

108TH CONGRESS
1ST SESSION

S. 666

To provide incentives to increase research by private sector entities to develop antivirals, antibiotics and other drugs, vaccines, microbicides, detection, and diagnostic technologies to prevent and treat illnesses associated with a biological, chemical, or radiological weapons attack.

IN THE SENATE OF THE UNITED STATES

MARCH 19, 2003

Mr. LIEBERMAN (for himself and Mr. HATCH) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To provide incentives to increase research by private sector entities to develop antivirals, antibiotics and other drugs, vaccines, microbicides, detection, and diagnostic technologies to prevent and treat illnesses associated with a biological, chemical, or radiological 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 “Biological, Chemical, and Radiological Weapons Counter-
6 measures Research Act”.

1 (b) IN HONOR.—This Act is enacted in honor of Rob-
 2 ert Stevens, Thomas Morris Jr., Joseph Curseen, Kathy
 3 Nguyen, Ottilie Lundgren, and Lisa J. Raines, victims of
 4 terrorist attacks in the United States in 2001.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Amendment to Homeland Security Act of 2002.

“TITLE XVIII—BIOLOGICAL, CHEMICAL, AND RADIOLOGICAL
 COUNTERMEASURES RESEARCH

- “Sec. 1801. Short title.
- “Sec. 1802. Definitions.

“Subtitle A—Strategy for the Development of Countermeasures

- “Sec. 1811. Biological, chemical and radiological agent, toxin, and mate-
 rial countermeasure research priority list.
- “Sec. 1812. Research registration requirements.
- “Sec. 1813. Detectors incentives.
- “Sec. 1814. Diagnostics incentives.
- “Sec. 1815. Research tools incentives.

“Subtitle B—Incentives for the Development of Countermeasures

“CHAPTER 1—PRIMARY INCENTIVES

- “Sec. 1821. Federal tax incentives.
- “Sec. 1822. Terror Weapon Countermeasure Purchase Fund.
- “Sec. 1823. Patent term protection and exclusive marketing.
- “Sec. 1824. Liability and indemnification.

“CHAPTER 2—OTHER INCENTIVES

- “Sec. 1831. Accelerated approval of countermeasures.
- “Sec. 1832. Biologics manufacturing capacity incentives.
- “Sec. 1833. Biologics manufacturing efficiency incentives.
- “Sec. 1834. Construction of biosafety level 3–4 research facilities.
- “Sec. 1835. National Institutes of Health countermeasures partnership
 challenge grants.

“Subtitle C—Administrative Provisions

- “Sec. 1841. Annual report.
- “Sec. 1842. International conference on research to develop counter-
 measures.
- Sec. 4. Tax incentives.
- Sec. 5. Patent term protection and exclusive marketing.
- Sec. 6. Approvals of certain drugs based on animal trials.

Sec. 7. Limited antitrust exemption.

Sec. 8. Incentives for the construction of biologics manufacturing facilities available for the production of countermeasures.

Sec. 9. Human clinical trials and drugs for rare diseases and conditions.

Sec. 10. Liability.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) The United States must be prepared with
4 diagnostic and medical countermeasures in the event
5 of the use of biological, chemical, and radiological
6 weapons by terrorists and others against military
7 and intelligence personnel, government officials, or
8 civilians.

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

11 (A) Members of the cult Aum Shinrikyo
12 were responsible for chemical weapons attacks
13 in Japan that killed 12 people and injured over
14 5,000 on March 20, 1995. In this attack, ter-
15 rorists placed plastic bags of diluted sarin, a le-
16 thal nerve agent, on crowded subway trains
17 during the morning rush-hour. It was found
18 that sect members had legally stockpiled sodium
19 cyanide and hundreds of tons of chemicals used
20 to make sarin, including sodium fluoride, phos-
21 phorous trichloride, isopropyl alcohol, and ace-
22 tonitrile. Aum Shinrikyo concealed its sarin
23 manufacturing plant in a shrine to a sect god-

1 dess. Investigators also found a biological weap-
2 ons research lab on the cult's compound. The
3 facility contained an incubator, an electron mi-
4 croscope, a growth medium for fermenting or
5 growing cultures, and cultures of the deadly
6 botulinum toxin. Aum Shinrikyo members were
7 apparently planning a more devastating offen-
8 sive. The cult also released anthrax spores and
9 botulinum in Tokyo nine times before it carried
10 out its nerve gas attack. Aum's attempted germ
11 attacks failed because the group's biologists cul-
12 tured the strain of anthrax used to make vac-
13 cine, which is harmless. Had they used a potent
14 culture, the outcome might have been very dif-
15 ferent. No one knows why the botulism attack
16 failed. The horror is only magnified by the
17 thought that individuals and nations would con-
18 sider attacking others with such viruses. In Oc-
19 tober 1993, Shoko Asahara, head of the Aum
20 Shinrikyo cult, and 40 followers traveled to
21 Zaire, ostensibly to help treat Ebola victims.
22 But the group's real intention, according to an
23 October 31, 1995, report by the Permanent
24 Subcommittee on Investigations of the Senate,

1 was probably to obtain virus samples, culture
2 them and use them in biological attacks.

