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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, Otilie 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:

5 (1) The United States must be prepared with
 6 diagnostic and medical countermeasures in the event
 7 of the use of biological and chemical weapons by ter-
 8 rorists and others against both military personnel
 9 and civilians.

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 that 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.

1 (6) Vaccines exist for some of the biological
2 agents that might be used by terrorists and others.
3 The current United States vaccine against anthrax
4 was formulated in the 1960s and licensed in 1970,
5 2 years before efficacy data were required for licens-
6 ing. Three problems with this vaccine have stimu-
7 lated interest in an improved human anthrax vac-
8 cine:

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

12 (B) Immunity is not protective against all
13 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 prod-
18 ucts. 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 weap-
2 ons.

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.

1 (12) Successful research and development of
2 countermeasures will necessitate breakthroughs in
3 virology, immunology, antibiotics, genetic analysis,
4 and many other disciplines in biology. There is no
5 established market or appropriate Food and Drug
6 Administration approval process for most counter-
7 measures. Biotechnology companies and their inves-
8 tors are sensitive to any possibility that successful
9 completion of breakthrough research leading to the
10 approval for the sale of a product, including a coun-
11 termeasure, will lead to challenges to their prices
12 and patents. They are especially sensitive to the
13 terms of sales that may arise when the only market
14 for a product is the Federal Government. These are
15 risks that companies, employees and investors in
16 other sectors of the economy do not face and that
17 may affect the willingness of investors and capital
18 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 (tularemia).

24 (5) Ebola hemorrhagic fever.

25 (6) Marburg hemorrhagic fever.

- 1 (7) Lassa fever.
- 2 (8) Junin (Argentine hemorrhagic fever).
- 3 (9) Crimean-Congo Hemorrhagic Fever.
- 4 (10) *Coxiella burnetii* (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 *clostridium 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.
- 9 (37) Nerve agents (including tabun, sarin,
10 soman, GF, and VX).
- 11 (38) Blood agents (including hydrogen cyanide
12 and cyanogen chloride).
- 13 (39) Blister agents (including lewisite,
14 nitrogenadn 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 vinly 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;

1 (5) the name of each individual who is con-
2 ducting the research involved; and

3 (6) any other information required under regu-
4 lations promulgated by the Director.

5 (b) AVAILABILITY OF INFORMATION.—

6 (1) IN GENERAL.—Not later than 90 days after
7 the date of enactment of this Act, the Secretary of
8 Health and Human Services shall promulgate regu-
9 lations with respect to the availability of information
10 under this subsection.

11 (2) INSPECTIONS.—Subject to regulations pro-
12 mulgated under paragraph (1), the Food and Drug
13 Administration shall make available for inspection,
14 to any person so requesting, any registration filed
15 pursuant to subsection (a), except as provided in
16 paragraph (3).

17 (3) CERTAIN INFORMATION NOT AVAILABLE.—
18 The Director shall promulgate regulations to exempt
19 certain information from disclosure under paragraph
20 (2), including proprietary commercial information of
21 the registrant, national security information, and in-
22 formation affecting the security of research and
23 other facilities.

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 (3) DETERMINATIONS REGARDING RESEARCH
4 TOOLS.—The Director may accept a registration
5 under this section from a commercial, for-profit es-
6 tablishment in a State, and may provide a certifi-
7 cation under this section if the Director determines
8 that the establishment intends to conduct research
9 that is designed to lead to the development of a re-
10 search tool that will make it possible to expeditiously
11 develop a countermeasure to an agent or toxin that
12 is not included on the list published under section 4.
13 An establishment that is certified under this para-
14 graph shall be eligible for the tax incentive provi-
15 sions 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:

1 (1) LIMITED PARTNERSHIP.—The entity may
2 establish a limited partnership for the certified coun-
3 termeasures research, but only if such entity is a
4 qualified small business as determined under section
5 1202(d) of the Internal Revenue Code of 1986, by
6 substituting “\$750,000,000” for “\$50,000,000”
7 each place that such appears. For purposes of the
8 Internal Revenue Code of 1986, section 469 of such
9 Code shall not apply with respect to a limited part-
10 nership established under this paragraph.

11 (2) 100-PERCENT EXCLUSION FOR GAIN FROM
12 STOCK.—The entity may issue a class of stock for
13 the certified research under section 1202 of the In-
14 ternal Revenue Code of 1986 with the following
15 modifications:

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.

1 (C) REDUCTION IN HOLDING PERIOD.—
2 Subsection (a) of section 1202 of such Code
3 shall be applied by substituting “3 years” for
4 “5 years”.

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 tion 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),

3 “(C) at all times during the period de-
4 scribed in subparagraph (A) has met the re-
5 quirements of subsection (h), and

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 designate 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—

10 “(i) the average of the annual
11 amounts of the qualified research corpora-
12 tion’s research NOL’s and research credits
13 arising in the 3 taxable years ending prior
14 to the taxable year of the election, or

15 “(ii) 20 percent of the qualified re-
16 search corporation’s research NOL
17 carryforwards and research credit
18 carryforwards.

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.”.

7 (D) EFFECTIVE DATE.—The amendments
 8 made by this paragraph shall apply to taxable
 9 years beginning after December 31, 2001.

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.

20 (2) ELIGIBLE COUNTERMEASURE.—The term
 21 “eligible countermeasure” means a countermeasure
 22 (as defined in section 3(1)) developed by an entity
 23 that has been certified under section 5(d) (other
 24 than a research tool).

1 (3) FUND.—The term “Fund” means the Bio-
2 terrorism Countermeasure Purchase Fund estab-
3 lished under subsection (c).

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.—

18 (1) IN GENERAL.—The Secretary is authorized
19 to expend amounts in the Fund for purchases of eli-
20 gible countermeasures. Such countermeasures shall
21 be made available to the Director and distributed as
22 the Director, in consultation with the Director of the
23 Office of Homeland Security and the Secretary of
24 Health and Human Services, determines appro-
25 priate.

1 (2) PURCHASE AND DISTRIBUTION OF COUN-
2 TERMEASURES.—Countermeasures purchased by the
3 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.

12 (3) DISTRIBUTION.—Eligible countermeasures
13 purchased by the Fund shall be distributed as pro-
14 vided for by the Director, in consultation with the
15 Director of Homeland Security and the Secretary of
16 Health and Human Services, determines appropriate
17 after—

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, Otilie
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, Otilie
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 appli-
15 cation 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, Otilie 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 Otilie 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, Otilie 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, Otilie
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.

8 (3) NUMBER OF GRANTS.—The Director of the
9 Office of Homeland Defense shall determine the
10 number of facilities that need to be constructed
11 under this section, not to exceed 10 such facilities
12 nationwide, and the Director of the National Insti-
13 tutes of Health shall award grants based on such de-
14 termination.

15 (c) APPLICATION.—

16 (1) IN GENERAL.—To be eligible to receive a
17 grant under this section an entity shall submit to
18 the Director an application at such time, in such
19 form and containing such information, as the Direc-
20 tor may require.

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;

1 (B) propose a design that includes offices
2 for personnel, visiting researchers, and facilities
3 for research and laboratory materials;

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

8 (D) provide assurances that the facilities
9 will be constructed as secure facilities.

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

15 (2) a “biosafety level 3–4 facility” means a fa-
16 cility for research on indigenous, exotic, or dan-
17 gerous agents with the potential for aerosol trans-
18 mission of disease that may have serious or lethal
19 consequences or that pose a high risk of life-threat-
20 ening disease, aerosol-transmitted laboratory infec-
21 tions, or related agents with unknown risk of trans-
22 mission.

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.

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