

107TH CONGRESS  
1ST SESSION

# S. 1764

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.

---

## IN THE SENATE OF THE UNITED STATES

DECEMBER 4, 2001

Mr. LIEBERMAN introduced the following bill; which was read twice and referred to the Committee on Finance

---

# 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.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4       (a) SHORT TITLE.—This Act may be cited as the  
5    “Robert Stevens, Thomas Morris Jr., Joseph Curseen,  
6    Kathy Nguyen, Ottilie Lundgren, and Lisa J. Raines Bio-  
7    logical and Chemical Weapons Research Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Definitions.
- Sec. 4. Biological and chemical agent research priority list.
- Sec. 5. Research registration requirements.
- Sec. 6. Federal tax incentives.
- Sec. 7. Bioterrorism Countermeasure Purchase Fund.
- Sec. 8. Patent term protection.
- Sec. 9. Liability and indemnification.
- Sec. 10. Construction of biosafety research facilities.
- Sec. 11. National Institutes of Health countermeasures partnership challenge grants.
- Sec. 12. Expanded human clinical trials qualifying for orphan drug credit.

### 3 SEC. 2. FINDINGS.

4 Congress makes the following findings:

10 (2) The threat of biological and chemical weap-  
11 ons is real.

12 (A) Members of the cult Aum Shinrikyo  
13 were responsible for chemical weapons attacks  
14 in Japan that killed 12 people and injured over  
15 5,000 on March 20, 1995. In this attack, ter-  
16 rorists placed plastic bags of diluted sarin, a le-  
17 thal nerve agent, on crowded subway trains  
18 during the morning rush-hour. It was found  
19 that sect members had legally stockpiled sodium

1 cyanide and hundreds of tons of chemicals used  
2 to make sarin, including sodium fluoride, phos-  
3 phorous trichloride, isopropyl alcohol, and ace-  
4 tonitrile. Aum Shinrikyo concealed its sarin  
5 manufacturing plant in a shrine to a sect god-  
6 dess. Investigators also found a biological weap-  
7 ons research lab on the cult's compound. The  
8 facility contained an incubator, an electron mi-  
9 croscope, a growth medium for fermenting or  
10 growing cultures, and cultures of the deadly  
11 botulinum toxin. Aum Shinrikyo members were  
12 apparently planning a more devastating offen-  
13 sive. The cult also released anthrax spores and  
14 botulinum in Tokyo nine times before it carried  
15 out its nerve gas attack. Aum's attempted germ  
16 attacks failed because the group's biologists cul-  
17 tured the strain of anthrax used to make vac-  
18 cine, which is harmless. Had they used a potent  
19 culture, the outcome might have been very dif-  
20 ferent. No one knows why the botulism attack  
21 failed. The horror is only magnified by the  
22 thought that individuals and nations would con-  
23 sider attacking others with such viruses. In Oc-  
24 tober 1992, Shoko Asahara, head of the Aum  
25 Shinrikyo cult, and 40 followers traveled to

1 Zaire, ostensibly to help treat Ebola victims.  
2 But the group's real intention, according to an  
3 October 31, 1995, report by the Permanent  
4 Subcommittee on Investigations of the Senate,  
5 was probably to obtain virus samples, culture  
6 them and use them in biological attacks.

7 (B) Before the 2001 anthrax attacks, the  
8 only recent successful biological attack in the  
9 United States, which was not recognized as  
10 such at the time, was with salmonella. Fol-  
11 lowers of Bhagwan Shree Rajneesh put the bac-  
12 teria in salad bars in restaurants in Dalles, Or-  
13 egon, in 1984, sickening 750 people.

14 (C) There is a long and sordid history of  
15 chemical and biological weapons, including use  
16 during the First and Second World Wars, an  
17 accidental release of anthrax spores in 1979  
18 from a Soviet military microbiological facility,  
19 use of mustard gas, tabun, and hydrogen cya-  
20 nide by Iraq in the Iran-Iraq War and against  
21 the Kurds, and development by Iraq of an of-  
22 fensive biological weapons capability including  
23 anthrax and botulium toxin.

24 (D) A Central Intelligence Agency report  
25 concluded that “clandestine production of chem-

1       ical and biological weapons for multiple casualty  
2       attacks raises no greater technical obstacles  
3       than does the clandestine production of chem-  
4       ical narcotics or heroin". One of the aspects  
5       which makes chemical and biological agents  
6       such an attractive weapon for a terrorist is the  
7       high shock value of these weapons.

8               (E) The Office of Technology Assessment  
9       estimated than 100 kilograms of anthrax re-  
10       leased upwind in an American city could cause  
11       between 130,000 and 3,000,000 deaths, de-  
12       pending on the weather and other variables.  
13       This degree of carnage is in the same range as  
14       that forecast for a hydrogen bomb.

15               (3) The United States must take steps to pre-  
16       vent access to the biological or chemical agents by  
17       terrorists and others, but attacks may nonetheless  
18       occur. The United States needs to respond to at-  
19       tacks with well-coordinated public health measures.  
20       We also need a broad array of effective diagnostics  
21       and medicines to treat those who are exposed to, or  
22       infected by, the agents.

23               (4) The United States faces a public health cri-  
24       sis with the spread of antibiotic resistant bacteria.  
25       This alone should lead us to take urgent action to

1 develop new medicines. The antibiotic vancomycin,  
2 our last line of defense against the often deadly bac-  
3 terium, *Staphylococcus aureus*, is losing its effective-  
4 ness. Worldwide, many strains of *S. aureus* are al-  
5 ready resistant to all antibiotics except vancomycin.  
6 Emergence of strains lacking sensitivity to  
7 vancomycin signifies that variants untreatable by  
8 every known antibiotic are on their way. *S. aureus*,  
9 a major cause of hospital-acquired infections, has  
10 thus moved one step closer to becoming an  
11 unstoppable killer. What is more, strains of at least  
12 three bacterial species capable of causing life-threat-  
13 ening illnesses (Enterococcus faecalis,  
14 *Mycobacterium tuberculosis* and *Pseudomonas*  
15 *aeruginosa*) already evade every antibiotic in the cli-  
16 nician's armamentarium, a stockpile of more than  
17 100 drugs. In part because of the rise in resistance  
18 to antibiotics, the death rates for some commu-  
19 nicable diseases (such as tuberculosis) have started  
20 to rise again, after having declined in the industrial  
21 nations.

22 (5) The possibility exists that terrorists or oth-  
23 ers will use biotechnology techniques to enhance the  
24 lethality of a biological agent.

(A) The immunization schedule involves six initial doses over 18 months followed by yearly boosters.

(B) Immunity is not protective against all natural anthrax strains in guinea pigs.

14 (C) There is a high incidence of local reac-  
15 tions (30 percent according to the package in-  
16 sert).

17 The vaccine is an undefined mix of bacterial products.  
18 Furthermore, the potency of both the UK and  
19 MDPH-PA vaccines is found to vary significantly  
20 between lots. Some are concerned that the vaccine  
21 might lead to chronic fatigue syndrome,  
22 fibromyalgia, multiple chemical sensitivity, auto-  
23 immune illnesses, or neuropathies. There is no vac-  
24 cine against plague or most of the other bacteria

1 and viruses that might be used as biological weapons.  
2

3 (7) Treatments for those who are not protected  
4 by vaccines are often not effective. Inhalation an-  
5 thrax (woolsorters' disease) results from inhaling an-  
6 thrax spores and, if untreated, it is about 90 percent  
7 fatal. Antibiotics and standard interventions pro-  
8 vided after symptoms have developed rarely prevent  
9 a fatal outcome.