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

10 (C) There is a long and sordid history of
11 chemical and biological weapons, including use
12 during the First and Second World Wars, an
13 accidental release of anthrax spores in 1979
14 from a Soviet military microbiological facility,
15 use of mustard gas, tabun, and hydrogen cya-
16 nide by Iraq in the Iran-Iraq War and against
17 the Kurds, and development by Iraq of an of-
18 fensive biological weapons capability including
19 anthrax and botulinum toxin. Before, during,
20 and after the Second World War, the Soviet
21 Union produced many tens of thousands of tons
22 of chemical weapons (both nerve and blister
23 agents). During the later half of the Cold War,
24 Soviet scientists developed a series of new and
25 more lethal “third generation” nerve agents.

1 Certain of these new agents produced and test-
2 ed in pilot and experimental quantities in the
3 late 1980s and early 1990s were up to 10
4 times more lethal than VX and soman. Addi-
5 tionally, because these are binary agents, i.e.,
6 they consist of two relatively non-toxic chemi-
7 cals that are mixed together when the weapon
8 is armed to produce the lethal chemical agent,
9 they can be manufactured at commercial chem-
10 ical plants that manufacture fertilizers and pes-
11 ticides. A new unitary agent was also developed
12 that could be produced from accessible raw ma-
13 terials that are used in civilian industry and
14 which cannot therefore be regulated by inter-
15 national experts. Although less lethal per unit
16 weight than traditional nerve agents, agricul-
17 tural organophosphate insecticides are available
18 in enormous quantities and can be used as
19 nerve agents.

20 (D) The United States bioterror weapons
21 program focused on anthrax, botulinum toxin,
22 brucellosis, tularemia, psittacosis, plague, Ven-
23 zuelan equine encephalitis, Q fever, cholera,
24 dengue, shigellosis dysentery, glanders, and
25 Rocky Mountain spotted fever. The United

1 States Army concocted a botulinum toxin that
2 was so toxic that a pound, if expertly dispersed,
3 could kill 1,000,000,000 people. Botulinum
4 toxin is 15,000 times more toxic than VX and
5 10,000 times more toxic than Sarin. The Soviet
6 bioterror program involved 47 laboratories and
7 65,000 people. It focused on 52 different patho-
8 gens, including smallpox, anthrax, plague,
9 Ebola and Marburg hemorrhagic fevers, yellow
10 fever, tularemia, brucellosis, Q fever, botulinum
11 toxin, and Venezuelan equine encephalitis. It
12 created 2,000 strains of anthrax with 7,000 em-
13 ployees working on nothing but anthrax. It pro-
14 duced 20 tons of smallpox virus each year, cre-
15 ated antibiotic resistant bacterial strains with
16 odd properties to confuse diagnosis, plague bac-
17 teria that secreted diphtheria toxin and resisted
18 antibiotics. The Iraqi bioterror program focused
19 on anthrax, botulinum toxin, cholera, plague,
20 gas gangrene, Salmonella, ricin, staphylococcal
21 enterotoxin, camelpox, cancer-causing molds
22 called aflatoxins, rotavirus, and hemorrhagic
23 conjunctivitis.

24 (E) 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 (F) 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 threat of terrorism using radiological
16 weapons is real.

17 (A) In April 2000, customs officers from
18 Uzbekistan discovered 10 lead-lined containers
19 at a remote border crossing with Kazakhstan.
20 These containers were filled with enough radio-
21 active material to make dozens of crude weap-
22 ons, each capable of contaminating a large area
23 for many years. The consignment was ad-
24 dressed to a company in Quetta, Pakistan,
25 called Ahmadjan Haji Mohammed. Quetta,

1 where border controls are virtually non-existent,
2 is the main Pakistani crossing into southern Af-
3 ghanistan and only a 6 hour drive from
4 Kandahar.

5 (B) In 1994 Czech police seized 3 kilo-
6 grams of highly enriched uranium. During the
7 same year German police seized 360 grams of
8 plutonium. In 2001 Turkish police seized two
9 men with 1.16 kilograms of weapons grade ura-
10 nium. Russian general Alexander Ledbed
11 claimed that 40 suitcase nuclear weapons were
12 unaccounted for.

13 (C) In 1995 Islamic Chechen rebels an-
14 nounced, and Russians confirmed, that they
15 had planted a 30 pound shielded container
16 holding the Cesium-137 core of a cancer treat-
17 ment device in a Moscow park.

