALTH COUNSELORS ASSOCIATION,
Alexandria, VA, November 28, 2001

Hon. BLANCHE L. LINCOLN,
U.S. Senate, Dirksen Senate Office Building, Washington, DC

DEAR SENATOR LINCOLN: I am writing on behalf of the American Mental Health Counselors Association (AMHCA) to express our strong support of the Seniors Mental Health Access Improvement Act, legislation to expand access to mental health providers in the Medicare program. As president of AMHCA and a Licensed Mental Health Counselor (LMHC), I commend you and Senator Thomas for introducing this important legislation.

AMHCA is the nation's largest professional organization exclusively representing the mental health counseling profession. Our members practice in a variety of settings, including hospitals, community mental health centers, managed behavioral health care organizations, employee assistance plans, substance abuse treatment centers, and private practice. Currently, there are more than 80,000 licensed or certified professional counselors practicing in the United States, including many in rural areas where access to mental health care is often scarce. The Arkansas Mental Health Counselors Association (ArMHCA), a state chapter of AMHCA, represents the interests of mental health counselors practicing in your state.

As you know, Medicare covers the services of independently practicing psychiatrists, clinical psychologists, clinical social workers, and clinical nurse specialists, but does not recognize mental health counselors or marriage and family therapists as separately reimbursable mental health providers. Specifically, the Seniors Mental Health Access Improvement Act would correct this inequity by including mental health counselors and marriage and family therapists among the list of providers who can deliver mental health services to Medicare beneficiaries, provided they are legally authorized to deliver such care under state law. Enactment of this provision would increase access to and the availability of mental health services to Medicare beneficiaries, particularly for those seniors who reside in rural and underserved areas. The inclusion of mental health counselors and marriage and family therapists as Medicare providers would also afford beneficiaries greater choice among qualified providers.

Again, thank you for the leadership you have shown in introducing this legislation and for your commitment to ensuring greater access for seniors affected by mental illness. If I can be of assistance to you as you work towards the enactment of the Seniors Mental Health Access Improvement Act, please feel free to contact me. Beth Powell, AMHCA's Director of Public Policy and Professional Issues, is also available to assist you and your staff.

Sincerely,

MIDGE WILLIAMS,
President.

ARKANSAS MENTAL HEALTH COUNSELORS ASSOCIATION,
Jonesboro, AR, November 27, 2001.

Hon. BLANCHE L. LINCOLN,
U.S. Senate, Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR LINCOLN: I am writing on behalf of the Arkansas Mental Health Counselors Association (ArMHCA) to express our strong support for the Seniors Mental Health Access Improvement Act and to convey our sincere appreciation to you for introducing this legislation. As a Licensed Professional Counselor (LPC) and a constituent, I want to express to you the importance of this legislation to LPCs in our state and to the nation's 39 million Medicare beneficiaries.

Mental health counselors-called Licensed Professional Counselor in Arkansas are mental health professionals with a master's or doctoral degree in counseling or related disciplines who provide services along a continuum of care. Currently, 45 states and the District of Columbia license or certify mental health counselors to independently provide mental health services, including the diagnosis and treatment of mental and emotional disorders. LPCs practice in a variety of settings, including hospitals, community mental health centers, managed behavioral health care organizations, employee assistance plans, substance abuse treatment centers, and private practice.

Medicare currently covers the services of independently practicing psychiatrists, clinical psychologists, clinical social workers, and clinical nurse specialists, however; it does not recognize mental health counselors or marriage and family therapists as separately reimbursable mental health providers. The Seniors Mental Health Access Improvement Act corrects this oversight by including mental Health counselors and marriage and family therapist among the list of providers who deliver mental health services to Medicare beneficiaries, provided they are legally authorized to perform the services under state law. Enactment of this provision would increase access to and the availability of mental health services to Medicare beneficiaries, particularly for those seniors who reside in rural and underserved area. The inclusion of mental health counselors and marriage and family therapists in the program would also afford beneficiaries a choice among qualified providers.

Again, thank you for the leadership you have shown in introducing this important legislation. If I can be of assistance to you as your work towards enactment of the Seniors Mental Health Improvement Access Act please feel free to contact me. Beth Powell, AMHCA's Director of Public and Professional Issues, is also available to assist you and your staff.

Sincerely,

DEE KERNODLE
President.

AMERICAN ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY,
Washington, DC, December 3, 2001.

Hon. CRAIG THOMAS,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR THOMAS: The American Association for Marriage and Family Therapy is writing on behalf of the 46,000 marriage and family therapists throughout the United States to commend you for sponsoring the Seniors Mental Health Access Improvement Act of 2001. This crucial legislation to expand the mental health benefits for our elderly will go a long way towards improving Medicare beneficiaries' access to critical mental health services provided by Marriage and Family Therapist (MFTs) and Mental Health Counselors (MHCs) across the nation.

As you know, mental illness is a major problem for many Americans, and particularly for the elderly. Research demonstrates that depression is disproportionately high among older persons, as is the incidence of suicide. The Surgeon General's Report on Mental Health has indicated that there are effective treatments for these and other mental illnesses. The Seniors Mental Health Access Improvement Act of 2001 helps make these treatments accessible to elderly citizens. By expanding the pool of qualified providers, the bill also achieves the important objective of increasing access to mental health services for elderly in rural areas, where there is a recognized shortage of professionals.

Passage of the Seniors Mental Health Access Improvement Act of 2001 will ensure that Medicare beneficiaries in need of mental health services will have the same freedom to choose a mental health professional available in their community as the non-Medicare population. The Archives of General Psychiatry projects that the number of people over 65 years with psychiatric disorders will increase from about 4 million in 1970 to 15 million in 2030. It also indicates that the current health care system is unprepared to meet the upcoming crisis in geriatric mental health. Providing access to licensed MFTs and MHCs will help ensure that there are an adequate number of providers available to meet the needs of the growing elderly population.

Your leadership and support to address the mental health needs of our seniors is greatly appreciated. It is about time the Medicare program is structured to respond to the demands of the elderly population it serves. AAMFT hopes the Seniors Mental Health Improvement Act of 2001 will become law. We look forward to working with you to meet this objective. Thank you again for your commitment to improving the lives of the elderly.

Sincerely,

DAVID M. BERGMAN,
Director of
Legal and Government Affairs.

AMERICAN ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY,
Washington, DC, December 3, 2001.

Hon. BLANCHE LAMBERT LINCOLN,
Dirksen Senate Office Building,
Washington, DC.

DEAR SENATOR LINCOLN: The American Association for Marriage and Family Therapy is writing on behalf of the 46,000 marriage and family therapists throughout the United States to commend you for sponsoring the Seniors Mental Health Access Improvement Act of 2001. This crucial legislation to expand the mental health benefits for our elderly will go a long way towards improving Medicare beneficiaries' access to critical mental health services provided by Marriage and Family Therapist (MFTs) and Mental health Counselors (MHCs) across the nation.

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Your leadership and support to address the mental health needs of our seniors is greatly appreciated. It is about time the Medicare program is structured to respond to the demands of the elderly population it serves. AAMFT hopes the Seniors Mental Health Improvement Act of 2001 will become law. We look forward to working with you to meet this objective. Thank you again for your commitment to improving the lives of the elderly.

Sincerely,

DAVID M. BERGMAN,
Director of
Legal and Government Affairs.

WYOMING ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY,
Jackson, WY, November 30, 2001.

Hon. CRAIG THOMAS,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR THOMAS: On behalf of the Wyoming Association for Marriage and Family Therapy, I want to thank you for agreeing to sponsor the Seniors Mental Health Improvement Act of 2001.

This important legislation will go a long way toward improving Medicare beneficiaries' access to critical mental health services in our state. As you know, more than 90 percent of Wyoming has been designated by the federal government as a mental health professional shortage area. By authorizing Medicare coverage for both Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs), you are more than doubling the number of mental health professionals available to provide services to the Medicare population in these underserved areas.

Your legislation will also ensure that Wyoming beneficiaries in need of mental health services will have the same freedom to choose the mental health professional available in their community as the non-Medicare population. As you are aware, our state has already authorized MFTs to provide a wide range of mental health services covered by the Medicare program. Unfortunately, because Medicare does not currently recognize MFTs, Medicare beneficiaries must often travel hundreds of miles to be seen by a mental health professional who is recognized by the Medicare program. This, despite the fact that there may be a Marriage and Family Therapist in their community that the state has already deemed qualified to provide the covered services.

Your support for improved access to mental health services is greatly appreciated. We look forward to working with you on this important legislation. I would also personally like to send my best wishes to you and Susan and hope that all is well in Washington.

Sincerely,

CINDY KNIGHT
President.

ARKANSAS ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY,
December 1, 2001.

Hon. BLANCHE LAMBERT LINCOLN,
Dirksen Senate Office Building,
Washington, DC.

DEAR SENATOR LINCOLN: I was part of a coalition of four mental health organizations that wrote to you last week on behalf of the Seniors Mental Health Improvement Act of 2001. However, I wanted to address that again with you specifically from the Arkansas Association for Marriage and Family Therapy. This is such an important piece of legislation on behalf of our aging population.

This important legislation will go a long way towards improving Medicare beneficiaries' access to critical mental health services in our state. As you know, more than 90 percent of Arkansas has been designated by the federal government as a mental health professional shortage area. By authorizing Medicare coverage for both Marriage and Family Therapists (MFTs) and Licensed Professional Counselors (LPCs) or Mental Health counselors (MHCs) you are more than doubling the number of mental health professionals available to provide services to the Medicare population in these under-served regions.

Your legislation will also ensure that Arkansas Medicare beneficiaries in need of mental health services will have the same freedom to choose the mental health professional available in their community as the non-Medicare population. As you are aware, our state has already authorized MFTs to provide a wide range of mental health services covered by the Medicare program. Unfortunately, because Medicare does not currently recognize MFTs, Medicare beneficiaries must often travel hundreds of miles to be seen by a mental health professional that is recognized by Medicare. In my practice, I am aware of long waits for seniors to see providers due to the few and the overload of those providers. This, despite the fact that there may be a Marriage and Family Therapist in their community that the state has already deemed qualified to provide the covered services.

Your support for improved access to mental health services is greatly appreciated. We look forward to working with you on this important legislation.

Sincerely,

DELL TYSON,
President.

NATIONAL RURAL HEALTH ASSOCIATION,
Kansas City, MO, December 3, 2001.

Hon. CRAIG THOMAS,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR THOMAS: On behalf of the National Rural Health Association, I would like to convey our strong support for the Seniors Mental Health Access Improvement Act of 2001.