10 (8) Vaccines and treatments for exposure to  
11 nerve toxins do not exist or are ineffective.

12 (9) The United States Government is directly  
13 funding biomedical research on vaccines and treat-  
14 ments for biological and chemical agents. These  
15 funding efforts could be matched many-fold if the  
16 1,300 biotechnology companies were able to secure  
17 the funding from private investors to conduct this  
18 research. Most biotechnology companies are early  
19 stage research ventures with no revenue from prod-  
20 uct sales to finance their medical research. Most bio-  
21 technology companies must rely on repeated and  
22 large infusions of investor capital to fund this re-  
23 search. To conduct research on countermeasures to  
24 biological agents and other toxins or any other type  
25 of research, these companies must persuade venture

1 capitalists and other investors that funding this re-  
2 search may lead to a rate of return commensurate  
3 with the risk and comparable to the rate of return  
4 available to other investment opportunities.

5 (10) Biotechnology companies are justifiably re-  
6 luctant to modify their ongoing research priorities  
7 and devote scarce management and scientific talent  
8 to new and risky projects. Their first priority and  
9 obligation is and must be to secure approval to mar-  
10 ket a product that will generate revenue sufficient to  
11 reduce the dependence of the company on continued  
12 infusions of investor capital and to provide a long-  
13 awaited return to patient investors.

14 (11) Biotechnology companies tend to focus on  
15 breakthrough research to develop medical treatments  
16 for diseases where no effective treatments are cur-  
17 rently available. They often specialize in research  
18 and development on rare diseases and they are par-  
19 ties in the vast majority of the collaborations in the  
20 United States between private industry and aca-  
21 demic medical centers and the National Institutes of  
22 Health. Many biotechnology companies do not have  
23 approval to market products with respect to which  
24 they might develop minor improvements to maintain  
25 a market advantage.

(12) Successful research and development of countermeasures will necessitate breakthroughs in virology, immunology, antibiotics, genetic analysis, and many other disciplines in biology. There is no established market or appropriate Food and Drug Administration approval process for most countermeasures. Biotechnology companies and their investors are sensitive to any possibility that successful completion of breakthrough research leading to the approval for the sale of a product, including a countermeasure, will lead to challenges to their prices and patents. They are especially sensitive to the terms of sales that may arise when the only market for a product is the Federal Government. These are risks that companies, employees and investors in other sectors of the economy do not face and that may affect the willingness of investors and capital markets to fund this critical medical research.

19 (13) The enactment of tax, patent, liability and  
20 other incentives will enable the biotechnology indus-  
21 try to raise equity and other capital from investors  
22 to fund research on countermeasures for biological  
23 and chemical attacks. This will supplement direct  
24 Federal funding for this research and speed develop-  
25 ment of life saving technologies. The existence of

1 these technologies will reassure the public that if at-  
2 tacks occur, effective medical treatments are avail-  
3 able and there is no reason for panic.

4 **SEC. 3. DEFINITIONS.**

5 In this Act:

6 (1) COUNTERMEASURES.—The term “counter-  
7 measures” means a vaccine, microbicide, diagnostic  
8 technology, drug, or other technology that can be  
9 used to diagnose, treat, or prevent infection with, or  
10 the spread of, a biological agent or toxin on the list  
11 described in section 4, or a research tool used to de-  
12 velop such countermeasure, and that has been ap-  
13 proved for use in accordance with applicable provi-  
14 sions of the Federal Food, Drug, and Cosmetic Act  
15 (21 U.S.C. 301 et seq.) and the Public Health Serv-  
16 ice Act (42 U.S.C. 201 et seq.).

17 (2) DIRECTOR.—The term “Director”, except  
18 as provided in section 6, means the Director of the  
19 Office of Homeland Security.

20 (3) OFFICE.—The term “Office” means the Of-  
21 fice of Homeland Security.

22 **SEC. 4. BIOLOGICAL AND CHEMICAL AGENT RESEARCH**  
23 **PRIORITY LIST.**

24 (a) DEVELOPMENT.—Not later than 90 days after  
25 the date of enactment of this Act, the Director, in con-

1 sultation with the Secretary of Defense and the Secretary  
2 of Health and Human Services, shall develop and publish  
3 in the Federal Register, or otherwise make available to  
4 holders of approved applications or other potential manu-  
5 facturers of bioterrorism countermeasures, a list of bio-  
6 logical and chemical agents and toxins that may be used  
7 as weapons of mass destruction. In determining which  
8 agents or toxins to place on the list, the Director shall  
9 consider whether the agent or toxin poses a significant se-  
10 curity or medical threat to the United States military and  
11 intelligence personnel or civilians and whether counter-  
12 measures are more likely to be developed with the avail-  
13 ability of the tax, purchase, patent, or liability provisions  
14 of this Act.

15 (b) INITIAL LIST.—The initial list published under  
16 subsection (a) may, at the discretion of the Director, con-  
17 tain the following biological and chemical agents and tox-  
18 ins:

19 (1) Variola major confluent pox, flat pox, and  
20 hemorrhagic smallpox.

21 (2) Bacillus anthracis (anthrax).

22 (3) Clostridium botulinum toxin (botulism).

23 (4) Francisella tularensis (tularaemia).

24 (5) Ebola hemorrhagic fever.

25 (6) Marburg hemorrhagic fever.

1 (7) Lassa fever.  
2 (8) Julin (Argentine hemmorrhagic fever).  
3 (9) Crimean-Congo Hemorrhagic Fever.  
4 (10) *Coxiella burnetti* (Q fever).  
5 (11) *Brucella* species (brucellosis).  
6 (12) *Burkholderia mallei* (glanders).  
7 (13) Venezuelan encephalomyelitis.  
8 (14) Eastern and Western equine  
9 encephalomyelitis.  
10 (15) Ricin toxin from *ricinus communis* (castor  
11 beans).  
12 (16) Epsilon toxin of *colistridium perfringens*.  
13 (17) *Staphylococcus enterotoxin* B.  
14 (18) *Salmonella* species.  
15 (19) *Shigella dysenteriae*.  
16 (20) *Escherichia coli* 0157:H7.  
17 (21) *Vibrio cholerae* (colera).  
18 (22) *Cryptosporidium parvum*.  
19 (23) Nipah virus.  
20 (24) Hantaviruses.  
21 (25) Tickborn hemorrhagic fever viruses.  
22 (26) Tickborn encephalitis virus.  
23 (27) Yellow fever.  
24 (28) Malaria.  
25 (29) Antibiotic resistant tuberculosis.

1 (30) Acquired immune deficiency syndrome  
2 (AIDS).

3 (31) *Entamoeba histolytica*.

4 (32) Bacillary dysentery.

## 5 (33) Giardiasis.

### 6 (34) Trichomoniasis.

### 7 (35) Trypanosomiasis.

## 8 (36) Leishmaniasis.

(37) Nerve agents (including tabun, sarin, soman, GF, and VX).

11 (38) Blood agents (including hydrogen cyanide  
12 and cyanogen chloride).

13 (39) Blister agents (including lewisite,  
14 nitrogen and sulfur mustards).