18 (D) The International Atomic Energy
19 Agency, a Vienna-based division of the United
20 Nations, has documented almost 400 cases of
21 trafficking in nuclear or radiological materials
22 since 1993. Many such supplies are subject to
23 few controls or are poorly guarded, particularly
24 in the former Soviet Union. Reports also have
25 cited weak protection of spent fuel at nuclear

1 facilities in the United States. Other experts
2 worry about the security of the nuclear facilities
3 in Pakistan, India, and other developing coun-
4 tries. An estimated 1300 kilograms of highly
5 enriched uranium and 180,000 kilograms of
6 plutonium, the main fuels for a nuclear device,
7 exists in civilian nuclear facilities around the
8 world. There are nearly 450 nuclear power
9 plants, nearly 300 nuclear research reactors,
10 and 250 nuclear fuel cycle plants around the
11 world.

12 (E) In September 1987, scavengers broke
13 into an abandoned cancer clinic in Goiania,
14 Brazil and stole a medical device containing
15 large amounts of radioactive cesium-137. An es-
16 timated 250 people were exposed to the source,
17 eight developed radiation sickness, and four
18 died.

19 (F) A crude but deadly radiation dispersal
20 device (RDD) fashioned from stolen nuclear
21 material (from a nuclear waster processor, a
22 nuclear power plant, a university research facil-
23 ity, a medical radiotherapy clinic, or an indus-
24 trial complex) and a few sticks of dynamite
25 could spread radioactive material across an area

1 without a nuclear detonation. Such a weapon
2 could kill many, contaminate a square mile for
3 10 years or more, and cause widespread panic.
4 The Chernobyl nuclear reactor meltdown in
5 1986 resulted in the uninhabitability of a 6 mile
6 belt around the reactor. That area is still un-
7 inhabitable today. It released about 400 times
8 as much radioactivity at the Hiroshima bomb.
9 Half of the atoms in a sample of cobalt-60 will
10 disintegrate over a 5 year period, but it takes
11 430 years for half of the atoms in a sample of
12 Americium-241 to decay.

13 (G) Even more threatening, during the
14 Cold War the United States and the Soviet
15 Union fashioned a few hundred portable nuclear
16 weapons and some of the Soviet weapons might
17 fall into the hands of terrorists.

18 (H) The panic at dispersal or detonation of
19 such a device might well be much more dam-
20 aging than the morbidity and mortality. Radi-
21 ation is invisible and there is widespread fear of
22 it. Few would understand the difference be-
23 tween a dirty and a nuclear bomb.

24 (I) Such a device or bomb can cause expo-
25 sure to a variety of radioactive materials, in-

1 including Plutonium, enriched or depleted Ura-
2 nium, Radium, Cesium, Strontium, Cobalt, Io-
3 dine, Americium, etc.

4 (J) Such exposure can cause immediate
5 death, as well as adverse effects on radiosensi-
6 tive tissues, including suppression of white and
7 red blood stem and platelet cells production.
8 Acute Radiation Syndrome (ARS), Central
9 Nervous System syndrome (CNS), gastro-
10 intestinal syndrome, and bone marrow radiation
11 syndrome are early effects of substantial acute
12 exposure to ionizing radiation. Leukemia and
13 other forms of cancer can arise many years
14 after exposure even to lower doses. Other symp-
15 toms include nausea, vomiting, hair loss, diar-
16 rhea, hemorrhages, and internal bleeding. The
17 United States has only one hospital emergency
18 room dedicated to treating patients exposed to
19 radiation hazards, at Oak Ridge, Tennessee.

20 (K) Medical responses currently available
21 with respect to exposure to radioactive mate-
22 rials are rather limited and can include use of
23 chelation agents to speed secretion of radio-
24 active metals from the body if radioactive mate-
25 rial was swallowed or inhaled, preventive block-

1 ing of thyroid uptake of radioactive iodine by
2 use of potassium iodine tablets, and use of In-
3 vestigational New Drugs like Prussian Blue.

4 (L) The United States needs to develop
5 additional medical responses, including
6 antiemetics, hematological colony-stimulating
7 factors, and chelating agents. The United
8 States also needs to develop better means of as-
9 sessing radiation exposure using new molecular,
10 biological, physical and other technologies.

11 (M) The ill-defined and uncontrolled na-
12 ture of radiation exposure and nuclear accidents
13 usually causes a non-uniform exposure with the
14 variable dose distribution complicating dosim-
15 etry, which is important for medical manage-
16 ment of exposed patient with a need to deter-
17 mine the degree to which bone marrow or gas-
18 trointestinal stem cells have survived.

19 (4) The United States must take steps to pre-
20 vent access to the biological and chemical agents and
21 toxins and radiological materials by terrorists and
22 others, but attacks may nonetheless occur. The
23 United States needs to respond to attacks with well-
24 coordinated public health measures. We also need a
25 broad array of effective diagnostics and medicines to

1 rapidly identify and treat those who are exposed to,
2 or infected by, the agents, toxins, or materials.