While a lack of primary care services in rural and frontier areas has long been acknowledged, the scarcity of rural mental health services has only recently received increased attention. At the end of 1997, 76% of designated mental health professional shortage areas were located in non-metropolitan areas with a total population of over 30 million Americans. Currently there is an increased need for intervention by mental health care professionals to help people cope with the aftermath of the September 11 terrorist attacks as well as the ongoing war on terrorism. Because there is less access to mental health care in rural America, rural residents will have a subsequent lack of professional guidance in dealing with the recent trauma experienced by our country.

The Seniors Mental Health Access Improvement Act of 2001 would help provide increased access to mental health car services in rural and frontier areas by allowing Licensed Professional Counselors and Marriage and Family Therapists to bill Medicare for their services and be paid 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist.

The membership of the NRHA appreciates your bringing attention to the critical issue of access to mental health care in rural areas as well as your ongoing leadership on rural health issues. The NRHA stands ready to work with you on enactment of the Seniors Mental Health Access Improvement Act of 2001, which would help to increase the availability of mental health care in rural and frontier areas.

Sincerely,

CHARLOTTE HARDT,
President.

NATIONAL RURAL HEALTH ASSOCIATION,
Kansas City, MO, December 3, 2001.

Hon. BLANCHE LINCOLN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

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CHARLOTTE HARDT,
President.

CALIFORNIA ASSOCIATION OF
MARRIAGE AND FAMILY THERAPISTS,
San Diego, CA, November 19, 2001.

Re Medicare Legislation to Recognize Marriage and Family Therapists and Professional Counselors.

Hon. CRAIG THOMAS,
U.S. Senate,
Washington, DC.

DEAR SENATOR THOMAS: We are writing to you in recognition and support of your willingness to cosponsor legislation that would dramatically improve access to mental health services for Medicare beneficiaries. By adding licensed marriage and family therapists and licensed professional counselors, it will open many opportunities within Medicare for patients to locate and receive therapy from appropriately trained and qualified professionals.

On behalf of the 24,500 members of the California Association of Marriage and Family Therapists, we support your willingness to co-sponsor this legislation. Under California law, licensed marriage and family therapists are legally authorized to provide mental health services and are reimbursed by most all third party payers for the diagnosis and treatment of mental disorders. However, because Medicare does not recognize this particular discipline, California licensed marriage and family therapists are precluded from providing these services and Medicare beneficiaries are precluded from utilizing marriage and family therapists to provide mental health counseling and treatment.

Marriage and family therapists are considered one of the five ''core mental health professions'' recognized by the federal government. Unfortunately, however, we are the only core mental health profession not recognized by Medicare.

We appreciate and thank you for you willingness to take on the challenge of sponsoring legislation to make LMFTs and LPCs eligible for reimbursement by Medicare.

Sincerely,

MARY RIEMERSMA,
Executive Director.

CALIFORNIA ASSOCIATION OF
MARRIAGE AND FAMILY THERAPISTS,
San Diego, CA, November 19, 2001.

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Sincerely,

MARY RIEMERSMA,
Executive Director.

Mrs. LINCOLN. Mr. President, I am pleased to join my colleague Senator THOMAS today in introducing the Seniors Mental Health Access Improvement Act of 2001.

This bill would expand Medicare coverage to licensed professional counselors and licensed marriage and family therapists. One result of this expanded coverage will be to increase seniors' access to mental health services, especially in rural and underserved areas.

Licensed professional counselors and marriage and family therapists are currently excluded from Medicare coverage even though they meet the same education, training, and examination requirements that clinical social workers do. The only difference is that clinical social workers have been covered under Medicare for over a decade.

Why do we need this legislation? The mental health needs of older Americans are not being met. Although the rate of suicide among older Americans is higher than for any other age group, less than three percent of older Americans report seeing mental health professionals for treatment. And going to their primary care physician is simply not enough. Research shows that most primary care providers receive inadequate mental health training, particularly in geriatrics.

Lack of access to mental health providers is one of the primary reasons why older Americans don't get the mental health treatment they need. Not surprisingly, this problem is exacerbated in rural and underserved areas.

Licensed professional counselors are often the only mental health specialists available in rural and underserved communities. This is true in my home State of Arkansas, where 91 percent of Arkansans reside in a mental health professional shortage area.

Since there are more licensed professional counselors practicing in my State than any other mental health professional, this legislation will significantly increase the number of Medicare—eligible mental health providers in Arkansas. Licensed professional counselors are already serving patients who have private insurance or Medicaid. It is time for Medicare patients to also have access to these professionals.

The bill we are introducing today is an important first step in expanding access to good mental health. By including licensed professional counselors and licensed marriage and family therapists among the list of providers who deliver mental health services to Medicare beneficiaries, we will help ensure that all seniors, no matter where they live, have the opportunity to receive mental health treatment.

By Mr. DORGAN (for himself, Mr. CAMPBELL, and Mr. BINGAMAN):

S. 1761. A bill to amend title XVII of the Social Security Act to provide for coverage of cholesterol and blood lipid screening under the Medicare Program; to the Committee on Finance.

Mr. DORGAN. Mr. President, today I am introducing the Medicare Cholesterol Screening Coverage Act of 2001, along with my colleagues Mr. CAMPBELL and Mr. BINGAMAN. This bipartisan legislation, which also has been introduced in the House of Representatives, would add blood cholesterol screening as a covered benefit for Medicare beneficiaries.

The most recent guidelines from the National Heart, Lung and Blood Institute recommends that all Americans over the age of 20 be screened for high cholesterol. Yet current Medicare policy only covers cholesterol testing for patients who already have heart disease, stroke or other disorders associated with elevated cholesterol levels. Thus, enactment of this bill will help save lives of the approximately one-third of Medicare recipients not already covered for cholesterol testing.

High cholesterol is a major risk factor for heart disease and stroke, the Nation's number 1 and number 3 killers of both men and women. Cardiovascular disease kills nearly a million people each year in this country, more than the next seven leading causes of death combined. In particular, Americans over the age of 65 have the highest rate of coronary heart disease, CHD, in the Nation and about 80 percent of the deaths from CHD occur in this age group. It is not surprising that cardiovascular diseases account for one-third of all Medicare's spending for hospitalizations.

Obviously, in order to slow the onset of CHD, it is first necessary to identify those with elevated cholesterol, which is why passage of this bill is so critical. The importance of identifying those at risk for CHD is illustrated by the results of just released research from Oxford University. This study showed that in elderly people, lowering of cholesterol was associated with a one-third reduction in heart attack and stroke and a substantially reduced need for surgery to repair or open clogged arteries.

Clearly, this bill can save lives. Yet despite the importance of identifying this major, changeable risk factor for cardiovascular disease, screening for cholesterol is not covered by Medicare. I have felt for a long while that our health care system, and Medicare in particular, needs to place a greater emphasis on preventative health care. Implementation of the measures in this bill can potentially decrease the incidence of cardiovascular disease resulting in reduced illness, debilitation and death. Early detection of illness is often an important factor in successful treatment and has been effective in reducing long-term health care costs.

Previously, Congress in its wisdom, has acted to provide for other screening tests including bone mass measurement, and screenings for glaucoma and for colorectal, prostate and breast cancer. Now we must take another step in the right direction by extending Medicare coverage for cholesterol screening.

It is only right that the Congress do what it can to help implement the guidelines of the National Heart, Lung and Blood Institute, and it is only right that we provide these benefits for all Medicare recipients. I urge my Senate colleagues to join me in cosponsoring this piece of legislation. 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. 1761

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 ''Medicare Cholesterol Screening Coverage Act of 2001''.

SEC. 2. MEDICARE COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

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

(1) in subsection (s)(2)—

(A) by striking ''and'' at the end of subparagraph (U);

(B) by adding ''and'' at the end of subparagraph (V); and

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

''(W) cholesterol and other blood lipid screening tests (as defined in subsection (ww)(1));''; and

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

''Cholesterol and Other Blood Lipid Screening Test

''(ww)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

''(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid screening tests for individuals who do not otherwise qualify for coverage for cholesterol and other blood lipid testing based on established clinical diagnoses.''.

(b) FREQUENCY.—Section 1862(a)(1) of such Act (42 U.S.C. 1395y(a)(1)) is amended—

(1) by striking ''and'' at the end of subparagraph (H);

(2) by striking the semicolon at the end of subparagraph (I) and inserting ''; and''; and

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

''(J) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(ww)(1)), which is performed more frequently than is covered under section 1861(ww)(2).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2003.

By Mr. DASCHLE (for himself and Mr. JOHNSON):

S. 1763. A bill to promote rural safety and improve rural law enforcement; to the Committee on Finance.

Mr. DASCHLE. Mr. President, in the weeks since September 11, we've heard a lot about homeland security. Right now, we're working to make our Nation's infrastructure more secure, our food and water supply safer, and to improve our government's ability to respond to chemical and biological weapons attacks.

To me, homeland security also means giving all of our Nation's law enforcement officers the tools and training they need to do their jobs. And that means recognizing that law enforcement in rural America has its own unique set of challenges: rural law enforcement officers patrol larger areas, and operate under tighter budgets with smaller staffs, than most of their urban and suburban counterparts.

In States like South Dakota, often, just a handful of people are responsible for patrolling an entire county. Law enforcement officers respond to a lot of calls alone, and often have to communicate with each other by cell phone. Backup can be several hours away. Yet we expect the same quality of service, and we demand lower crime rates.

I believe Washington can and must do a better job of helping rural law enforcement do their work. That is why I am proud to join my colleague and friend, Senator TIM JOHNSON, in introducing the Rural Safety Act of 2001.

While TIM and I are the ones introducing this bill, we want to thank all of the South Dakota sheriffs with whom we've spoken whose ideas and experiences are incorporated within it. For my part, I'd like to recognize: Sheriff Mike Milstead of Minnehaha County, Sheriff Mark Milbrandt of Brown County, Sheriff Leidholt of Hughes County, Chief Al Aden of Pierre, Chief Duane Heeney of Yankton, Chief Ken Schwab of my hometown, Aberdeen, Chief Doug Feltman of Mitchell; and Chief Craig Tieszen of Rapid City.

One theme I've heard repeated on visit after visit is this: Washington needs to do a better job working with State and local law enforcement agencies. To me, that means building on what we know works, and developing new initiatives that respond to the special law enforcement challenges of small towns and rural communities. To that end, this bill does six things: First, it builds on our success with the COPS program. COPS has enabled South Dakota communities to hire more than 300 law enforcement officers. Across the country, it's added more than 100,000 new officers to the ''thin blue line.'' Under this proposal, rural communities that hire officers through the COPS program will be eligible for federal funding to keep those offices on for a fourth year.