15 (40) Heavy metals (including arsenic, lead, and  
16 mercury).

17 (41) Colatile toxins (including benzene, chloro-  
18 form and trihalomethanes)

19 (42) Pulmonary agents (including phosgene and  
20 chlorine vinyl chloride)

### 21 (43) Incapacitating agents (BZ)

22 (c) REVISIONS.—The Director shall revise the list  
23 published under subsection (a) on at least an annual basis,  
24 and publish such revised list in the Federal Register, or  
25 otherwise make such list available to holders of approved

1 applications or other potential manufacturers of bioter-  
2 rorism countermeasures.

3 (d) NO JUDICIAL REVIEW.—Notwithstanding any  
4 other provision of law, there shall be no judicial review  
5 of the list, or revised list, published by the Director under  
6 this section.

7 **SEC. 5. RESEARCH REGISTRATION REQUIREMENTS.**

8 (a) IN GENERAL.—On or before December 31 of each  
9 year each entity that operates any commercial, for-profit  
10 establishment in any State that seeks to be eligible for  
11 the tax, procurement, intellectual property, and liability  
12 incentives provided for in this Act, and that is engaged  
13 in the conduct of research to develop countermeasures,  
14 shall register with the Food and Drug Administration.

15 Such registration shall contain—

16 (1) the name and address of the entity;  
17 (2) the name and address of the establishment  
18 at which the research is being conducted;  
19 (3) the name of the agent or toxin with respect  
20 to which the entity seeks to develop counter-  
21 measures;

22 (4) a description of the research that is being,  
23 or that will be, conducted to develop counter-  
24 measures to such agent or toxin;

5 (b) AVAILABILITY OF INFORMATION.—

24 (c) INSPECTIONS.—Every establishment in any State  
25 registered with the Food and Drug Administration pursu-

1 ant to this section shall be subject to inspection, limited  
2 to such information as may be necessary relating to the  
3 development of countermeasures and facility security, pur-  
4 suant to regulations promulgated by the Director.

5 (d) CERTIFICATION.—

6 (1) IN GENERAL.—With respect to each entity  
7 that registers with the Food and Drug Administra-  
8 tion under this section, the Director, in consultation  
9 with the Food and Drug Administration, shall deter-  
10 mine whether the research to be conducted under  
11 such registration is intended to lead to the develop-  
12 ment of countermeasures (other than a research tool  
13 as defined in paragraph (3)).

14 (2) DETERMINATION.—If the Director makes  
15 an affirmative determination under paragraph (1)  
16 with respect to an entity, the Director shall certify  
17 the entity as being eligible—

18 (A) for the tax incentive provisions de-  
19 scribed in section 6;

20 (B) for participating in the Bioterrorism  
21 Countermeasures Purchase Fund program  
22 under section 7;

23 (C) for patent extension protection under  
24 section 156a or 158 of title 35, United States  
25 Code, as added by section 8; and

1 (D) for the liability protections provided  
2 for under the amendment made by section 9.

(3) DETERMINATIONS REGARDING RESEARCH TOOLS.—The Director may accept a registration under this section from a commercial, for-profit establishment in a State, and may provide a certification under this section if the Director determines that the establishment intends to conduct research that is designed to lead to the development of a research tool that will make it possible to expeditiously develop a countermeasure to an agent or toxin that is not included on the list published under section 4. An establishment that is certified under this paragraph shall be eligible for the tax incentive provisions described in section 6.

16 (e) RULE OF CONSTRUCTION.—Nothing in this sec-  
17 tion shall be construed to prohibit a commercial, for-profit  
18 establishment from filing more than 1 registration con-  
19 cerning research and from obtaining more than 1 certifi-  
20 cation of eligibility under this section.

## 21 SEC. 6. FEDERAL TAX INCENTIVES.

22 Any entity certified as eligible for any taxable year  
23 under section 5(d) may irrevocably elect 1 of the following  
24 Federal tax incentives to fund research to develop counter-  
25 measures:

16 (A) INCREASED EXCLUSION.—Subsection  
17 (a) of section 1202 of such Code shall be ap-  
18 plied by substituting “100 percent” for “50  
19 percent”.

20 (B) STOCK OF LARGER BUSINESSES ELIGI-  
21 BLE FOR EXCLUSION.—Paragraph (1) of sec-  
22 tion 1202(d) of such Code (defining qualified  
23 small business) shall be applied by substituting  
24 “\$750,000,000” for “\$50,000,000” each place  
25 it appears.

5 (D) NONAPPLICATION OF PER-ISSUER LIM-  
6 ITATION.—Section 1202 of such Code shall be  
7 applied without regard to subsection (b) (relat-  
8 ing to per-issuer limitations on taxpayer's eligi-  
9 ble gain).

10 (E) MODIFICATION OF WORKING CAPITAL  
11 LIMITATION.—Section 1202(e)(6) of such Code  
12 shall be applied—

13 (i) in subparagraph (B), by sub-  
14 stituting “5 years” for “2 years”, and  
15 (ii) without regard to the last sen-  
16 tence.

17 (F) NONAPPLICATION OF MINIMUM TAX  
18 PREFERENCE.—Section 57(a) of such Code  
19 shall be applied without regard to paragraph  
20 (7).

21 (3) BREAKTHROUGH RESEARCH REFUNDABLE  
22 CREDIT.—

23 (A) IN GENERAL.—The Internal Revenue  
24 Code of 1986 is amended by redesignating sec-

1 section 35 as section 36 and by inserting after sec-  
2 tion 34 the following new section:

### 3 "SEC. 35. BREAKTHROUGH RESEARCH CREDIT."

4       “(a) GENERAL RULE.—There shall be allowed as a  
5 credit against the tax imposed by this subtitle an amount  
6 equal to the sum of a qualified research corporation’s dis-  
7 counted research credits and discounted research NOL’s.

8        "(b) QUALIFIED RESEARCH CORPORATION.—

9               “(1) IN GENERAL.—For the purposes of this  
10              section, the term ‘qualified research corporation’  
11              means any domestic corporation subject to tax under  
12              subchapter C of this chapter—

13                     “(A) which has not incurred regular tax li-  
14                     ability (as defined in section 55(c)) under this  
15                     chapter for a period of at least 3 consecutive  
16                     taxable years (other than short taxable years)  
17                     immediately prior to the commencement of the  
18                     taxable year as to which any election is made  
19                     under this section.

20                   “(B) which has not been controlled by, or  
21                   been under common control (as determined  
22                   under section 267(b)) with, a corporation which  
23                   has incurred regular tax liability (as so defined)  
24                   under this chapter for any taxable year com-

1                   mencing during the period described in sub-  
2                   paragraph (A),

6                         “(D) which is not the subject of any pro-  
7                         ceeding under Federal or State bankruptcy or  
8                         insolvency laws.

9                 “(2) SPECIAL RULE.—A qualified research cor-  
10                 poration, in claiming the credit provided for in this  
11                 section, shall not take into account any expenditures  
12                 for which it is reimbursed by another taxpayer, ex-  
13                 cept to the extent that the reimbursing taxpayer  
14                 provides a certification to the qualified research cor-  
15                 poration that—

16                   “(A) the reimbursing taxpayer would be  
17                   entitled to take such expenditures into account  
18                   in the same manner, and

19                   “(B) the reimbursing taxpayer shall not  
20                   take such expenditures into account in claiming  
21                   any credits under this section.