3 (5) The United States faces a public health cri-
4 sis with the spread of antibiotic resistant bacteria.
5 This alone should lead us to take urgent action to
6 develop new vaccines and medicines. The antibiotic
7 vancomycin, our last line of defense against the
8 often deadly bacterium, *Staphylococcus aureus*, is
9 losing its effectiveness. Worldwide, many strains of
10 *S. aureus* are already resistant to all antibiotics ex-
11 cept vancomycin. Emergence of strains lacking sen-
12 sitivity to vancomycin signifies that variants untreat-
13 able by every known antibiotic are on their way. *S.*
14 *aureus*, a major cause of hospital-acquired infec-
15 tions, has thus moved one step closer to becoming an
16 unstoppable killer. What is more, strains of at least
17 three bacterial species capable of causing life-threat-
18 ening illnesses (*Enterococcus faecalis*,
19 *Mycobacterium tuberculosis* and *Pseudomonas*
20 *aeruginosa*) already evade every antibiotic in the cli-
21 nician's armamentarium, a stockpile of more than
22 100 drugs. In part because of the rise in resistance
23 to antibiotics, the death rates for some commu-
24 nicable diseases (such as tuberculosis) have started

1 to rise again, after having declined in the industrial
2 nations.

3 (6) The possibility exists that terrorists or oth-
4 ers will use biotechnology techniques to enhance the
5 lethality of a biological agent. According to the De-
6 fense Science Board, “Motivated researchers using
7 advanced genetics techniques can engineer pathogens
8 with unnatural characteristics that enhance their of-
9 fensive properties by altering such characteristics as
10 stability, dissemination properties, host range, con-
11 tagiousness, resistance to drugs and vaccines, and
12 persistence in the environment, among others”.

13 (7) Vaccines exist for some of the biological
14 agents that might be used by terrorists and others,
15 but these vaccines need substantial additional devel-
16 opment. The development of new vaccines is a dif-
17 ficult, costly, and time-consuming endeavor with no
18 assurance of success. In the last 25 years, the Fed-
19 eral Government though its efforts to protect the
20 public health and the military against disease has
21 successfully developed very few new vaccines. The
22 development of vaccines against highly lethal bio-
23 terror agents may face far greater difficulties. For
24 such vaccines often there may be no animal model
25 or the animal will be of questionable value. The de-

1 velopment of vaccines against many such disease
2 agents will require clinical trials in countries where
3 the disease agent is endemic and the prevalence of
4 infection is sufficiently high to prove efficacy. The
5 current United States vaccine against anthrax was
6 formulated in the 1960s and licensed in 1970. Be-
7 fore and subsequent to the licensing of this vaccine
8 in the United States, additional preclinical and clin-
9 ical studies have been conducted to confirm its safe-
10 ty and efficacy. The current Food and Drug Admin-
11 istration-licensed immunization schedule for the an-
12 thrax vaccine involves 6 doses over 18 months fol-
13 lowed by yearly boosters. Since this is a cumbersome
14 schedule for immunizing both military personnel and
15 civilian laboratory workers and first responders at
16 occupational risk of exposure to the biothreat from
17 an anthrax attack, the Centers for Disease Control
18 and Prevention has initiated multi-center studies to
19 develop the next generation of the anthrax vaccine
20 by reducing the number of doses and changing its
21 route of administration. Additional early develop-
22 ment phase studies of experimental recombinant and
23 live attenuated anthrax vaccines are underway to de-
24 termine their suitability, safety and efficacy.

1 (8) Treatments for those who are not protected
2 by vaccines are often not effective. Inhalation an-
3 thrax (woolsorters' disease) results from inhaling an-
4 thrax spores disseminated from either a natural
5 source or a biological attack and, if untreated, it is
6 considered to be 99 percent fatal. Antibiotics and
7 standard interventions provided after symptoms have
8 developed rarely prevent a fatal outcome.

9 (9) The United States does not currently have
10 available the diagnostics, drugs, and vaccines needed
11 in the event of a bioterror attack. It has been esti-
12 mated by the Defense Science Board that the United
13 States is adequately protected with respect to only
14 13 of the top 50 pathogens that might be
15 weaponized. For example, while the United States
16 has a vaccine for smallpox, that vaccine has side ef-
17 fects and is one that cannot be well tolerated by
18 many, and for those who are infected, the United
19 States has no effective treatment. The United States
20 has a treatment for early stage inhalation anthrax,
21 but those treatments are ineffective when there are
22 delays in diagnosis. The United States has very few
23 products that are effective against viruses. The
24 United States is not well protected with broad-spec-
25 trum antibiotics that are needed to deal with patho-

1 gens that have been modified or selected for anti-
2 biotic resistance. It takes more than 24 hours to di-
3 agnose many of the most dangerous pathogens.

4 (10) A ring vaccination strategy may well be
5 impossible to implement given the mobility of Ameri-
6 cans. Twenty-three million international airline pas-
7 sengers embarked or disembarked at United States
8 airports in the fourth quarter of 2001. Nearly
9 500,000,000 people crossed the United States-Can-
10 ada and United States-Mexico borders by land in
11 2000. Tens of millions of people each day cross from
12 one metropolitan area to another. For the same rea-
13 sons, it may not be possible to enforce a quarantine.
14 If, however, the United States has safe and effective
15 treatments to deploy, there will be less need to at-
16 tempt to implement a ring vaccination strategy or
17 quarantine.