Second, because rural law enforcement officers have to cover such large areas, rural law enforcement agencies arguably have a greater need for advanced communications equipment than many urban and suburban departments, but have fewer resources to purchase them. Recently, I received a letter from Sgt. Marty Goetsch in the Lawrence County Sheriff's Office in Deadwood, SD. He told me that his office, and its staff of 11, are ''very much behind in the available technology.'' This bill provides funds to help rural communities obtain things like mobile data computers and dash-mounted

video cameras. It will also provide additional funds for training to use new technologies.

Third, this bill will establish a Rural Policing Institute as a way to help rural law enforcement officers upgrade their skills and tactics.

Fourth, it will expand and improve the 9-1-1 emergency assistance systems in rural areas. Many of us take for granted that in an emergency, we can call 9-1-1, and help will be there. In rural and remote areas, the nearest help may be miles away. We need to make sure that people in rural areas can rely on a modern, integrated system of communication between law enforcement, and fire and other safety officials. The Rural Safety Act will provide the resources to finish the job and develop a seamless 9-1-1 system all across America.

Fifth, the bill will help communities create ''restorative justice'' for first-time, non-violent juvenile offenders. These programs offer victims the opportunity to confront youthful offenders and require that these offenders make meaningful restitution to their victims. In many cases, that will meet our societal goals more effectively and more efficiently that costly incarceration.

Sixth, it will enable us to stop the spread of ''meth'' now, before it becomes a crisis. A study released last year by the Center on Addiction and Substance Abuse at Columbia University shows that eighth graders living in rural communities are 104 percent more likely to have used amphetamines, including methamphetamine. We need to stop the use of all of these drugs, but in rural America, meth is particularly addictive, and devastatingly destructive. This proposal will increase prevention and treatment of meth use, and cleanup of meth labs that have been discovered and shut down.

Seventh and finally, our plan will offer gun owners tax credits to purchase gun safes. It will also provide law enforcement agencies with resources to buy and install gun safes or gun storage racks for officers' homes. I don't believe Washington should restrict the right of law-abiding citizens to own guns. But if gun owners want help in preventing accidental gun tragedies, I believe Washington can, and should, help.

When we talk about homeland security, I believe we need to think about the law enforcement needs of those who live in America's rural areas. That is what this bill does, and that is why I encourage all of my colleagues to support it.

By Mr. LIEBERMAN:

S. 1764. A bill to provide incentives to increase research by commercial, for-profit entities to develop vaccines, microbicides, diagnostic technologies, and other drugs to prevent and treat illnesses associated with a biological or chemical weapons attack; to the Committee on Finance.

Mr. LIEBERMAN. Mr. President, America has a major flaw in its defenses against bioterrorism. Recent hearings I chaired in the Government Affairs Committee on bioterrorism demonstrated that America has not made a national commitment to research and development of treatments and cures for those who might be exposed to or infected by a biological agent or chemical toxin. Correcting this critical gap is the purpose of legislation I am introducing today.

Obviously, our first priority must be to attempt to prevent the use of these agents and toxins by terrorists, quickly assess when an attack has occurred, take appropriate public health steps to contain the exposure, stop the spread of contagion, and then detoxify the site. These are all critical functions, but in the end we must recognize that some individuals may be exposed or infected. Then the critical issue is whether we can treat and cure them and prevent death and disability.

We need a diversified portfolio of medicines. In cases where we have ample advance warning of an attack and specific information about the agent or toxin, we may be able to vaccinate the vulnerable population in advance. In other cases, even if we have a vaccine, we might well prefer to use medicines that would quickly stop the progression of the disease or the toxic effects. We also need a powerful capacity quickly to develop new countermeasures where we face a new agent or toxin.

Unfortunately, we are woefully short of vaccines and medicines to treat individuals who are exposed or infected. We have antibiotics that seem to work for most of those infected in the current anthrax attack, but these have not prevented five deaths. We have no effective vaccines or medicines for most other biological agents and chemical toxins we might confront. In some cases we have vaccines to prevent, but no medicines to treat, an agent. We have limited capacity to speed the development of vaccines and medicines to prevent or treat novel agents and toxins not currently known to us.

We have provided, and should continue to provide, direct Federal funding for research and development of new medicines, however, this funding is unlikely to be sufficient. Even with ample Federal funding, many private companies will be reluctant to enter into agreements with government agencies to conduct this research. Other companies would be willing to conduct the research with their own capital and at their own risk but are not able to secure the funding from investors.

The legislation I introduce today would provide incentives for private biotechnology companies to form capital to develop countermeasures, medicines, to prevent, treat and cure victims of bioterror attacks. This will enable this industry to become a vital part of the national defense infrastructure and do so for business reasons that make sense for their investors on the bottom line.

Enactment of these incentives is necessary as most biotech companies have no approved products or revenue from product sales to fund research. They rely on investors and equity capital markets to fund the research. They must necessarily focus on research that will lead to product sales and revenue and, thus, to an end to their dependence on investor capital. There is no established or predictable market for countermeasures. Investors are justifiably reluctant to fund this research, which will present challenges similar in complexity to AIDS. Investors need assurances that research on countermeasures has the potential to provide a rate of return commensurate with the risk, complexity and cost of the research, a rate of return comparable to that which may arise from a treatment for cancer, MS, Cystic Fibrosis and other major diseases.

It is in our national interest to enlist these companies in the development of countermeasures as biotech companies tend to be innovative and nimble and intently focused on the intractable diseases for which no effective medical treatments are available.

The incentives I have proposed are innovative and some may be controversial. I invite everyone who has an interest and a stake in this research to enter into a dialogue about the issue and about the nature and terms of the appropriate incentives. I have attempted to anticipate the many complicated technical and policy issues that this legislation raises. The key focus of our debate should be how, not whether, we address this critical gap in our public health infrastructure and the role that the private sector should play. Millions of Americans will be at risk if we fail to enact legislation to meet this need.

My proposal is complimentary to legislation on bioterrorism preparedness sponsored by Senators FRIST and KENNEDY. Their bill, the Bioweapons Preparedness Act of 2001, S. 1715, focuses on many needed improvements in our public health infrastructure. It builds on their proposal in the 106th Congress, S. 2731, and H.R. 4961, sponsored by Congressman RICHARD BURR.

Among the provisions in these bills are initiatives on improving bioterrorism preparedness capacities, improving communication about bioterrorism, protection of children, protection of food safety, and global pathogen surveillance and response. The Senate Appropriations Committee reported legislation to appropriate the funds for the purposes authorized in the Frist-Kennedy proposal and that was incorporated in the stimulus package pending in the Senate before the Thanksgiving recess.

Title IV of their bill includes provisions to expand research on biological agents and toxins, as well as new treatments and vaccines for such agents and

toxins. Since the effectiveness of vaccines, drugs, and therapeutics for many biological agents and toxins often may not ethically be tested in humans, the bill ensures that the Food and Drug Administration, FDA, will finalize by a date certain its rule regarding the approval of new countermeasures on the basis of animal data. Priority countermeasures will also be given enhanced consideration for expedited review by the FDA. They rely on the authority, through an existing Executive Order, to ensure indemnification of sponsors who supply vaccines to the Government. And the bill provides a limited antitrust exemption to allow potential sponsors to discuss and agree upon how to develop, manufacture, and produce new countermeasures, including vaccines, and drugs. Federal Trade Commission and the Department of Justice approval of such agreements is required to ensure such agreements are not anti-competitive.

My legislation builds on these provisions by providing incentives to enable the biotechnology industry acting on its own initiative to fund and conduct research on countermeasures. It includes tax, procurement, intellectual property and liability incentives. Accordingly, my proposal raises issues falling within the jurisdiction of the HELP, Finance, and Judiciary Committees.

The Frist-Kennedy bill and my bill are complimentary. We do need to conform the two bills to one another on some issues: the bills have different definitions of the term ''countermeasure,'' my bill gives the Director of Homeland Defense authority over the countermeasure list whereas the Secretary of Health and Human Services would have authority under Frist/Kennedy, and my bill establishes a ''purchase fund'' and Frist-Kennedy is a ''stockpile.'' The best, most comprehensive approach would be to meld the two bills together.

The bottom line is that we need both bills, one focusing on public health and one focusing on medical research. Without medical research, public health workers will not have the single most important tool to use in an attack, medicine to prevent death and disability and medicine that will help us avoid public panic.

We are fortunate that we have broad-spectrum antibiotics including Cipro to treat the type of anthrax to which so many have been exposed. This treatment seems to be effective before the anthrax symptoms become manifest, and effective to treat cutaneous anthrax, and we have been able to effectively treat some individuals who have inhalation anthrax. I am thankful that this drug exists to treat those who have been exposed, including my own Senate staff. Our offices are immediately above those of Senator DASCHLE.

We have seen how reassuring it is that we have an effective treatment for this biological agent. We see long lines of Congressional staffers and postal workers awaiting their Cipro. Think what it would be like if we could only say, ''We have nothing to treat you and hope you don't contract the disease.'' Think of the public panic that we might see.

I am grateful that this product exists and proud of the fact that the Bayer Company is based in Connecticut. The last thing we should be doing is criticizing this company for their research success. The company has dispensed millions of dollars worth of Cipro free of charge. Criticizing it for the price that it charges tells other research companies that the more valuable their products are in protecting the public health, the more likely they are to be criticized and bullied.

It is fortuitous that Cipro seems to be effective against anthrax. The product was not developed with this use in mind. My point with this legislation is we cannot rely on good fortune and chance in the development of countermeasures. We need to make sure that these countermeasures will be developed. We need more companies like Bayer, we need them focused specifically on developing medicines to deal with the new bioterror threat, and we need to tell them that there are good business reasons for this focus.

We also are fortunate to have an FDA-licensed vaccine, made by BioPort Corporation, that is recommended by our country's medical experts at the DOD and CDC for pre-anthrax exposure vaccination of individuals in the military and some individuals in certain laboratory and other occupational settings where there is a high risk of exposure to anthrax. This vaccine is also recommended for use with Cipro after exposure to anthrax to give optimal and long-lasting protection. That vaccine is not now available for use. We must do everything necessary to make this and other vaccines available in adequate quantities to protect against future attacks. But the point of this legislation is that we need many more Cipro-like and antrax vaccine-like products. That we have these products is the good news; that we have so few others is the problem.

One unfortunate truth in this debate is that we cannot rely upon international legal norms and treaties alone to protect our citizens from the threat of biological or chemical attack.

The United States ratified the Biological and Toxin Weapons Convention, BWC, on January 22, 1975. That Convention now counts 144 nations as parties. Twenty-two years later, on April 24, 1997, the United States Senate joined 74 other countries when it ratified the Chemical Weapons Convention, CWC. While these Conventions serve important purposes, they do not in any way guarantee our safety in a world with rogue states and terrorist organizations.