22        "(c) DEFINITIONS.—For the purposes of this  
23 section—

24               “(1) RESEARCH CREDIT.—The term ‘research  
25               credit’ means the sum of those portions of a quali-

1 fied research corporation's current year business  
2 credit and business credit carryforwards, as deter-  
3 mined under section 38(a), which are attributable to  
4 the credit determined under section 41 (for increases  
5 in research activities) and which are attributable to  
6 countermeasures research activities.

7 "(2) RESEARCH NOL.—The term 'research  
8 NOL' means that portion of a qualified research cor-  
9 poration's net operating loss (as defined in section  
10 172(c)) attributable to qualified countermeasure re-  
11 search expenditures.

12 "(3) DISCOUNTED RESEARCH CREDIT.—The  
13 term 'discounted research credit' shall mean the re-  
14 search credit amounts subject to an election under  
15 this section multiplied by 75 percent.

16 "(4) DISCOUNTED RESEARCH NOL.—The term  
17 'discounted research NOL' shall mean the research  
18 NOL subject to an election under this section multi-  
19 plied by 75 percent of the highest marginal tax rate  
20 in effect under section 11.

21 "(5) ORDERING RULE.—For purposes of deter-  
22 mining the portion of a taxpayer's net operating loss  
23 that is attributable to research expenditures (within  
24 the meaning of paragraph (2)) for any taxable year,  
25 research expenditures shall be considered to be offset

1       against the taxpayer's gross income on a pro rata  
2       basis with all other allowable expenses and charges  
3       paid or incurred in the taxable year.

4       “(d) ELECTION TO RELINQUISH RESEARCH-RE-  
5       LATED NET OPERATING LOSSES AND TAX CREDITS FOR  
6       CASH REFUNDS.—

7           “(1) GENERAL RULE; BENEFITS ARISING IN  
8       CURRENT YEAR.—A qualified research corporation  
9       may make an election under this section to relin-  
10       quish all of its current year research NOL's and re-  
11       search credits in exchange for cash refunds. The cor-  
12       poration shall make the election on its timely filed  
13       tax return (including extensions) for the taxable year  
14       in which the research NOL's and research credits  
15       arise.

16           “(2) SPECIAL RULE; NET OPERATING LOSS AND  
17       UNUSED TAX CREDIT CARRYFORWARDS.—

18           “(A) IN GENERAL.—If a qualified research  
19       corporation has unabsorbed research NOL's or  
20       research credits not subject to an election under  
21       this section, which arose in a previous taxable  
22       year and which the qualified research corpora-  
23       tion would be entitled to carry forward to a tax-  
24       able year for which it makes an election under  
25       paragraph (1), then the taxpayer shall des-

1               ignate such research NOL carryforwards and  
2               such research credit carryforwards to be cov-  
3               ered by its election under this section.

4                         “(B) LIMITATION.—For any taxable year,  
5                         the amount of research NOL carryforwards and  
6                         research credit carryforwards to the taxable  
7                         year which may be designated as covered by an  
8                         election under this section shall be the greater  
9                         of—

19                     “(3) PROCEDURES AND RECORDKEEPING BY  
20                     ELECTING CORPORATION.—An election under this  
21                     section may be revoked by the taxpayer only with  
22                     the consent of the Secretary. Qualified research cor-  
23                     porations making such an election shall provide such  
24                     information in connection with such election as may  
25                     be required by the Secretary and shall maintain

1 records sufficient to permit the Secretary to identify  
2 and to audit the specific research credits and re-  
3 search NOL's that are subject to an election under  
4 this section.

5       “(e) EXTINGUISHMENT OF RELINQUISHED TAX  
6 BENEFITS.—

7           “(1) DEDUCTIONS.—No deduction shall be al-  
8 lowed to a qualified research corporation under the  
9 alternative minimum tax provisions of section  
10 56(a)(4) or the net operating loss provisions of sec-  
11 tion 172 with respect to that portion of a net oper-  
12 ating loss for which an election under this section is  
13 in effect.

14           “(2) CREDITS.—No credit shall be allowed to a  
15 qualified research corporation under section 38(a)  
16 with respect to any credit amounts determined under  
17 section 41 for which an election under this section  
18 is in effect.

19           “(f) LIMITATION ON USE OF NONRELINQUISHED  
20 TAX BENEFITS BY ELECTING CORPORATION.—A quali-  
21 fied research corporation which has received refunds pur-  
22 suant to an election under this section shall not be entitled  
23 to utilize any carrybacks or carryforwards of net operating  
24 losses or tax credits (which are not subject to an election  
25 under this section and are otherwise available to be uti-

1 lized in the taxable year) to reduce taxable income or to  
2 offset any tax liability for taxable years after the year of  
3 such election, until such corporation has paid tax imposed  
4 under this chapter for such taxable years in an aggregate  
5 amount equal to the aggregate amount of the refunds pre-  
6 viously received, less any underpayment amount deter-  
7 mined under subsection (g).

8       “(g) CREDIT PROCEEDS FROM EXCHANGE OF RE-  
9 SEARCH CREDITS AND RESEARCH NOL'S MUST BE USED  
10 EXCLUSIVELY FOR RESEARCH OR EXPERIMENTATION  
11 PURPOSES; RECAPTURE.—

12       “(1) RECAPTURE OF CREDIT IN THE EVENT OF  
13 FAILURE TO INCREASE RESEARCH AND EXPERIMEN-  
14 TATION ACTIVITY.—If—

15       “(A) the sum of—

16           “(i) the credit received by a qualified  
17 research corporation from an election  
18 under this section made on its tax return  
19 for a taxable year (the election year), plus

20           “(ii) the amount of its research or ex-  
21 perimental expenditures (within the mean-  
22 ing of section 174, but prior to application  
23 of section 280C) paid or incurred during  
24 the election year, exceeds

1                   “(B) the amount of such research or ex-  
2                   perimental expenditures paid or incurred by the  
3                   qualified research corporation during the tax-  
4                   able year immediately following the election  
5                   year,

6                   then the election shall be void to the extent of the  
7                   excess, and the excess shall be treated as an under-  
8                   payment of tax imposed by this chapter for the elec-  
9                   tion year without regard to any credit otherwise al-  
10                   lowable under this chapter.

11                   “(2) UNDERPAYMENT NOT SUBJECT TO CER-  
12                   TAIN PENALTIES.—An underpayment of tax deter-  
13                   mined under paragraph (1) shall not be taken into  
14                   account in determining any penalties or additions to  
15                   tax under sections 6655 and 6662.

16                   “(3) RECAPTURE PENALTY LIMITED TO THE  
17                   AMOUNT OF EXCHANGE ELECTION PAYMENTS RE-  
18                   CEIVED.—An underpayment of tax determined  
19                   under paragraph (1) shall not exceed the amount  
20                   taken into account under paragraph (1)(A)(i).

21                   “(4) EXCEPTION.—No increase in the aggre-  
22                   gate amounts paid by a qualified research corpora-  
23                   tion to a person with whom the corporation has a re-  
24                   lationship specified in section 267(b) shall be taken

1 into account in determining the amount of any ex-  
2 cess under paragraph (1).