18 (11) Vaccines and treatments for exposure to
19 nerve toxins and radiological materials do not exist
20 or are ineffective.

21 (12) The United States Government is directly
22 funding biomedical research on vaccines and treat-
23 ments for biological and chemical agents and radio-
24 logical materials. These funding efforts could be
25 matched many-fold if the 1,500 biotechnology com-

1 panies, 100 pharmaceutical companies, medical de-
2 vice and research tool companies, and research insti-
3 tutions were able to secure the funding from private
4 investors, or justify the investment of retained earn-
5 ings, to conduct this research.

6 (13) The enactment of tax, procurement, pat-
7 ent, liability, and other incentives will enable the bio-
8 technology, pharmaceutical, device, and research tool
9 industries to raise equity and other capital from in-
10 vestors to fund research on countermeasures for bio-
11 logical, chemical, and radiological attacks. This will
12 supplement direct Federal funding for this research
13 and speed development of life saving technologies.
14 The existence of these technologies will reassure the
15 public that if attacks occur, effective medical treat-
16 ments are available and there is no reason for panic.

17 (14) Past efforts by agencies of the Federal
18 Government to contract for the development and
19 manufacture of countermeasures have been, and
20 likely will continue to be, ineffective. These efforts
21 have been under-funded, too complex, financially re-
22 strictive, and unreliable and therefore have failed to
23 attract the commitment of capital and research-in-
24 tensive biotechnology, pharmaceutical, medical de-
25 vice, and research tool companies. These short-

1 comings are likely to be even more apparent and se-
2 vere with respect to proposals to use Federal tax-
3 payer dollars for Federal Government construction,
4 ownership, and operation of research and develop-
5 ment and manufacturing facilities for the production
6 of vaccines for military and civilian use (GOGOs and
7 GOCOs) or for the establishment of a National Vac-
8 cine Authority for the research and development and
9 production of vaccines for the protection of civilians
10 against bioterrorist attacks. These federalized pro-
11 posals will result in significantly higher costs for
12 taxpayers, add significant additional layers of Fed-
13 eral bureaucracy, and delay the availability of need-
14 ed countermeasures.

15 (15) Efforts by the Department of Defense to
16 acquire drugs and vaccines for bioterror agents have
17 been ineffective. The Defense Science Board has
18 found that “DOD has failed to implement a
19 proactive strategy for engagement of the private sec-
20 tor in gaining access to new technologies relevant to
21 biodefense . . . (There are) significant obstacles to
22 engagement of the private sector. Neither the DOD
23 nor the nation can achieve a robust biodefense with-
24 out engagement of private sector R&D and leading
25 scientists in academia and closer ties to industry

1 . . . A program of longer-term investment in new
2 R&D initiatives to address major gaps in drug and
3 vaccine coverage is crucial but it will take 10 to 15
4 years to bring such investments to fruition.”

5 (16) The Defense Science Board has noted the
6 “private sector’s declared lack of interest in seeking
7 Government R&D contracts.” It has found that the
8 “medical-related industry differs from traditional de-
9 fense industries. The financial disincentives inherent
10 in producing products for limited markets (i.e. DOD
11 only) with no commitment to longterm supply in the
12 face of massive capitalization needs and the long,
13 multi-year lead times to build new manufacturing fa-
14 cilities for drugs, biologics, and vaccines are consid-
15 erable. Nonetheless, it is difficult to see how DOD
16 or the nation can pursue a successful biodefense
17 strategy if they do not engage leading companies
18 and top scientists from outside the physics/engineer-
19 ing circles of traditional defense contractors.”

20 (17) This Act is premised on the belief that the
21 most effective strategy is to capitalize on the experi-
22 ence and entrepreneurship of America’s world pre-
23 eminent biotechnology, pharmaceutical, medical de-
24 vice, research tool companies, and research institu-
25 tions engaged in this research, development, and

1 manufacturing at their own risk, their own expense,
 2 for their own good business reasons.

3 **SEC. 3. AMENDMENT TO HOMELAND SECURITY ACT OF**
 4 **2002.**

5 The Homeland Security Act of 2002 (Public Law
 6 107–296) is amended by adding at the end thereof the
 7 following:

8 **“TITLE XVIII—BIOLOGICAL,**
 9 **CHEMICAL, AND RADIO-**
 10 **LOGICAL COUNTER-**
 11 **MEASURES RESEARCH**

12 **“SEC. 1801. SHORT TITLE.**

13 “This title may be cited as the ‘Biological, Chemical,
 14 and Radiological Weapons Countermeasures Research Act
 15 of 2003’.