The effectiveness of both Conventions is constrained by the fact that many countries have failed to sign on to either of them. Furthermore, two signatories of the BWC, Iran and Iraq, are among the seven governments that the Secretary of State has designated as state sponsors of international terrorism, and we know for a fact that they have both pursued clandestine biological weapons programs. The BWC, unlike the CWC, has no teeth, it does not include any provisions for verification or enforcement. Since we clearly cannot assume that any country that signs on to the Convention does so in good faith, the Convention's protective value is limited.

On November 1 of this year, the President announced his intent to strengthen the BWC as part of his comprehensive strategy for combating terrorism. A BWC review conference, held every 5 years to consider ways of improving the Convention's effectiveness, will convene in Geneva beginning November 19. In anticipation of that meeting, the President has urged that all parties to the Convention enact strict national criminal legislation to crack down on prohibited biological weapons activities, and he has called for an effective United Nations procedure for investigating suspicious outbreaks of disease or allegations of biological weapons use.

These steps are welcomed, but they are small. Even sweeping reforms, like creating a more stringent verification and enforcement regime, would not guarantee our safety. The robust verification and enforcement mechanisms in the CWC, for instance, have proven to be imperfect, and scientists agree that it is much easier to conceal the production of biological agents than chemical weapons.

The inescapable fact, therefore, is that we cannot count on international regimes to prevent those who wish us ill from acquiring biological and chemical weapons. We must be prepared for the reality that these weapons could fall into the hands of terrorists, and could be used against Americans on American soil. And we must be prepared to treat the victims of such an attack if it were ever to occur.

On November 26, the Centers for Disease Control issued its interim working draft plan for responding to an outbreak of smallpox. The plan does not call for mass vaccination in advance of a smallpox outbreak because the risk of side effects from the vaccine outweighs the risks of someone actually being exposed to the smallpox virus. At the heart of the plan is a strategy sometimes called ''search and containment.''

This strategy involves identifying infected individual or individuals with confirmed smallpox, identifying and locating those people who come in contact with that person, and vaccinating those people in outward rings of contact. The goal is to produce a buffer of immune individuals and was shown to prevent smallpox and to ultimately eradicate the outbreak. Priorities

would be set on who is vaccinated, perhaps focusing on the outward rings before those at the center of the outbreak. The plan assumes that the smallpox vaccination is effective for persons who have been exposed to the disease as long as the disease has not taken hold.

In practice it may be necessary to set a wide perimeter for these areas because smallpox is highly contagious before it might be diagnosed. There may be many areas subject to search and containment because people in our society travel frequently and widely. Terrorists might trigger attacks in a wide range of locations to multiply the confusion and panic. The most common form of smallpox has a 30-percent mortality rate, but terrorists might be able to obtain supplies of ''flat-type'' smallpox with a mortality rate of 96 percent and hemorrhagic-type smallpox, which is almost always fatal. For these reasons, the CDC plan accepts the possibility that whole cities or other geographic areas could be cordoned off, letting no one in or out, a quarantine enforced by police or troops.

The plan focuses on enforcement authority through police or National Guard, isolation and quarantine, mandatory medical examinations, and rationing of medicines. It includes a discussion of ''population-wide quarantine measures which restrict activities or limit movement of individuals [including] suspension of large public gatherings, closing of public places, restriction on travel [air, rail, water, motor vehicle, and pedestrian], and/or 'cordon sanitaire' [literally a 'sanitary cord' or line around a quarantined area guarded to prevent spread of disease by restricting passage into or out of the area].'' The CDC recommends that States update their laws to provide authority for ''enforcing quarantine measures'' and it recommends that States in ''preevent planning'' identify ''personnel who can enforce these isolation and quarantine measures, if necessary.'' Guide C, Isolation and Quarantine, page 17.

On October 23, 2001, the CDC published a ''Model State Emergency Health Powers Act.'' It was prepared by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, in conjunction with the National Governors Association, National Conference of State Legislatures, Association of State and Territorial Health Officials, National Association of City and County Health Officers, and National Association of Attorneys General. A copy of the model law is printed at www.publichealthlaw.net. The law would provide powers to enforce the ''compulsory physical separation, including the restriction of movement or confinement, of individuals and/or groups believed to have been exposed to or known to have been infected with a contagious disease from individuals who are believed not to have been exposed or infected, in order to prevent or limit the transmission of the disease to others.'' Federal law on this subject is very strong and the Administration can always rely on the President's Constitution authority as Commander in Chief.

Let us try to imagine, however, what it would be like if a quarantine is imposed. Let us assume that there is not enough smallpox vaccine available for use in a large outbreak, that the priority is to vaccinate those in the outward rings of the containment area first, that the available vaccines cannot be quickly deployed inside the quarantined area, that it is not possible to quickly trace and identify all of the individuals who might have been exposed, and/or that public health workers themselves might be infected. We know that there is no medicine to treat those who do become infected. We know the mortality rates. It is not hard to imagine how much force might be necessary to enforce the quarantine. It would be quite unacceptable to permit individuals to leave the quarantined area no matter how much panic had taken hold.

Think about how different this scenario would be if we had medicines that could effectively treat and cure those who become infected by smallpox. We still might implement the CDC plan but a major element of the strategy would be to persuade people to visit their local clinic or hospital to be dispensed their supply of medicine. We could trust that there would be a very high degree of voluntary compliance. This would give us more time, give us options if the containment is not successful, give us options to treat those in the containment area who are infected, and enable us to quell the public panic.

Because we have no medicine to treat those infected by smallpox, we have to be prepared to implement a plan like the one CDC has proposed. Theirs is the only option because our options are so limited. We need to expand our range of options.

We should not be lulled by the apparent successes with Cipro and the strains of anthrax we have seen in the recent attacks. We have not been able to prevent death in some of the patients with late-stage inhalation anthrax and Robert Stevens, Thomas Morris Jr., Joseph Curseen, Kathy Nguyen, and Ottilie Lundgren have died. This legislation is named in honor of them. What we needed for them, and did not have, is a drug or vaccine that would treat late stage inhalation anthrax.

As I have said, we need an effective treatment for those who become infected with smallpox. We have a vaccine that effectively prevents smallpox infection, and administering this vaccine within four days of first exposure has been shown to offer some protections against acquiring infection and significant protection against a fatal outcome. The problem is that administering the vaccine in this time frame to all those who might have been exposed may be exceedingly difficult. And once infection has occurred, we have no effective treatment options.

In the last century 500 million people have died of smallpox, more than have from any other infectious diseases, as compared to 320 million deaths in all the wars of the twentieth century. Smallpox was one of the diseases that nearly wiped out the entire Native American population in this hemisphere. The last naturally acquired case of smallpox occurred in Somalia in 1977 and the last case from laboratory exposure was in 1978.

Smallpox is a nasty pathogen, carried in microscopic airborne droplets inhaled by its victims. The first signs are headache, fever, nausea and backache, sometimes convulsions and delirium. Soon, the skin turns scarlet. When the fever lets up, the telltale rash appears, flat red spots that turn into pimples, then big yellow pustules, then scabs. Smallpox also affects the throat and eyes, and inflames the heart, lungs, liver, intestines and other internal organs. Death often came from internal bleeding, or from the organs simply being overwhelmed by the virus. Survivors were left covered with pockmarks, if they were lucky. The unlucky ones were left blind, their eyes permanently clouded over. Nearly one in four victims died. The infection rate is estimated to be 25–40 percent for those who are unvaccinated and a single case can cause 20 or more additional infections.

During the 16th Century, 3.5 million Aztecs, more than half the population, died of smallpox during a 2-year span after the Spanish army brought the disease to Mexico. Two centuries later, the virus ravaged George Washington's troops at Valley Forge. And it cut a deadly path through the Crow, Dakota, Sioux, Blackfoot, Apache, Comanche and other American Indian tribes, helping to clear the way for white settlers to lay claim to the western plains. The epidemics began to subside with one of medicine's most famous discoveries: the finding by British physician Edward Jenner in 1796 that English milkmaids who were exposed to cowpox, a mild second cousin to smallpox that afflicts cattle, seemed to be protected against the more deadly disease. Jenner's work led to the development of the first vaccine in Western medicine. While later vaccines used either a killed or inactivated form of the virus they were intended to combat, the smallpox vaccine worked in a different way. It relied on a separate, albeit related virus: first cowpox and the vaccinia, a virus of mysterious origins that is believed to be a cowpox derivative. The last American was vaccinated back in the 1970s and half of the U.S. population has never been vaccinated. It is not known how long these vaccines provide protection, but it is estimated that the term is 3–5 years.

In an elaborate smallpox biowarfare scenario enacted in February 1999 by

the Johns Hopkins Center for Civilian Biodefense Studies, it was projected that within 2 months 15,000 people had died, epidemics were out of control in fourteen countries, all supplies of smallpox vaccine were depleted, the global economy was on the verge of collapse, and military control and quarantines were in place. Within twelve months it was projected that eighty million people worldwide had died.

A single case of smallpox today would become a global public health threat and it has been estimated that a single smallpox bioterror attack on a single American city would necessitate the vaccination of 30–40 million people.

The U.S. Government is now in the process of purchasing substantial stocks of the smallpox vaccine. We then face a very difficult decision on deploying the vaccine. We know that some individuals will have an adverse reaction to this vaccine. No one in the United States has been vaccinated against smallpox in 25 years. Those that were vaccinated back then may not be protected against the disease today. If we had an effective treatment for those who might become infected by smallpox, we would face much less pressure regarding deploying the vaccine. If we face a smallpox epidemic from a bioterrorism attack, we will have no Cipro to reassure the public and we will be facing a highly contagious disease and epidemic. To be blunt, it will make the current anthrax attack look benign by comparison.

Smallpox is not the only threat. We have seen other epidemics in this century. The 1918 influenza epidemic provides a sobering admonition about the need for research to develop medicines. In 2 years, a fifth of the world's population was infected. In the United States the 1918 epidemic killed more than 650,000 people in a short period of time and left 20 million seriously ill, one-fourth of the entire population. The average lifespan in the U.S. was depressed by ten years. In just 1 year, the epidemic killed 21 million human beings worldwide—well over twice the number of combat deaths in the whole of World War I. The flu was exceptionally virulent to begin with and it then underwent several sudden and dramatic mutations in its structure. Such mutations can turn flu into a killer because its victims' immune systems have no antibodies to fight off the altered virus. Fatal pneumonia can rapidly develop.