3       **“(h) ADDITIONAL REQUIREMENTS FOR A QUALIFIED**  
4 **RESEARCH CORPORATION.—**

5           “(1) IN GENERAL.—A corporation shall be con-  
6 sidered as meeting the requirements of this sub-  
7 section for any taxable year if during such taxable  
8 year—

9               “(A) at least 80 percent (by value) of the  
10 assets of such corporation are used by such cor-  
11 poration in the active conduct of 1 or more  
12 qualified trades or businesses,

13               “(B) such corporation is an eligible cor-  
14 poration, and

15               “(C) such corporation has aggregate gross  
16 assets (as defined in section 1202(d)(2)) of not  
17 more than \$750,000,000.

18           “(2) SPECIAL RULE FOR CERTAIN ACTIVI-  
19 TIES.—For purposes of paragraph (1), if, in connec-  
20 tion with any future qualified trade or business, a  
21 corporation is engaged in—

22               “(A) startup activities described in section  
23 195(c)(1)(A),

24               “(B) activities resulting in the payment or  
25 incurring of expenditures which may be treated

1 as research and experimental expenditures  
2 under section 174, or

3 “(C) activities with respect to in-house re-  
4 search expenses described in section 41(b)(4),  
5 assets used in such activities shall be treated as used  
6 in the active conduct of a qualified trade or busi-  
7 ness. Any determination under this paragraph shall  
8 be made without regard to whether a corporation  
9 has any gross income from such activities at the  
10 time of the determination.

11 “(3) QUALIFIED TRADE OR BUSINESS.—For  
12 purposes of this subsection, the term ‘qualified trade  
13 or business’ means any trade or business other  
14 than—

15 “(A) any trade or business involving the  
16 performance of services in the fields of health,  
17 law, engineering, architecture, accounting, actu-  
18 arial science, performing arts, consulting, ath-  
19 letics, financial services, brokerage services, or  
20 any trade or business where the principal asset  
21 of such trade or business is the reputation or  
22 skill of 1 or more of its employees,

23 “(B) any banking, insurance, financing,  
24 leasing, investing, or similar business,

1               “(C) any farming business (including the  
2               business of raising or harvesting trees),

3               “(D) any business involving the production  
4               or extraction of products of a character with re-  
5               spect to which a deduction is allowable under  
6               section 613 or 613A, and

7               “(E) any business of operating a hotel,  
8               motel, restaurant, or similar business.

9               “(4) ELIGIBLE CORPORATION.—For purposes  
10               of this subsection, the term ‘eligible corporation’  
11               means any domestic corporation, except that such  
12               term shall not include—

13               “(A) a DISC or former DISC,

14               “(B) a corporation with respect to which  
15               an election under section 936 is in effect or  
16               which has a direct or indirect subsidiary with  
17               respect to which such an election is in effect,

18               “(C) a FSC (as defined in section 922, as  
19               in effect on the day before the date of the en-  
20               actment of the FSC Repeal and Extraterritorial  
21               Income Exclusion Act of 2000),

22               “(D) a regulated investment company, real  
23               estate investment trust, REMIC, or FASIT, or

24               “(E) a cooperative.

25               “(5) STOCK IN OTHER CORPORATIONS.—

1                     “(A) LOOK-THRU IN CASE OF SUBSIDI-  
2                     ARIES.—For purposes of this subsection, stock  
3                     and debt in any subsidiary corporation shall be  
4                     disregarded and the parent corporation shall be  
5                     deemed to own its ratable share of the subsidi-  
6                     ary’s assets, and to conduct its ratable share of  
7                     the subsidiary’s activities.

8                     “(B) PORTFOLIO STOCK OR SECURITIES.—  
9                     A corporation shall be treated as failing to meet  
10                    the requirements of paragraph (1) for any pe-  
11                    riod during which more than 10 percent of the  
12                    value of its assets (in excess of liabilities) con-  
13                    sist of stock or securities in other corporations  
14                    which are not subsidiaries of such corporation  
15                    (other than assets described in paragraph (7)).

16                    “(C) SUBSIDIARY.—For purposes of this  
17                    paragraph, a corporation shall be considered a  
18                    subsidiary if the parent owns more than 50 per-  
19                    cent of the combined voting power of all classes  
20                    of stock entitled to vote, or more than 50 per-  
21                    cent in value of all outstanding stock, of such  
22                    corporation.

23                    “(6) WORKING CAPITAL.—For purposes of  
24                    paragraph (2)(A), any assets which—

1               “(A) are held as a part of the reasonably  
2               required working capital needs of a qualified  
3               trade or business of the corporation, or

4               “(B) are held for investment and are rea-  
5               sonably expected to be used within 5 years to  
6               finance research and experimentation in a  
7               qualified trade or business or increases in work-  
8               ing capital needs of a qualified trade or busi-  
9               ness,

10               shall be treated as used in the active conduct of a  
11               qualified trade or business. For periods after the  
12               corporation has been in existence for at least 5  
13               years, in no event may more than 50 percent of the  
14               assets of the corporation qualify as used in the ac-  
15               tive conduct of a qualified trade or business by rea-  
16               son of this paragraph.

17               “(7) MAXIMUM REAL ESTATE HOLDINGS.—A  
18               corporation shall not be treated as meeting the re-  
19               quirements of paragraph (2) for any period during  
20               which more than 10 percent of the total value of its  
21               assets consists of real property which is not used in  
22               the active conduct of a qualified trade or business.  
23               For purposes of the preceding sentence, the owner-  
24               ship of, dealing in, or renting of real property shall

1 not be treated as the active conduct of a qualified  
2 trade or business.

3 “(8) COMPUTER SOFTWARE ROYALTIES.—For  
4 purposes of paragraph (2), rights to computer soft-  
5 ware which produces active business computer soft-  
6 ware royalties (within the meaning of section  
7 543(d)(1)) shall be treated as an asset used in the  
8 active conduct of a trade or business.

9 “(i) REGULATIONS.—The Secretary may prescribe  
10 such regulations as may be necessary to carry out the pur-  
11 poses of this section, including regulations coordinating  
12 the application of this section with the consolidated return  
13 regulations and regulations providing for the application  
14 of this section to short taxable years.”.

15 (B) CONFORMING AMENDMENTS.—

16 (i) Section 55(c)(1) of the Internal  
17 Revenue Code of 1986 is amended by  
18 striking “section 49(b)” and inserting  
19 “section 35(g), 49(b),”.

20 (ii) Section 1324(b)(2) of title 31,  
21 United States Code, is amended by strik-  
22 ing “or” before “enacted” and by inserting  
23 before the period at the end “, or from sec-  
24 tion 35 of such Code”.

1 (C) CLERICAL AMENDMENT.—The table of  
2 sections for subpart C of part IV of subchapter  
3 A of chapter 1 of the Internal Revenue Code of  
4 1986 is amended by striking the item relating  
5 to section 35 and inserting the following new  
6 items:

“Sec. 35. Breakthrough research credit.  
“Sec. 36. Overpayments of tax.”.

10 SEC. 7. BIOTERRORISM COUNTERMEASURE PURCHASE  
11 FUND.

12 (a) PURPOSE.—It is the purpose of this section to  
13 create incentives for private for-profit sector research that  
14 is intended to lead to the development of countermeasures  
15 to respond to an attack with biological agents or toxins.

16 (b) DEFINITIONS.—In this section:

17 (1) DIRECTOR.—The term “Director” means  
18 the Director of the Centers for Disease Control and  
19 Prevention.