16 **“SEC. 1802. DEFINITIONS.**

17 “In this title:

18 “(1) BIOLOGICAL OR CHEMICAL AGENT; TOXIN;
 19 NUCLEAR OR RADIOLOGICAL MATERIAL; TERROR
 20 WEAPON.—The term—

21 “(A) ‘biological agent’, ‘biological toxin’,
 22 ‘chemical agent’, or ‘chemical toxin’, or any var-
 23 iation of any such term, means any microorga-
 24 nism, virus, infectious substance, biological
 25 product, toxic or poisonous chemical, or pre-

1 cursor of a toxic or poisonous chemical, that
2 may be used in a manner that is intended to
3 cause widespread death or serious bodily injury,
4 including biological agents and toxins described
5 in paragraphs (1) and (2) of section 178 of title
6 18, United States Code;

7 “(B) ‘nuclear or radiological material’
8 means any radioactive material that may be
9 used in a manner that is intended to cause
10 widespread death or serious bodily injury; and

11 “(C) ‘terror weapon’ and ‘weapon of mass
12 destruction’ mean any matter described in sub-
13 paragraph (A) or (B) that may be used in a
14 manner that is intended to cause widespread
15 death or serious bodily injury.

16 “(2) COUNTERMEASURES.—The term ‘counter-
17 measures’ means—

18 “(A) a vaccine and related delivery system,
19 antiviral, microbicide, diagnostic technology,
20 drug, or other technology that can be used to
21 diagnose, treat, or prevent infection with or
22 bodily harm from, or the spread of, a biological
23 or chemical agent or toxin on the list described
24 in section 1811, and that is subject to applica-
25 ble provisions of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 301 et seq.), the Pub-
2 lic Health Service Act (42 U.S.C. 201 et seq.),
3 or the Virus-Serum-Toxin Act (21 U.S.C. 151
4 et seq.); and

5 “(B) a therapy, diagnostic, or piece of
6 equipment that may be used to detect, treat, or
7 prevent bodily harm that may be caused by the
8 use of nuclear or radiological material as a ter-
9 ror weapon.

10 “(3) DEPARTMENT.—The term ‘Department’
11 means the Department of Homeland Security.

12 “(4) DETECTION EQUIPMENT.—The term ‘de-
13 tection equipment’ means a device for the detection
14 of the presence, concentration, or characteristics of
15 a biological, chemical, or radiological agent in
16 environmental or field samples.

17 “(5) DEVELOPMENT.—The term ‘development’
18 or ‘to develop’ includes research leading to the iden-
19 tification and isolation of suitable compounds or bio-
20 logical materials, engineering/modification, produc-
21 tion, and formulation of such compounds or mate-
22 rials, the conduct of preclinical and clinical studies,
23 the preparation of an application for marketing ap-
24 proval, and other actions related to preparation of a
25 countermeasure.

1 “(6) DIAGNOSTICS.—The term ‘diagnostics’ in-
2 cludes products, devices, and technologies to detect,
3 identify, or analyze, the potential presence or ab-
4 sence of 1 or more biological or chemical agents or
5 toxins in patient samples to enable effective medical
6 intervention through the administration of appro-
7 priate countermeasures.

8 “(7) MANUFACTURER.—The term ‘manufac-
9 turer’ means an entity responsible for research, de-
10 velopment, and production of a terror weapons coun-
11 termeasure and, except for countermeasures that are
12 not subject to review and approval by the Food and
13 Drug Administration prior to marketing (such as re-
14 search tools), the potential or actual holder of the
15 approved new drug application, biologic license appli-
16 cation, or product license application or equivalent
17 for such countermeasure. Such term does not re-
18 quire that a manufacturer conduct the actual re-
19 search, development, or production in its own facili-
20 ties, but may enter into arrangements with third
21 parties including contracts and cooperative agree-
22 ments for research, development, or production of
23 the countermeasure.

24 “(8) RESEARCH TOOL.—The term ‘research
25 tool’ includes the full range of tools that scientists

1 may use in the laboratory, including cell lines,
2 monoclonal antibodies, reagents, drug delivery tech-
3 nologies, vaccine adjuvants, laboratory animals-large
4 animals including nonhuman primates, growth fac-
5 tors, combinatorial chemistry and DNA libraries,
6 clones and cloning tools (such as PCR), methods,
7 laboratory equipment and machines, databases, and
8 other technologies that enable the rapid and effective
9 development of countermeasures, including
10 diagnostics, vaccines, and drugs.

11 “(9) SECRETARY.—The term ‘Secretary’ means
12 the Secretary of the Department of Homeland Secu-
13 rity.

14 **“Subtitle A—Strategy for the**
15 **Development of Countermeasures**

16 **“SEC. 1811. BIOLOGICAL, CHEMICAL AND RADIOLOGICAL**
17 **AGENT, TOXIN, AND MATERIAL COUNTER-**
18 **MEASURE RESEARCH PRIORITY LIST.**

19 “(a) DEVELOPMENT.—

20 “(1) IN GENERAL.—Not later than 180 days
21 after the date of enactment of this title, the Sec-
22 retary, in consultation with the Secretary of Defense
23 and the Secretary of Health and Human Services,
24 shall develop and make available to potential manu-
25 facturers of terror weapons countermeasures and,

1 except as provided in paragraph (5) publish, a list
2 of biological and chemical agents and toxins and nu-
3 clear and radiological materials that may be used as
4 weapons of mass destruction with respect to which
5 the Secretary finds that research to develop new and
6 improved countermeasures is in the national security
7 interest of the United States.