Another deadly toxin, ricin toxin, was of interest to the al-Qaeda terrorist network. At an al-Qaeda safehouse in Saraq Panza, Kabul reporters found instructions for making ricin. The instructions make chilling reading. ''A certain amount, equal to a strong dose, will be able to kill an adult, and a dose equal to seven seeds will kill a child,'' one page reads. Another page says: ''Gloves and face mask are essential for the preparation of ricin. Period of death varies from 3–5 days minimum, 4–14 days maximum.'' The instructions listed the symptoms of ricin as vomiting, stomach cramps, extreme thirst, bloody diarrhoea, throat irritation, respiratory collapse and death.

No specific treatment or vaccine for ricin toxin exists. Ricin is produced easily and inexpensively, highly toxic, and stable in aerosolized form. A large amount of ricin is necessary to infect whole populations, the amount of ricin necessary to cover a 100-km^2 area and cause 50 percent lethality, assuming aerosol toxicity of 3 mcg/kg and optimum dispersal conditions, is approximately 4 metric tons, whereas only 1 kg of Bacillus anthracis is required. But it can be used to terrorize a large population with great effect because it is so lethal.

Use of ricin as a terror weapon is not theoretical. In 1991 in Minnesota, 4 members of the Patriots Council, an extremist group that held antigovernment and antitax ideals and advocated the overthrow of the U.S. Government, were arrested for plotting to kill a U.S. marshal with ricin. The ricin was produced in a home laboratory. They planned to mix the ricin with the solvent dimethyl sulfoxide, DMSO, and then smear it on the door handles of the marshal's vehicle. The plan was discovered, and the 4 men were convicted. In 1995, a man entered Canada from Alaska on his way to North Carolina. Canadian custom officials stopped the man and found him in possession of several guns, $98,000, and a container of white powder, which was identified as ricin. In 1997, a man shot his stepson in the face. Investigators discovered a makeshift laboratory in his basement and found agents such as ricin and nicotine sulfate. And, ricin was used by the Bulgarian secret police when they killed Georgi Markov by stabbing him with a poison umbrella as he crossed Waterloo Bridge in 1978.

Going beyond smallpox, influenza, and ricin, we do not have an effective vaccine or treatment for dozens of other deadly and disabling agents and toxins. Here is a partial list of some of the other biological agents and chemical toxins for which we have no effective treatments: clostridium botulinum toxin, botulism; francisella tularensis, tularaemia; Ebola hemorrhagic fever, Marbug hemorrhagic fever, Lassa fever, Julin, Argentine hemorrhagic fever; Coxiella burnetti, Q fever; brucella species, brucellosis; burkholderia mallei, glanders; Venezuelan encephalomyelitis, eastern and western equine encephalomyelitis, epsilon toxin of clostridium perfringens, staphylococcus entretoxin B, salmonella species, shigella dysenteriae, escherichia coli O157:H7, vibrio cholerae, cryptosporidium parvum, nipah virus, hantaviruses, tickborne hemorrhagic fever viruses, tickborne encephalitis virus, yellow fever, nerve agents, tabun, sarin, soman, GF, and VX; blood agents, hydrogen cyanide and cyanogens chloride; blister agents, lewisite, nitrogenadn sulfur mustards, and phosgene oxime; heavy metals, arsenic, lead, and mercury; and volatile toxins, benzene, chloroform, trihalomethanes; pulmonary agents, Phosgene, chlorine, vinly chloride; and incapacitating agents, BZ.

The naturally occurring forms of these agents and toxins are enough to cause concern, but we also know that during the 1980s and 1990s the Soviet Union conducted bioweapons research at 47 laboratories and testing sites, employed nearly 50,000 scientists in the work, and that they developed genetically modified versions of some of these agents and toxins. The goal was to develop an agent or toxin that was particularly virulent or not vulnerable to available antibiotics.

The United States has publicly stated that five countries are developing biological weapons in violation of the Biological Weapons convention, North Korea, Iraq, Iran, Syria, and Libya, and stated that additional countries not yet named, possibly including Russia, China, Israel, Sudan and Egypt, are also doing so as well.

What is so insidious about biological weapons is that in many cases the symptoms resulting from a biological weapons attack would likely take time to develop, so an act of bioterrorism may go undetected for days or weeks. Affected individuals would seek medical attention not from special emergency response teams but in a variety of civilian settings at scattered locations. This means we will need medicines that can treat a late stage of the disease, long after the infection has taken hold.

We must recognize that the distinctive characteristic of biological weapons is that they are living micro-organisms and are thus the only weapons that can continue to proliferate without further assistance once released in a suitable environment.

The lethality of these agents and toxins, and the panic they can cause, is quite frightening. The capacity for terror is nearly beyond comprehension. I do not believe it is necessary to describe the facts here. My point is simple: we need more than military intelligence, surveillance, and public health capacity. We also need effective medicines. We also need more powerful research tools that will enable us to quickly develop treatments for agents and toxins not on this or any other list.

We need to do whatever it takes to be able to reassure the American people that hospitals and doctors have powerful medicines to treat them if they are exposed to biological agents or toxins, that we can contain an outbreak of an infectious agent, and that there is little to fear. To achieve this objective, we need to rely on the entrepreneurship of the biotechnology industry.

There is already some direct funding of research by the Defense Advanced Research Projects Agency, DARPA, the National Institutes of Health, NIH, and the Centers for Disease Control, CDC. This research should go forward.

DARPA, for instance, has been described as the Pentagon's ''venture capital fund,'' its mission to provide seed money for novel research projects that offer the potential for revolutionary findings. Last year, DARPA's Unconventional Pathogen Countermeasures program awarded contracts totalling $50 million to universities, foundations, pharmaceutical and biotechnology companies seeking new ways to fight biological agents and toxins.

The Unconventional Pathogen Countermeasures program now funds 43 separate research efforts on antibacterials, anti-toxins, anti-virals, decontamination, external protection from pathogens, immunization and multi-purpose vaccines and treatments. A common thread among many of these undertakings is the goal of developing drugs that provide broad-spectrum protection against several different pathogens. This year, with a budget of $63 million, the program has received over 100 research proposals in the last two months alone.

Some of this DARPA research is directed at developing revolutionary, broad-spectrum, medical countermeasures against significantly pathogenic microorganisms and/or their pathogenic products. The goal is to develop countermeasures that are versatile enough to eliminate biological threats, whether from natural sources or modified through bioengineering or other manipulation. The countermeasures would need the potential to provide protection both within the body and at the most common portals of entry, e.g., inhalation, ingestion, transcutaneous. The strategies might include defeating the pathogen's ability to enter the body, traverse the bloodstream or lymphatics, and enter target tissues; identifying novel pathogen vulnerabilities based on fundamental, critical molecular mechanisms of survival or pathogenesis, e.g., Type III secretion, cellular energetics, virulence modulation; constructing unique, robust vehicles for the delivery of countermeasures into or within the body; and modulating the advantageous and/or deleterious aspects of the immune response to significantly pathogenic microorganisms and/or the pathogenic products in the body

While DAPRA's work is specifically aimed at protecting our military personnel, the National Institutes of Health also spent $49.7 million in the last fiscal year to find new therapies for those who contract smallpox and on systems for detecting the disease. In recent years, NIH's research programs have sought to create more rapid and accurate diagnostics, develop vaccines for those at risk of exposure to biological agents, and improve treatment for those infected. Moreover, in the last fiscal year, the Centers for Disease Control has allocated $18 million to continue research on an anthrax vaccine and $22.4 million on smallpox research.

Some companies are willing to enter into a research relationships funded by DARPA and other agencies to develop countermeasures. Relationships between the Government and private industry can be very productive, but they can also involve complex issues reflecting the different cultures of government and industry. Some companies, including some of the most entrepreneurial, might prefer to take their own initiative to conduct this research. Relationships with government entities involve risks, issues, and bureaucracy that are not present in relationships among biotechnology companies and between them and non-governmental partners.

The Defense Departments Joint Vaccine Acquisition Program, JVAP, illustrates the problems with a government led and managed program. A report in December 2000 by a panel of independent experts found that the current program ''is insufficient and will fail'' and recommended it adopt an approach more on the model of a private sector effort. It needs to adopt ''industry practices,'' ''capture industry interest,'' ''implement an organizational alignment that mirrors the vaccine industry's short chain of command and decision making,'' ''adopt an industry-based management philosophy,'' and ''develop a sound investment strategy.'' It bemoaned the ''extremely limited'' input from industry in the JVAP program.

It is clear from this experience that we should not rely exclusively on government funding of countermeasures research. We should take advantage of the entrepreneurial fervor, and the independence, of our biotechnology industry entrepreneurs. It is not likely that the Government will be willing or able to provide sufficient funding for the development of the countermeasures we need. Some of the most innovative approaches to vaccines and medicines might not be funded with the limited funds available to the Government. We need to provide incentives that will encourage every biotech company to review its research priorities and technology portfolio for its relevance and potential for countermeasure research. Some of this research is early stage, basic research that is being developed and considered only for its value in treating an entirely different disease. We need to kindle the imagination of biotechnology companies and their tens of thousands of scientists regarding countermeasures research.

My proposal would supplement direct Federal government funding of research with incentives that make it possible for private companies to form the capital to conduct this research on their own initiative, utilizing their own capital, and at their own risk, all for good business reasons going to their bottom line.

The U.S. biotechnology industry, approximately 1,300 companies, spent $13.8 billion on research last year. Only 350 of these companies have managed to go public. The industry employs 124,000, Ernest & Young data, people. The top five companies spent an average of $89,000 per employee on research, making it the most research-intensive industry in the world. The industry has 350 products in human clinical trials targeting more than 200 diseases. Losses for the industry were $5.8 billion in 2001, $5.6 billion in 2000, $4.4 billion in 1999, $4.1 billion in 1998, $4.5 billion in 1997, $4.6 billion in 1996, and similar amounts before that. In 2000 fully 38 percent of the public biotech companies had less than 2 years of funding for their research. Only one-quarter of the biotech companies in the United States are publicly traded and they tend to be the best funded.

There is a broad range of research that could be undertaken under this legislation. Vaccines could be developed to prevent infection or treat an infection from a bioterror attack. Broad-spectrum antibiotics are needed. Also, promising research has been undertaken on antitoxins that could neutralize the toxins that are released, for example, by anthrax. With anthrax it is the toxins, not the bacteria itself, that cause death. An antitoxin could act like a decoy, attaching itself to sites on cells where active anthrax toxin binds and then combining with normal active forms of the toxin and inactivating them. An antitoxin could block the production of the toxin.

We can rely on the innovativeness of the biotech industry, working in collaboration with academic medical centers, to explore a broad range of innovative approaches. This mobilizes the entire biotechnology industry as a vital component of our national defense against bioterror weapons.