4 (4) SECRETARY.—The term “Secretary” means  
5 the Secretary of the Treasury.

6 (c) ESTABLISHMENT OF FUND.—As of the date that  
7 the Secretary determines that any eligible countermeasure  
8 is available for purchase, there is established in the Treas-  
9 ury of the United States a fund to be known as the “Bio-  
10 terrorism Countermeasure Purchase Fund” consisting of  
11 amounts appropriated under subsection (f).

12 (d) INVESTMENT OF FUND.—Amounts in the Fund  
13 shall be invested in accordance with section 9702 of title  
14 31, United States Code, and any interest on, and proceeds  
15 from any such investment shall be credited to and become  
16 part of the Fund.

17 (e) USE OF FUND.—

4 (A) shall be purchased at a negotiated unit  
5 price;

6 (B) shall be approved by the Food and  
7 Drug Administration; and

8 (C) shall be made under a formula estab-  
9 lishing a minimum price per dose, minimum  
10 number of doses, and minimum technical re-  
11 quirements for the eligible countermeasure.

18 (A) consideration of the prevalence of the  
19 infection to be treated by the eligible counter-  
20 measure; and

21 (B) consideration of the ability of the re-  
22 cipient to effectively and safely deliver the coun-  
23 termeasures.

24 (4) RULE OF CONSTRUCTION.—Nothing in this  
25 subsection shall be construed to require that the

1 Fund purchase more than one eligible counter-  
2 measure for each agent or toxin contained on the  
3 Biological and Chemical Agent Priority List devel-  
4 oped under section 4.

5 (5) REGULATIONS.—The Director shall promul-  
6 gate such regulations as are necessary to carry out  
7 the provisions of this subsection.

8 (f) APPROPRIATIONS.—

9 (1) IN GENERAL.—Subject to paragraph (2),  
10 there are appropriated out of any funds in the  
11 Treasury not otherwise appropriated such sums as  
12 may be necessary to carry out the purposes of the  
13 Fund for each of 10 fiscal years beginning with the  
14 first fiscal year after the date that the Secretary de-  
15 termines that any eligible countermeasure is avail-  
16 able for purchase by the Fund.

17 (2) TRANSFER TO FUND.—The Secretary shall  
18 transfer the amount appropriated under paragraph  
19 (1) for a fiscal year to the Fund.

20 (3) AVAILABILITY.—Amounts appropriated  
21 under this section shall remain available until ex-  
22 pended.

23 (g) TERMS OF CONTRACTS.—Notwithstanding any  
24 other provision of law, a contract entered into by the Di-

1 rector under this section shall be for a period of not to  
2 exceed 10 years.

3 (h) RULE OF CONSTRUCTION.—Nothing in this sec-  
4 tion shall be construed to limit in any manner, the sale  
5 or terms of sale of an eligible countermeasure to any other  
6 entity or individual.

7 **SEC. 8. PATENT TERM PROTECTION.**

8 (a) ELECTION.—

9 (1) IN GENERAL.—An entity that is certified  
10 under section 5(d) may elect to receive patent pro-  
11 tection under either section 156a or 158 of title 35,  
12 United States Code, (as amended by this section) if  
13 the countermeasure involved is an eligible counter-  
14 measure as defined under section 7. An entity that  
15 is not a qualified small business as defined in section  
16 1202 of the Internal Revenue Code of 1986 (as  
17 amended by section 6) may elect only the first of  
18 these provisions.

19 (2) TIME FOR ELECTION.—An election shall be  
20 made by an entity under paragraph (1) within 60  
21 days after the date on which the countermeasure in-  
22 volved is available for purchase under section 7. An  
23 election under this subsection shall be irrevocable.

1       (b) EXTENSION OF PATENT TERMS RELATING TO  
2 COUNTERMEASURES FOR CERTAIN BIOLOGICAL OR  
3 CHEMICAL AGENTS OR TOXINS.—

4           (1) IN GENERAL.—Chapter 14 of title 35,  
5 United States Code, is amended by inserting after  
6 section 156 the following:

7   **“§ 156a. Extension of patent terms relating to coun-**  
8           **termeasures for certain biological or**  
9           **chemical agents or toxins**

10       “(a) DEFINITIONS.—In this section, the term—

11           “(1) ‘product’ means the new drug, antibiotic  
12 drug, or human biological product to which sub-  
13 section (b) applies; and

14           “(2) ‘regulatory review period’ means—

15           “(A) the period beginning on the date a  
16 patent is issued through the date of the first fil-  
17 ing of an application relating to human clinical  
18 trials for the subject of that patent with the  
19 Food and Drug Administration under the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
21 301 et seq.) or the Public Health Service Act  
22 (42 U.S.C. 201 et seq.), and includes any pe-  
23 riod prior to such issuance during which the  
24 Food and Drug Administration is reviewing  
25 such application;

1                   “(B) the period beginning on the date an  
2                   exemption under section 505(i) of the Federal  
3                   Food, Drug, and Cosmetic Act (21 U.S.C.  
4                   355(i)) became effective for the approved prod-  
5                   uct and ending on the date an application was  
6                   initially submitted for such product under sec-  
7                   tion 351 of the Public Health Service Act (42  
8                   U.S.C. 262) or section 505 of the Federal  
9                   Food, Drug, and Cosmetic Act (21 U.S.C.  
10                   355); and

11                   “(C) the period beginning on the date the  
12                   application was initially submitted for the ap-  
13                   proved product under section 351 of the Public  
14                   Health Service Act (42 U.S.C. 262) or section  
15                   505 of the Federal Food, Drug, and Cosmetic  
16                   Act (21 U.S.C. 355) and ending on the date  
17                   such application was approved under the appli-  
18                   cable section.

19                   “(b) PATENT.—A patent referred to under subsection  
20                   (c) is any patent that—

21                   “(1) encompasses within its scope a composition  
22                   of matter, a method of using such composition, a  
23                   method of manufacturing such composition, or a  
24                   process for using such composition relating to a new  
25                   drug, antibiotic drug, or human biological product

1 (as those terms are used in the Federal Food, Drug,  
2 and Cosmetic Act (21 U.S.C. 301 et seq.) and the  
3 Public Health Service Act (42 U.S.C. 201 et seq.));  
4 and

5 “(2) is an eligible countermeasure as defined  
6 under section 7 of the Robert Stevens, Thomas Mor-  
7 ris Jr., Joseph Curseen, Kathy Nguyen, Ottlie  
8 Lundgren, and Lisa J. Raines Biological and Chem-  
9 ical Weapons Research Act.

10 “(c) PATENT EXTENSION.—Notwithstanding any  
11 specific limitations on the terms of patent extensions  
12 under section 156, the term of a patent described under  
13 subsection (b) shall be extended under this section from  
14 the original expiration date of the patent by the period  
15 of time that is equal to the full regulatory review period  
16 for the product, and which shall include any patent term  
17 adjustment under section 154(b).

18 “(d) ADMINISTRATIVE PROVISIONS.—

19 “(1) IN GENERAL.—To obtain an extension of  
20 the term of a patent under this section, the owner  
21 of record of the patent or its agent shall submit an  
22 application to the Patent and Trademark Office.