8 “(2) REQUIREMENTS.—

9 “(A) IN GENERAL.—The Secretary shall
10 only include on the list developed under para-
11 graph (1) agents, toxins, and materials—

12 “(i) that pose a significant security or
13 medical threat to the United States mili-
14 tary and intelligence personnel, govern-
15 ment officials, or civilians;

16 “(ii) that are more likely to be subject
17 to a countermeasure that is developed as a
18 result of the availability of the tax, pro-
19 curement, intellectual property, liability,
20 and other provisions of this title (and the
21 amendment made by the Biological, Chem-
22 ical, and Radiological Weapons Counter-
23 measures Research Act); and

24 “(iii) with respect to which safe and
25 effective countermeasures are not available

1 or with respect to which the development
2 of safer and more effective counter-
3 measures, or countermeasures that may be
4 deployed more safely or effectively, is in
5 the public interest.

6 “(B) CERTAIN DETERMINATIONS.—For
7 purposes of subparagraph (A)(ii), in deter-
8 mining whether the agents, toxins, and mate-
9 rials are more likely to be subject to a counter-
10 measure, the Secretary shall consider—

11 “(i) the status of existing public and
12 private sector research to develop such
13 countermeasure;

14 “(ii) the status of public and private
15 sector research that could be adapted or
16 redirected to develop such countermeasure;

17 “(iii) the availability of products that
18 could be utilized as countermeasures;

19 “(iv) the extent to which such coun-
20 termeasures may be utilized for purposes
21 other than as a countermeasure for a bio-
22 logical agent or toxin or radiological mate-
23 rial on the list developed under this sec-
24 tion;

1 “(v) the extent to which market-based
2 reimbursement is available for uses of the
3 countermeasure other than as a counter-
4 measure for a biological agent or toxin or
5 radiological material on the list developed
6 under this section; and

7 “(vi) the most effective strategy for
8 expediting development of such counter-
9 measure, including reliance on Government
10 contracts, grants and cooperative research
11 agreements and utilization of the incen-
12 tives provided for in this title (and the
13 amendments made by the Biological,
14 Chemical, and Radiological Weapons Coun-
15 termeasures Research Act).

16 “(3) USE OF EXISTING LISTS AND DATA.—The
17 list developed under paragraph (1) may, at the dis-
18 cretion of the Secretary, make reference to or incor-
19 porate elements of the list of biological agents and
20 toxins established and maintained by the Secretary
21 of Health and Human Services under section 351A
22 of the Public Health Service Act (as added by sec-
23 tion 201 of the Public Health Security and Bioter-
24 rorism Preparedness and Response Act of 2002) and
25 under section 178 of title 18, United States Code.

1 “(4) INFORMATION AND DETERMINATIONS RE-
2 LATING TO POTENTIAL MANUFACTURERS.—With re-
3 spect to the list developed under paragraph (1), the
4 Secretary shall—

5 “(A) provide such information regarding
6 such weapons of mass destruction as the Sec-
7 retary determines to be necessary to enable
8 such potential manufacturers to structure and
9 manage their research and development pro-
10 grams for the development of terror weapons
11 countermeasures; and

12 “(B) determine when such a manufacturer
13 has successfully developed a countermeasure
14 and therefore becomes entitled to the procure-
15 ment, intellectual property, market exclusivity,
16 and liability provisions of this title (or an
17 amendment made by the Biological, Chemical,
18 and Radiological Weapons Countermeasures
19 Research Act), except that in the absence of
20 such a determination, the approval of the Food
21 and Drug Administration of the manufacturer’s
22 new drug application, biologic license applica-
23 tion, or product license application for a coun-
24 termeasure to an agent or toxin listed by the
25 Secretary shall be deemed to be a determination

1 of successful development of a safe and effective
2 countermeasure and entitle the manufacturer to
3 the same benefits as though the determination
4 was made by the Secretary.

5 “(5) EXEMPTION.—

6 “(A) IN GENERAL.—The Secretary may
7 exempt certain information concerning weapons
8 of mass destruction from publication if the Sec-
9 retary determines that such publication would
10 (or could) be detrimental to the security of the
11 United States. In providing an exemption under
12 the preceding sentence, the Secretary shall de-
13 velop procedures for making such list or infor-
14 mation available on a confidential basis to po-
15 tential manufacturers of countermeasures.

16 “(B) SUFFICIENCY OF INFORMATION.—In
17 developing the procedures described in subpara-
18 graph (A), the Secretary shall ensure that the
19 information provided to potential manufacturers
20 of countermeasures is sufficient to enable the
21 Federal Government and the manufacturer to
22 determine when such a manufacturer has suc-
23 cessfully developed a countermeasure and there-
24 fore becomes entitled to the procurement, intel-
25 lectual property, and liability provisions of this

1 title (or an amendment made by the Biological,
2 Chemical, and Radiological Weapons Counter-
3 measures Research Act).