The legislation takes a comprehensive approach to the challenges the biotechnology industry faces in forming capital to conduct research on countermeasures. It includes capital formation tax incentives, guaranteed purchase funds, patent protections, and liability protections. I believe we will have to include each of these types of incentives to ensure that we mobilize the biotechnology industry for this urgent national defense research.

I am aware that all three of the tax incentives I have proposed, and both of the two patent incentives I have proposed, may be controversial. In my view, we can debate tax or patent policy as long as you want, but let's not lose track of the issue here, development of countermeasures to treat people infected or exposed to lethal and disabling bioterror weapons.

We know that incentives can spur research. In 1983 we enacted the Orphan Drug Act to provide incentives for companies to develop treatments for rare diseases with small potential markets deemed to be unprofitable by the industry. In the decade before this legislation was enacted, fewer than 10 drugs for orphan diseases were developed and these were mostly chance discoveries. Since the Act became law, 218

orphan drugs have been approved and 800 more are in the pipeline. The Act provides 7 years of market exclusivity and a tax credit covering some research costs. The effectiveness of the incentives we have enacted for orphan disease research show us how much we can accomplish when we set a national priority for certain types of research.

The incentives I have proposed differ from those set by the Orphan Drug Act. We need to maintain the effectiveness of the Orphan Drug Act and not undermine it by adding many other disease research targets. In addition, the tax credits for research for orphan drug research have no value for most biotechnology companies because few of them have tax liability with respect to which to claim the credit. This explains why I have not proposed to utilize tax credits to spur countermeasures research. It is also clear that the market for countermeasures is even more speculative than the market for orphan drugs and we need to enact a broader and deeper package of incentives.

The Government determines which research is covered by the legislation. The legislation confers on the Director of the Office of Homeland Security, in consultation with the Secretary of Defense and Secretary of Health and Human Services, authority to set the list of agents and toxins with respect to which the legislation applies. The Director determines which agents and toxins present a threat and on whether the countermeasures are more likely to be developed with the application of the incentives of the legislation. The Director may determine that an agent or toxin does not present a threat or that countermeasures are not more likely to be developed with the incentives. The legislation includes an illustrative list of agents and toxins that might be selected by the Director. The decisions of the Director are final and cannot be subject to judicial review.

Once the list of agents and toxins is set, companies may register with the Food and Drug Administration their intent to undertake research and development of a countermeasure to prevent or treat the agent or toxin. This registration is required only for companies that seek to be eligible for the tax, purchase, patent, and liability provisions of the legislation. The registration does not apply to non-profit entities or to companies that do not seek such eligibility. The registration requirement gives the FDA vital information about the research effort and the personnel involved with the research.

The Director of the Office of Homeland Security then may certify that the company is eligible for the tax, purchase, patent, and liability incentives in the legislation. Eligibility for the purchase fund, patent and liability incentives is contingent on successful development of a countermeasure according to the standards set in the legislation.

The legislation contemplates that a company might well register and seek certification with respect to more than one research project and become eligible for the tax, purchase, patent, and liability incentives for each. There is no policy rationale for limiting a company to one registration and one certification.

This process is similar to the current registration process for research on orphan, rare, diseases. In that case, companies that are certified by the FDA become eligible for both tax and market exclusivity incentives. This process gives the Government complete control on the number of registrations and certifications. This gives the Government control over the cost and impact of the legislation on private sector research.

The legislation includes three tax incentives to enable biotechnology companies to form capital to fund research and development of countermeasures. Companies must irrevocably elect only one of the incentives with regard to the research. These tax incentives are available only to biotechnology companies with less than $750,000,000 in paid-in capital.

The paid-in capital of a corporation is quite distinct from the market capitalization of the firm. The paid-in capital is the aggregate amount paid by investors into the corporation when this stock was issued, the price at issue multiplied by the number of shares sold. The market capitalization is the value of this stock in the stock market as it is traded among investors. I have focused on the paid-in capital as this is the amount of capital actually available to the corporation to fund its research.

The legislation includes three different tax incentives to give companies flexibility in forming capital to fund the research. Each of the options comes with advantages and limitations that may make it appropriate or inappropriate for a given company or research project. We do not now know fully how investors and capital markets will respond to the different options, but we assume that companies will consult with the investor community about which option will work best for a given research project. Capital markets are diverse and investors have different needs and expectations. Over time these markets and investor expectations evolve. If companies register for more than one research project, they may well utilize different tax incentives for the different projects.

Companies are permitted to undertake a series of discrete and separate research projects and make this election with respect to each project. They may only utilize one of the options with respect to each of these research projects.

The company is eligible to establish an R&D Limited Partnership to conduct the research. The partnership passes through all business deductions and credits to the partners. For example, under this arrangement, the research and development tax credits and depreciation deductions for the company may be passed by the corporation through to its partners to be used to offset their individual tax liability. These deductions and credits are then lost to the corporation.

The company is eligible to issue a special class of stock for the entity to conduct the research. The investors would be entitled to a zero capital gains tax rate on any gains realized on the stock held for at least 3 years. This is a modification of the current Section 1202 where only 50 percent of the gains are not taxed. This provision is adapted from legislation I have introduced, S. 1134, and introduced in the House by Representatives DUNN and MATSUI, H.R. 2383. A similar bill has been introduced by Senator COLLINS, S. 455.

The company is eligible to receive refunds for Net Operating Losses, NOLs, to fund the research. Under current law, net operating losses can only be used to offset a company's tax liability. If a company has no profits and therefore no tax liability, it cannot use its net operating losses. It can carry them forward, but the losses have no current value. This option would allow the company to receive a refund of its NOLs at a rate of 75 percent of their value. Once the company becomes profitable, and incurs tax liability, it must repay all of the refunds it has received. The provision in my legislation is adapted from bills introduced by Senator TORRICELLI, S. 1049, and Congressman ROBERT MATSUI, H.R. 2153.

A company that elects to utilize one of these incentives is not eligible to receive benefits of the Orphan Drug Tax Credit. Companies that can utilize tax credits, companies with taxable income and tax liability, might find the Orphan Credit more valuable. The legislation includes an amendment to the Orphan Credit to correct a defect in the current credit. The amendment has been introduced in the Senate as S. 1341 by Senators HATCH, KENNEDY and JEFFORDS. The amendment simply states that the Credit is available starting the day an application for orphan drug status is filed, not the date the FDA finally acts on it. The amendment was one of many initiatives championed by Lisa J. Raines, who died on September 11 in the plane that hit the Pentagon, and the amendment is named in her honor. As we go forward in the legislative process, I hope we will have an opportunity to speak in more detail about the service of Ms. Raines on behalf of medical research, particularly on rare diseases.

My legislation does not include an enhanced tax credit for this research. Very few biotechnology companies can utilize a tax credit as they have no taxable revenue and tax liability with respect to which to claim a credit. Instead, they can carry the credit forward and utilize it when they do have tax liability. But that may be many years from now. That is why I have focused on other incentives to assist the

biotechnology industry to form capital to fund this countermeasures research.

The guaranteed purchase fund, and the patent bonus and liability provisions described below provide an additional incentive for investors to fund the research. Without capital from investors these biotechnology companies do not have the capacity, irrespective of their interest, to conduct the research.

The market for countermeasures is speculative and small. This means that if a company successfully develops a countermeasure, it may not receive sufficient revenue on sales to justify the risk and expense of the research. This is why the legislation establishes a countermeasures purchase fund that will define the market for the products with some specificity before the research begins.

The fund managers will set standards for which countermeasures it will purchase and define the financial terms of the purchase commitment. This will enable companies to evaluate the market potential of its research before it launches into the project. The specifications will need to be set with sufficient specificity so that the company, and its investors, can evaluate the market and with enough flexibility so that it does not inhibit the innovativeness of the researchers. This approach is akin to setting a performance standard for a new military aircraft.

The legislation provides that the purchase fund is not obligated to purchase more than one product per class. This seeks to avoid a situation where the Government must purchase more than one product when it only intends to use one. But it might make more sense, as an incentive, for the Government to commit to purchasing more than one product so that many more than one company conducts the research. A winner-take-all system may well intimidate some companies and we may end up without a countermeasure to be purchased. It is also possible that we will find that we need more than one countermeasure because different products are useful for different patients. We may also find that the first product developed is not the most effective. Given the urgency of the research, we would like to have the problem of seeing more than one effective countermeasure developed. How we reconcile these competing considerations is a key issue we need to resolve.

My legislation provides that the countermeasure must be approved by the FDA. The standards that the FDA should apply in reviewing these types of products is an issue have been discussed in some detail and we need to fashion the most effective provision on this subject. We need to recognize that the requirement for FDA approval might, in some cases, not be needed, appropriate or possible.

The purchase commitment for countermeasures is available to any company irrespective of its paid-in capital.

Intellectual property protection of research is essential to biotechnology companies for one simple reason: they need to know that if they successfully develop a medical product another company cannot expropriate it. It's a simple matter of incentives.

The patent system has its basis in the U.S. Constitution where the Federal Government is given the mandate to ''promote the Progress of Science and the Useful Arts by securing for a limited time to Authors and Inventors the exclusive right to their respective Writings and Discoveries.'' In exchange for full disclosure of the terms of their inventions, inventors are granted the right to exclude others from making, using, or selling their inventions for a limited period of time. This quid pro quo provides investors with the incentive to invent. In the absence of the patent law, discoverable inventions would be freely available to anyone who wanted to use them and inventors would not be able to capture the value of their inventions or secure a return on their investments.

The patent system strikes a balance. Companies receive limited protection of their inventions if they are willing to publish the terms of their invention for all to see. At the end of the term of the patent, anyone can practice the invention without any threat of an infringement action. During the term of the patent, competitors can learn from the published description of the invention and may well find a new and distinct patentable invention.

The legislation provides two types of intellectual property protection. One simply provides that the term of the patent on the countermeasure will be the term of the patent granted by the Patent and Trademark Office without any erosion due to delays in approval of the product by the Food and Drug Administration. The second provides that a company that successfully develops a countermeasure will receive a bonus of 2 years on the term of any patent held by that company. Companies must elect one of these two protections and only small biotechnology companies may elect the second protection. Large, profitable pharmaceutical companies may elect only the first of the two options.

The first protection against erosion of the term of the patent is an issue that is partially addressed in current law, the Hatch-Waxman Patent Term Restoration Act. That act provides partial protection against erosion of the term, length of a patent when there are delays at the FDA in approving a product. The erosion occurs when the PTO issues a patent before the product is approved by the FDA. In these cases, the term of the patent is running but the company cannot market the product. The Hatch-Waxman Act provides some protections against erosion of the term of the patent, but the protections are incomplete. As a result, many companies end up with a patent with a reduced term, sometimes substantially reduced.