23 “(2) CONTENT.—The application shall  
24 contain—

1               “(A) the identity of the approved product  
2               and the Federal statute under which regulatory  
3               review occurred;

4               “(B) the identity of the patent for which  
5               an extension applies;

6               “(C) documentation that the product is an  
7               eligible countermeasure as defined under section  
8               7 of the Robert Stevens, Thomas Morris Jr.,  
9               Joseph Curseen, Kathy Nguyen, Ottlie  
10               Lundgren, Lisa J. Raines Biological and Chem-  
11               ical Weapons Research Act; and

12               “(D) such patent or other information as  
13               the Office may require.

14               “(3) SUBMISSION OF APPLICATION.—An applica-  
15               tion may only be submitted within the 60-day pe-  
16               riod beginning on the date the product became eligi-  
17               ble for purchase under section 7 of the Robert Ste-  
18               vens, Thomas Morris Jr., Joseph Curseen, Kathy  
19               Nguyen, Ottlie Lundgren, and Lisa J. Raines Bio-  
20               logical and Chemical Weapons Research Act. The  
21               submission of an application under this section is an  
22               irrevocable election of the application of this section  
23               to a patent consistent with paragraph (4).

1           “(4) EXCLUSIVE APPLICATION.—Sections 156  
2        shall not apply to any patent for which an applica-  
3        tion is filed under this section.

4           “(5) RULE OF CONSTRUCTION.—Nothing in  
5        this section shall be construed to prohibit an exten-  
6        sion of the term of patent relating to a product that,  
7        before the effective date of this section—

8           “(A) was approved for commercial mar-  
9        keting for non-countermeasure uses; or

10           “(B) was approved for commercial mar-  
11        keting.”.

12           (2) TECHNICAL AND CONFORMING AMEND-  
13        MENT.—The table of sections for chapter 14 of title  
14        35, United States Code, is amended by inserting  
15        after the item relating to section 156 the following:

“156a. Extension of patent terms relating to countermeasures for certain bio-  
logical or chemical agents or toxins.”.

16           (c) GENERAL EXTENSION OF CERTAIN PATENT  
17        TERMS.—

18           (1) IN GENERAL.—Chapter 14 of title 35,  
19        United States Code, is amended by adding at the  
20        end the following:

21        **“§ 158. Patent term for patents held by entities with  
22           certain research certifications”**

23           “(a) PATENT TERM.—The term of a patent described  
24        under subsection (b) shall be for a period of 2 years in

1 addition to the term which would otherwise apply except  
2 for this section.

3       “(b) PATENT.—A patent referred to under subsection  
4 (a) is any patent that—

5           “(1) is held by an entity that holds a certifi-  
6 cation under section 5(d)(2) of the Robert Stevens,  
7 Thomas Morris Jr., Joseph Curseen, Kathy Nguyen,  
8 Ottolie Lundgren, and Lisa J. Raines Biological and  
9 Chemical Weapons Research Act with respect to a  
10 product, a method of manufacturing such product,  
11 and a method of using such product;

12           “(2) is an eligible countermeasure as defined  
13 under section 7 of such Act; and

14           “(3) subject to subsections (c) and (d), is des-  
15 ignated by that entity as the patent to which this  
16 section applies.

17       “(c) LIMITATIONS AND CONDITIONS.—In the admin-  
18 istration of this section—

19           “(1) only 1 patent may be designated with re-  
20 spect to each certification held by an entity;

21           “(2) no redesignation of another patent may be  
22 made; and

23           “(3) the patent designated by the entity—

24               “(A) shall be issued before the date of a  
25 filing under subsection (d);

1               “(B) shall be held by that entity for at  
2               least 1 year before the date of the filing under  
3               subsection (d);

4               “(C) may not have been acquired by that  
5               entity from another entity for the purpose of  
6               the treatment of that patent under subsection  
7               (a); and

8               “(D) is not required to be related to the  
9               subject of the certification held by the entity.

10             “(d) FILING.—

11             “(1) IN GENERAL.—An entity that holds a cer-  
12               tification under section 5(d)(2) of the Robert Ste-  
13               vens, Thomas Morris Jr., Joseph Curseen, Kathy  
14               Nguyen, Ottilie Lundgren, and Lisa J. Raines Bio-  
15               logical and Chemical Weapons Research Act shall,  
16               with respect to a product that is an eligible counter-  
17               measure as defined under section 7 of such Act, file  
18               with the Patent and Trademark Office—

19             “(A) a copy of that certification; and

20             “(B) a designation of the patent to which  
21               this section applies.

22             “(2) IRREVOCABLE AND EXCLUSIVE.—

23             “(A) IRREVOCABLE ELECTION.—A filing  
24               under this section is an irrevocable election of

1           the application of this section to a patent con-  
2           sistent with subparagraph (B).

3           “(B) EXCLUSIVE.—Sections 156 shall not  
4           apply to any patent for which there is a filing  
5           under this section.”.

6           (2) TECHNICAL AND CONFORMING AMEND-  
7           MENT.—The table of sections for chapter 14 of title  
8           35, United States Code, is amended by adding at  
9           the end the following:

“158. Patent term for patents held by entities with certain research certifi-  
cations.”.

10          (d) EXCLUSIVE LICENSING.—Notwithstanding sec-  
11       tions 200, 203, and 209 of title 35, United States Code,  
12       an establishment that is certified under section 5(d) with  
13       respect to a product that is an eligible countermeasure as  
14       defined under section 7 may exclusively license such pat-  
15       ented product.

16 **SEC. 9. LIABILITY AND INDEMNIFICATION.**

17          Title III of the Public Health Service Act is amended  
18       by inserting after section 352 (42 U.S.C. 263) the fol-  
19       lowing:

20 **“SEC. 352A. LIABILITY AND INDEMNIFICATION.**

21          “(a) INDEMNIFICATION AND DEFENSE AGREE-  
22       MENTS.—Notwithstanding sections 1341, 1342, 1349,  
23       1350, and 1351 and subchapter II of chapter 15, of title

1 31, United States Code, or any other provision of law, the  
2 Secretary—

3       “(1) shall enter into agreements to indemnify  
4 and defend persons or entities engaged in the re-  
5 search, development, production, distribution, ad-  
6 ministration or use of countermeasures (as defined  
7 in section 3(1) of the Robert Stevens, Thomas Mor-  
8 ris Jr., Joseph Curseen, Kathy Nguyen, Ottolie  
9 Lundgren, and Lisa J. Raines Biological and Chem-  
10 ical Weapons Research Act);

11       “(2) shall enter into agreements to indemnify  
12 and defend persons or entities engaged in the re-  
13 search, development, production, distribution, ad-  
14 ministration or use of countermeasures; and

15       “(3) may enter into such agreements with other  
16 persons if the Secretary determines that the national  
17 interest in combating terrorism, or the protection of  
18 the public health, or both, reasonably requires such  
19 an agreement.

20       “(b) PROTECTIONS.—An indemnification and defense  
21 agreement shall protect against claims or civil actions (in-  
22 cluding reasonable expenses of litigation or settlement) by  
23 third persons, for damages (including death, bodily injury,  
24 economic losses, non-economic losses, or loss of or damage  
25 to property or punitive damages), allegedly caused by the

1 research, development, production, distribution, adminis-  
2 tration or use of a countermeasure (including a vaccine  
3 or antitoxin).