The issue of patent term erosion has become more serious due to changes at the PTO in the patent system. The term of a patent used to be fixed at 17 years from the date the patent was granted by the PTO. It made no difference how long it took for the PTO to process the patent application and sometimes the processing took years, even decades. Under this system, there were cases where the patent would issue before final action at the FDA, but there were other cases where the FDA acted to approve a product before the patent was issued. Erosion was an issue, but it did not occur in many cases.

Since 1995 the term of a patent has been set at 20 years from the date of application for the patent. This means that the processing time by the PTO of the application all came while the term of the patent is running. This gives companies a profound incentive to rush the patent through the PTO. Under the old system, companies had the opposite incentive. With patents being issued earlier by the PTO, the issue of erosion of patent term due to delays at the FDA is becoming more serious and more common.

The provision in my legislation simply states that in the case of bioterrorism countermeasures, no erosion in the term of the patent will occur. The term of the patent at the date of FDA approval will be the same as the term of the patent when it was issued by the PTO. There is no extension of the patent, simply protections against erosion. Under the new 20-year term, patents might be more or less than 17 years depending on the processing time at the PTO, and all this legislation says is that whatever term is set by the PTO will govern irrespective of the delays at the FDA. This option is available to any company that successfully develops a countermeasure eligible to be purchased by the fund.

The second option, the bonus patent term, is only available to small biotechnology companies. It provides that a company that successfully develops a countermeasure is entitled to a 2-year extension of any patent in its portfolio. This does not apply to any patent of another company bought or transferred in to the countermeasure research company.

I am well aware that this bonus patent term provision will be controversial with some. A company would tend to utilize this option if it owned the patent on a product that still had, or might have, market value at the end of the term of the patent. Because this option is only available to small biotechnology companies, most of whom have no product on the market, in most cases they would be speculating about the value of a product at the end of its patent. The company might apply this provision to a patent that otherwise would be eroded due to FDA delays or it might apply it to a patent that was not eroded. The result might be a patent term that is no longer than the patent term issued by the PTO. It all depends on which companies elect

this option and which patent they select. In some cases, the effect of this provision might be to delay the entry onto the market of lower priced generics. This would tend to shift some of the cost of the incentive to develop a countermeasure to insurance companies and patients with an unrelated disease.

My rationale for including the patent bonus in the legislation is simple: I want this legislation to say emphatically that we mean business, we are serious, and we want biotechnology companies to reconfigure their research portfolios to focus in part on development of countermeasures. The other provisions in the legislation are powerful, but they may not be sufficient.

This proposal protects companies willing to take the risks of producing anti-terrorism products for the American public from potential losses incurred from lawsuits alleging adverse reactions to these products. It also preserves the right for plaintiffs to seek recourse for alleged adverse reactions in Federal District Court, with procedural and monetary limitations.

Under the plan, the Secretary of HHS is authorized, and in the case of contractors with HHS, is required, to indemnify and defend persons engaged in research, development and other activities related to biological defense products through execution of ''indemnification and defense agreements.'' An exclusive means of resolving civil cases that fall within the scope of the indemnification and defense agreements is provided with litigation rights for injured parties. Non-economic damages are limited to $250,000 per plaintiff and no punitive or exemplary damages may be awarded.

Some have tried to apply the existing Vaccine Injury Compensation Program, VICP, to this national effort. That is inappropriate because that program will be extremely difficult to use, both administratively and scientifically. For example, it would take several years to develop the appropriate ''table'' that identifies a compensable injury. Companies will be liable during this process. Note that when VICP was created, there had been studies of what adverse reactions to mandated childhood vaccines had occurred and the table was based largely on this experience. Even so, it has taken years of effort, ultimately resulting in wholesale revisions to the table by regulation, to get the current table in place. For antibioterrorism products currently being developed, it will simply be impossible to construct a meaningful Vaccine Injury Table, there will be no experience with the product.

The Frist-Kennedy bill relies on the President's Executive Order regarding liability protections, so there is a basis for an agreement regarding this issue as applied to bioterrorism countermeasures. The provisions that I have proposed are superior to those in the Executive Order because the order provides protection only on a contract basis. So, it doesn't provide protection based on the product being developed, only if that product is being developed under a specific government contract. Therefore, it's negotiated case by case by HHS and a company. Your proposal provides assurance to companies, especially small and medium sized companies, that they will be protected. This will allow them to go forward with their development plans. Their lawyers may be leery of trying to negotiate their own deal with HHS. So, the EO may be effective for a large company when it negotiates making additional smallpox vaccine, but it provides little assurance to a small company that wants to start development. Also, the administration says the EO will be used to protect companies, however, the next administration could interpret it differently. That's why a statutory provision will provide greater assurance to companies.

The legislation focuses intently on development of vaccines and medicines, but it is possible that we will face biological agents and chemical agents we've never seen before. As I've mentioned, the Soviet Union bioterror research focused in part on use of genetic modification technology to develop agents and toxins that currently-available antibiotics can not treat. Australian researchers accidentally created a modified mousepox virus, which does not affect humans, but it was 100 percent lethal to the mice. Their research focused on trying to make a mouse contraceptive vaccine for pest control. The surprise was that it totally suppressed the ''cell-mediated response,'' the arm of the immune system that combats viral infection. To make matters worse, the engineered virus also appears unnaturally resistant to attempts to vaccinate the mice. A vaccine that would normally protect mouse strains that are susceptible to the virus only worked in half the mice exposed to the killer version. If bioterrorists created a human version of the virus, vaccination programs would be of limited use. This highlights the drawback of working on vaccines against bioweapons rather than treatments.

With the advances in gene sequencing, genomics, we will know the exact genetic structure of a biological agent. This information in the wrong hands could easily be manipulated to design and possibly grow a lethal new bacterial and viral strains not found in nature. A scientist might be able to mix and match traits from different microorganisms, called recombinant technology, to take a gene that makes a deadly toxin from one strain of bacteria and introduce it into other bacterial strains. Dangerous pathogens or infectious agents could be made more deadly, and relatively benign agents could be designed as major public health problems. Bacteria that cause diseases such as anthrax could be altered in such a way that would make current vaccines or antibiotics against them ineffective. It is even possible that a scientist could develop an organism that develops resistance to antibiotics at an accelerated rate.

This means we need to develop technology, research tools, that will enable us to quickly develop a tailor-made, specific countermeasure to a previously unknown organism or agent. These research tools will enable us to develop a tailor-made vaccine or drug to deploy as a countermeasure against a new threat. The legislation authorizes companies to register and receive a certification making them eligible for the tax incentives in the bill for this research.

Perhaps the greatest strength of our biomedical research establishment in the United States is the synergy between our superb basic research institutions and private companies. The Bayh-Dole Act and Stevenson-Wydler Act form the legal framework for mutually beneficially partnerships between academia and industry. My legislation strengthens this synergy and these relationships with two provisions, one to upgrades in the basic research infrastructure available to conduct research on countermeasures and the other to increase cooperation between the National Institutes of Health and private companies.

Research on countermeasures necessitates the use of special facilities where biological agents can be handled safely without exposing researchers and the public to danger. Very few academic institutions or private companies can justify or capitalize the construction of these special facilities. The Federal Government can facilitate research and development of countermeasures by financing the construction of these facilities for use on a fee-for-service basis. The legislation authorizes appropriations for grants to nonprofit and for-profit institutions to construct, maintain, and manage up to ten Biosafety Level 3–4 facilities, or their equivalent, in different regions of the country for use in research to develop countermeasures. BSL 3–4 facilities are ones used for research on indigenous, exotic or dangerous agents with potential for aerosol transmission of disease that may have serious or lethal consequences or where the agents pose high risk of life-threatening disease, aerosol-transmitted lab infections, or related agents with unknown risk of transmission. The Director of the Office and NIH shall issue regulations regarding the qualifications of the researchers who may utilize the facilities. Companies that have registered with and been certified by the Director, to develop countermeasures under Section 5(d) of the legislation, shall be given priority in the use of the facilities.

The legislation also reauthorizes a very successful NIH-industry partnership program launched in FY 2000 in Public Law 106–113. The funding is for partnership challenge grants to promote joint ventures between NIH and

its grantees and for-profit biotechnology, pharmaceutical and medical device industries with regard to the development of countermeasures, as defined in Section 3 of the bill, and research tools, as defined in Section 4(d)(3) of the bill. Such grants shall be awarded on a one-for-one matching basis. So far the matching grants have focused on development of medicines to treat malaria, tuberculosis, emerging and resistant infections, and therapeutics for emerging threats. My proposal should be matched by reauthorization of the challenge grant program for these deadly diseases.

My legislation is carefully calibrated to provide incentives only where they are needed. This accounts for the choices in the legislation about which provisions are available to small biotechnology companies and large pharmaceutical companies.

Most biotechnology companies rely on infusions of investor capital to fund research, so the capital formation tax incentives only apply to them. Large pharmaceutical companies have ample revenues from product sales, and access to debt capital, so they do not need these incentives for capital formation.

The guaranteed purchase fund applies to any company that successfully develops a countermeasure. There is no reason to make any distinction between small and large companies. They all need to know the terms and dimensions of the potential market for the products they seek to develop. With countermeasures the market may well be uncertain or small, necessitating the creation of the purchase fund.

The patent protection provisions are also well calibrated. Both small and large companies face the patent term erosion problem due to delays at the FDA. There is no reason why companies that successfully develop a countermeasure should end up with a patent with an eroded term.

With regard to the patent bonus provision, this is included to supplement the capital formation tax incentives for small biotechnology companies. It provides a dramatic statement to investors that this research makes good business sense. As capital formation is not a challenge for a large pharmaceutical company, this patent bonus provision is not available to them.

Finally, with regard to the liability provisions, there is no reason to make any distinction between small and large companies.

The legislation makes choices. It sets the priorities. It provides a dose of incentives and seeks a response in the private sector. We are attempting here to do something that has not been done before. This is uncharted territory. And it's also an urgent mission.

There may be cases where a countermeasure developed to treat a biological toxin or chemical agent will have applications beyond this use. A broad-spectrum antibiotic capable of treating many different biological agents may well have the capacity to treat naturally occurring diseases.

This same issue arises with the Orphan Drug Act, which provides both tax and FDA approval incentives for companies that develop medicines to treat rare diseases. In some cases these treatments can also be used for larger disease populations. There are few who object to this situation. We have come to the judgment that the urgency of this research is worth the possible additional benefits that might accrue to a company.

In the context of research to develop countermeasures, I do not consider it a problem that a company might find a broader commercial market for a countermeasure. Indeed, it may well be the combination of the incentives in this legislation and these broader markets that drives the successful development of a countermeasure. If our intense focus on developing countermeasures, and research tools, provides benefits for mankind going well beyond terror weapons, we should rejoice. If this research helps us to develop an effective vaccine or treatment for AIDS, we should give the company the Nobel Prize for Medicine. If we do not develop a vaccine or treatment for AIDS, we may see 100 million people die of AIDS. We also have 400 million people infected with malaria and more than a million annual deaths. Millions of children die of diarrhea, cholera and other deadly and disabling diseases. Countermeasures research may deepen our understanding of the immune system and speed development of treatments for cancer and autoimmune diseases. That is not the central purpose of this legislation, but it is an additional rationale for it.

The issue raised by my legislation is very simple: do we want the Federal Government to fund and supervise much of the research to develop countermeasures or should we also provide incentives that make it possible for the private sector, at its own expense, and at its own risk, to undertake this research for good business reasons. The Frist-Kennedy legislation focuses effectively on direct Federal funding and coordination issues, but it does not include sufficient incentives for the private sector to undertake this research on its own initiative. Their proposal and mine are perfectly complimentary. We need to enact both to ensure that we are prepared for bioterror attacks.

I ask unanimous consent that an outline of my legislation appear at this point in the RECORD.

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

BIOLOGICAL AND CHEMICAL WEAPONS COUNTERMEASURES RESEARCH ACT OF 2001

The premise of the legislation is that there will be limits on direct Federal funding of research and development of countermeasures, vaccines, drugs, and other medicines, to prevent or treat infections from biological and chemical agents and toxins. The legislation proposes incentives that will enable biotechnology companies to take the initiative, for good business reasons, to conduct research to develop these countermeasures.

The incentives are needed because most biotech companies have no approved products or revenue from product sales to fund research. They rely on investors and equity capital markets to fund the research. These companies must focus on research that will lead to product sales and revenue and end their dependence on investor capital. When they are able to form the capital to fund research, biotech companies tend to be innovative and nimble and focused on the intractable diseases for which no effective medical treatments are available.

There is no established or predictable market for countermeasures. Investors are justifiably reluctant to fund this research, which will present technical challenges similar in complexity to development of effective treatments for AIDS. Investors need assurances that research on countermeasures has the potential to provide a rate of return commensurate with the risk, complexity and cost of the research, a rate of return comparable to that which may arise from a treatment for cancer, MS, Cystic Fibrosis and other major diseases or from other investments.

The legislation provides tax incentives to enable biotech companies to form capital to conduct the research. It then provides a guaranteed and pre-determined market for the countermeasures and special intellectual property protections to serve as a substitute for a market. Finally, it establishes liability protections for the countermeasures that are developed.

Specifics of the legislation are as follows: one, Office of Homeland Security sets research priorities in advance. Biotech companies that seek to be eligible for the incentives in the legislation must register with the Food and Drug Administration and be certified as eligible for the incentives; two, once a company is certified as eligible for the incentives, it becomes eligible for the tax, purchasing, patent, and liability provisions. A company is eligible for certification for the tax and patent provisions if it seeks to develop a research tool that will make it possible to quickly develop a countermeasure to a previously unknown agent or toxin, or an agent or toxin not targeted for research; three, Capital Formation for Countermeasures Research: The legislation provides that a company seeking to fund research is eligible to elect from among three tax incentives. The three alternatives are as follows: a. The company is eligible to establish an R&D Limited Partnership to conduct the research. The partnership passes through all business deductions and credits to the partners; b. The company is eligible to issue a special class of stock for the entity to conduct the research. The investors would be entitled to a zero capital gains tax rate on any gains realized on the stock; and, c. The company is eligible to receive refunds for Net Operating Losses, NOLs, to fund the research.

These tax incentives are available only to biotechnology companies with less than $750,000 in paid-in capital.

A company must elect only one of these incentives and, if it elects one of these incentives, it is then not eligible to receive benefits under the Orphan Drug Act. The legislation includes amendments to the Orphan Drug Act championed by Senators HATCH, KENNEDY and JEFFORDS, S. 1341. The amendments make the Credit available from the date of the application for Orphan Drug status, not the date the application is approved as provided under current law; four, Countermeasure Purchase Fund: The legislation provides that a company that successfully develops a countermeasure, through FDA approval, is eligible to sell the product to the Federal Government at a pre-established

price and in a pre-determined amount. The company is given notice of the terms of the sale before it commences the research. Sales to this fund may be made by any company irrespective of its paid-in capital; five, Intellectual Property Incentives: The legislation provides that a company that successfully develops a countermeasure is eligible to elect one of two patent incentives. The two alternatives are as follows: a. The company is eligible to receive a patent for its invention with a term as long as the term of the patent when it was issued by the Patent and Trademark Office, without any erosion due to delays in the FDA approval process. This alternative is available to any company that successfully develops a countermeasure irrespective of its paid-in capital; b. The company is eligible to extend the term of any patent owned by the company for two years. The patent may not be one that is acquired by the company from a third party. This is included as a capital formation incentive for small biotechnology companies with less than $750,000 in paid-in capital.

Six, Liability Protections: The legislation provides for protections against liability for the company that successfully develops a countermeasure. This option is available to any company that successfully develops a countermeasure irrespective of its paid-in capital; and seven, Strengthening of Biomedical Research Infrastructure: Authorizes appropriations for grants to construct specialized biosafety containment facilities where biological agents can be handled safely without exposing researchers and the public to danger. Also reauthorizes a successful NIH-industry partnership challenge grants to promote joint ventures between NIH and its grantees and for-profit biotechnology, pharmaceutical and medical device industries with regard to the development of countermeasures and research tools.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 186—TO AUTHORIZE REPRESENTATION OF SENATOR LOTT IN THE CASE OF LEE V. LOTT

Mr. DASCHLE submitted the following resolution; which was considered and agreed to:

S. RES. 186

Whereas, in the case of Lee v. Lott, Case No. 01–CV–792, pending in the United States District Court for the Southern District of Mississippi, the plaintiff has named Senator Trent Lott as the sole defendant; and

Whereas, pursuant to sections 703(a) and 704(a)(1) of the Ethics in Government Act of 1978, 2 U.S.C. §§288b(a) and 288c(a)(1), the Senate may direct its counsel to defend Members of the Senate in civil actions relating to their official responsibilities: Now, therefore, be it

Resolved, That the Senate Legal Counsel is authorized to represent Senator Lott in the case of Lee v. Lott.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ARMED SERVICES

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on Tuesday, December 4, 2001, at 9:30 a.m., in open session to consider the nomination of Claude M. Bolton, Jr. to be Assistant Secretary of the Army for Acquisition, Logistics, and Technology and, following the open session, to meet in executive session to consider certain pending nominations.

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

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on Environment and Public Works be authorized to meet on Tuesday, December 4, 2001, at 9:30 a.m. to conduct a hearing on the remediation process of biologically contaminated buildings. Specifically, the Committee is interested in the challenges of, and technologies available for, remediating buildings contaminated by biological contaminants. The hearing will be held in the Rm. SD–406.

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

COMMITTEE ON FOREIGN RELATIONS

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Tuesday, December 4, 2001, at 2:15 p.m. to hold a nomination hearing.

Agenda

Nominees: Adolfo Franco, of Virginia, to be an Assistant Administrator (Latin America and the Caribbean) of the United States Agency for International Development; Frederick Schieck, of Virginia, to be Deputy Administrator of the United States Agency for International Development; and Roger Winter, of Maryland, to be an Assistant Administrator (Democracy, Conflict, and Humanitarian Assistance) of the United States Agency for International Development.

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

COMMITTEE ON FOREIGN RELATIONS

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Tuesday, December 4, 2001, at 4:30 p.m. to hold a nomination hearing.

Agenda

Nominees: William R. Brownfield, of Texas, to be Ambassador to the Republic of Chile; and Charles S. Shapiro, of Georgia, to be Ambassador to the Bolivarian Republic of Venezuela.

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

COMMITTEE ON THE JUDICIARY

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on ''Department of Justice Oversight: Preserving Our Freedoms While Defending Against Terrorism,'' Tuesday, December 4, 2001, at 10 a.m. in Dirksen Room 226.

Tentative Witness List

Panel I: The Honorable Pierre-Richard Prosper, Ambassador-at-Large for War Crimes Issues, Department of State, Washington, DC.

Panel II: George J. Terwilliger III, Partner, White and Case, former Deputy Attorney General, Washington, DC; Professor Laurence H. Tribe, Harvard Law School, Cambridge, MA; Major General Michael J. Nardotti, Jr., Partner, Patton Boggs LLP, former Army Judge Advocate General, Washington, DC; Professor Cass R. Sunstein, University of Chicago Law School, Chicago, IL; and Timothy Lynch, Esq., Director, Project on Criminal Justice, Cato Institute, Washington, DC.

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

COMMITTEE ON THE JUDICIARY

Ms. STABENOW. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on ''Department of Justice Oversight: Preserving Our Freedoms While Defending Against Terrorism,'' Tuesday, December 4, 2001, at 2 p.m. in Dirksen Room 226.

Witness List

Panel I: Viet D. Dinh, Assistant Attorney General, Office of Legal Policy, U.S. Department of Justice.

Panel II: Ali Al-Maqtari, New Haven, CT; Michael J. Boyle, Esq., Law Offices of Michael J. Boyle, North Haven CT; Steven Emerson, The Investigative Project, Washington, DC; Gerald H. Goldstein, Esq., Goldstein, Goldstein & Hilley, San Antonio, TX; Nadine Strossen, President, American Civil Liberties Union, Professor, New York Law School, New York, NY; and Victoria Toensing, Esq., DiGenova & Toensing, Washington, DC.

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

PRIVILEGE OF THE FLOOR

Mr. REID. Mr. President, John Stewart and Scott Donelly are interns in the office of the Finance Committee chairman, Senator BAUCUS. I ask unanimous consent that the privilege of the floor be granted to them today during the pendency of the Railroad Retirement Act.

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

UNANIMOUS CONSENT AGREEMENT—H.R. 10

Mr. REID. Mr. President, I ask unanimous consent that at 9:30 a.m. tomorrow Senator NICKLES be recognized to raise a point of order against the pending substitute with Senator BAUCUS then immediately to be recognized to make a motion to waive. Further, I ask unanimous consent that there then be 30 minutes equally divided between Senators BAUCUS and NICKLES or their designees. I also ask unanimous consent that following the debate time the Senate proceed to a vote on the motion to waive, and if the motion to waive is