4       “(c) EXCLUSIVE REMEDY.—

5           “(1) IN GENERAL.—This section shall con-  
6 stitute the exclusive remedy with respect to a civil  
7 action filed against persons or entities within the  
8 scope of an indemnification and defense agreement  
9 entered into under subsection (a), for damages (in-  
10 cluding bodily injury, death, economic losses, non-  
11 economic losses or damage to property or punitive  
12 damages), consistent with the limitations contained  
13 in paragraph (2), to the extent that the civil action  
14 arises from the research, development, production,  
15 distribution, administration or use of a counter-  
16 measure (including vaccines and antitoxins).

17           “(2) LIMITATION.—No exclusive civil action  
18 under this section shall be permitted unless the  
19 amount in controversy exceeds \$10,000.

20       “(d) REQUIREMENTS.—An indemnification and de-  
21 fense agreement shall—

22           “(1) require notice to be provided to the United  
23 States of any claim or civil action (including an ex-  
24 clusive civil action) that is filed against persons or  
25 entities who are parties to such agreement for any

1       alleged damages (including bodily injury, death, eco-  
2       nomic losses, non-economic losses, and loss of or  
3       damage to property or punitive damages) allegedly  
4       caused by the research, development, production,  
5       distribution, administration or use of a counter-  
6       measure; and

7               “(2) require control of, or assistance in, the de-  
8       fense by the United States of such claim or civil ac-  
9       tion.

10       “(e) VENUE; APPLICATION OF LAW; AND DAM-  
11       AGES.—

12               “(1) VENUE.—An exclusive civil action under  
13       this section shall be filed in any United States dis-  
14       trict court of otherwise appropriate jurisdiction. Ap-  
15       peals from appealable actions of such courts in such  
16       actions shall be taken to the Court of Appeals for  
17       the Federal Circuit and, as appropriate, to the  
18       United States Supreme Court.

19               “(2) APPLICATION OF LAW.—An exclusive civil  
20       action filed under this section shall be governed by  
21       Federal law. No State or political subdivision of a  
22       State shall have any authority to enforce any other  
23       law or common law standard governing a civil action  
24       for damages (including damages for bodily injury,  
25       death, economic damages, noneconomic damages, or

1 loss or damage to property or punitive damages)  
2 arising out of the conduct or actions covered by an  
3 indemnification and defense agreement. Any civil ac-  
4 tion in State or Federal Court that is barred from  
5 consideration by this section shall be removed or  
6 transferred to the appropriate Federal district court  
7 or dismissed, as appropriate.

8       “(3) LIMITATIONS ON DAMAGES.—In an exclu-  
9 sive civil action filed under this section an award for  
10 non-economic damages shall not exceed \$250,000  
11 per plaintiff. In no such cases shall punitive or ex-  
12 emplary damages be awarded.

13       “(4) REDUCTION IN AMOUNTS.—In an exclusive  
14 civil action under this section, an award to a plain-  
15 tiff shall be reduced, by the presiding judge, to the  
16 extent that the plaintiff has otherwise received com-  
17 pensation for the damages at issue from a govern-  
18 ment, an insurance provider, or other third party.

19       “(f) DEFINITIONS.—In this section:

20           “(1) EXCLUSIVE CIVIL ACTION.—The term ‘ex-  
21 clusive civil action’ means a civil action described in  
22 subsection (c)(1).

23           “(2) INDEMNIFICATION AND DEFENSE AGREE-  
24 MENTS.—The term ‘indemnification and defense

1 agreements' means the agreements described in sub-  
2 section (a).".

3 **SEC. 10. CONSTRUCTION OF BIOSAFETY RESEARCH FACILI-  
4 TIES.**

5 (a) FINDINGS.—Congress finds that—

6 (1) research to develop countermeasures re-  
7 quires the use of special facilities where biological  
8 agents can be handled safely;

9 (2) very few companies can capitalize the con-  
10 struction of these special facilities; and

11 (3) the Federal Government can facilitate re-  
12 search and development of countermeasures by fi-  
13 nancing the construction of these special facilities.

14 (b) GRANTS AUTHORIZED.—

15 (1) IN GENERAL.—The Director of the National  
16 Institutes of Health is authorized to award grants  
17 and contracts to grantees to construct, maintain,  
18 and manage (including funding for staff and staff  
19 training) biosafety level 3–4 facilities.

20 (2) REQUIREMENTS.—To be eligible for a grant  
21 under paragraph (1) an entity shall—

22 (A) allow use of the facility involved by  
23 only those researchers who meet qualifications  
24 set by the Director of the Office of Homeland  
25 Security;

1 (B) give priority for the use of the facility  
2 involved to those entities that have been reg-  
3 istered and certified by the Director of the Of-  
4 fice of Homeland Security to develop counter-  
5 measures; and

6 (C) allow the National Institutes of Health  
7 to inspect the facility involved at any time.

15 (c) APPLICATION.—

21 (2) CONTENTS.—Each application submitted  
22 pursuant to paragraph (1) shall—

23 (A) provide detailed information on the  
24 technical specifications of proposed facilities;

4 (C) provide assurances that the facilities  
5 shall be available on a fee-for-service or other  
6 basis to companies and academic researchers;  
7 and

10 (d) DEFINITIONS.—For the purposes of this  
11 section—

12 (1) unless otherwise specifically identified, the  
13 term "Director" means the Director of the National  
14 Institutes of Health; and

23 (e) AUTHORIZATION OF APPROPRIATIONS.—There  
24 are authorized to be appropriated such sums as may be  
25 necessary to carry out this section.

1 **SEC. 11. NATIONAL INSTITUTES OF HEALTH COUNTER-**2 **MEASURES PARTNERSHIP CHALLENGE**3 **GRANTS.**

4 (a) **GRANTS AUTHORIZED.**—The Director of the Na-  
5 tional Institutes of Health (in this section referred to as  
6 the “Director”) is authorized to award partnership chal-  
7 lenge grants to promote joint ventures between the Na-  
8 tional Institutes of Health, its grantees, and for-profit bio-  
9 technology, pharmaceutical, and medical device industries  
10 for the development of countermeasures and research  
11 tools.

12 (b) **REGULATIONS.**—The Director shall issue regula-  
13 tions within 90 days of the date of enactment of this sec-  
14 tion to implement the awarding of grants under subsection  
15 (a).

16 (c) **AUTHORIZATION OF APPROPRIATIONS.**—There  
17 are authorized to be appropriated \$200,000,000 for each  
18 of fiscal years 2002, 2003, 2004, 2005, and 2006 for the  
19 purpose of carrying out this section.

20 **SECTION 12. EXPANDED HUMAN CLINICAL TRIALS QUALI-**21 **FYING FOR ORPHAN DRUG CREDIT.**

22 (a) **IN GENERAL.**—Subclause (I) of section  
23 45C(b)(2)(A)(ii) of the Internal Revenue Code of 1986 is  
24 amended to read as follows:

1                             “(I) after the date that the applica-  
2                             tion is filed for designation under  
3                             such section 526, and”.

4                             (b) CONFORMING AMENDMENT.—Clause (i) of sec-  
5     tion 45C(b)(2)(A) of the Internal Revenue Code of 1986  
6     is amended by inserting “which is” before “being” and  
7     by inserting before the comma at the end “and which is  
8     designated under section 526 of such Act”.

9                             (c) EFFECTIVE DATE.—The amendments made by  
10    this section shall apply to amounts paid or incurred after  
11    December 31, 2001.

○