4 “(b) INITIAL LIST.—The initial list developed under
5 subsection (a) may, at the discretion of the Secretary, con-
6 tain the following biological agents and diseases caused by
7 biological agents, chemical toxins, and nuclear and radio-
8 logical materials:

9 “(1) Variola major (confluent, flat, and hemor-
10 rhagic smallpox).

11 “(2) Bacillus anthracis (anthrax).

12 “(3) Clostridium botulinum (botulism).

13 “(4) Francisella tularensis (tularemia).

14 “(5) Yersina pestis (Black Death: bubonic
15 plague, pneumonic plague).

16 “(6) Filoviridae (Ebola hemorrhagic fever).

17 “(7) Filoviridae (Marbug hemorrhagic fever).

18 “(8) Arenaviridae (Lassa fever).

19 “(9) Arenaviridae Junin (Argentine
20 hemmorrhagic fever).

21 “(10) Filoviridae (Crimean-Congo
22 Hemmorrhagic Fever).

23 “(11) Coxiella burnetti (Q fever).

24 “(12) Coccidioidomycosis (San Joaquin Valley
25 or desert fever).

- 1 “(13) *Clostridium perfringens* (gas gangrene,
2 necrotizing enteritis).
- 3 “(14) *Chlamydia psittaci* (parrot fever).
- 4 “(15) Bunyaviridae (Rift Valley Fever).
- 5 “(16) *Rickettsia rickettsii* (Rocky Mountain
6 Spotted Fever).
- 7 “(17) *Brucella* species (brucellosis).
- 8 “(18) *Burkholderia mallei* (glanders).
- 9 “(19) Arboviridae (Venezuelan
10 encephalomyelitis).
- 11 “(20) Arboviridae (Eastern and Western equine
12 encephalomyelitis).
- 13 “(21) Ricin toxin from *ricinus communis* (cas-
14 tor beans).
- 15 “(22) Trichothecene Mycotoxins (Yellow Rain).
- 16 “(23) Dinoflagellate neurotoxin (Paralytic
17 Shellfish Toxin).
- 18 “(24) Aflatoxins.
- 19 “(25) Epsilon toxin of *clostridium perfringens*
20 (CNS effects, lethal).
- 21 “(26) *Staphylococcus enterotoxin B* (*Staphy-*
22 lococcus enterotoxin B intoxication).
- 23 “(27) *Salmonella* species (gastrointestinal
24 upset, enteric fever).
- 25 “(28) *Salmonella Typhi* (typhoid fever).

- 1 “(29) *Shigella dysenteriae* (dysentery, hemo-
2 lytic-uremic syndrome).
- 3 “(30) *Escherichia coli* 0157:H7 (severe diar-
4 rhea, hemolytic-uremic syndrome).
- 5 “(31) *Vibrio cholerae* (cholera).
- 6 “(32) *Cryptosporidium parvum*.
- 7 “(33) Nipah virus.
- 8 “(34) Bunyaviridae (Hantaviruses).
- 9 “(35) Tickborne hemorrhagic fever viruses.
- 10 “(36) Tickborne encephalitis virus.
- 11 “(37) Flaviviridae (Yellow fever).
- 12 “(38) *Plasmodium falciparum*, *P. ovale*, *P.*
13 *vivax*, *P. malariae* (Malaria).
- 14 “(39) *Rickettsia typhi* (typhus).
- 15 “(40) Antibiotic resistant tuberculosis.
- 16 “(41) *Entamoeba histolytica* (amebiasis).
- 17 “(42) *Shigella* sp. (bacillary dysentery,
18 Shigellosis).
- 19 “(43) *Giardia lamblia* (giardiasis).
- 20 “(44) *Trichomonas vaginalis* (trichomoniasis).
- 21 “(45) *Trypanosoma brucei gambiense* or
22 *rhodesiense* (trypanosomiasis, sleeping sickness).
- 23 “(46) *Leishmania donovane* (visceral leishmani-
24 asis, black fever, Kala Azar).

1 “(47) Nerve agents (including Tabun, Sarin,
2 Soman, GF, VX, V-gas, third generation nerve
3 agents and organophosphate pesticides).

4 “(48) Blood agents (including hydrogen cyanide
5 and cyanogen chloride).

6 “(49) Blister agents (including Lewisite, nitro-
7 gen and sulfur mustards).

8 “(50) Heavy metals (including arsenic, lead,
9 and mercury).

10 “(51) Volatile toxins (including benzene, chloro-
11 form, and trihalomethanes).

12 “(52) Pulmonary agents (including phosgene
13 and chlorine vinyl chloride).

14 “(53) Incapacitating agents (including BZ).

15 “(54) Nuclear and radiological materials.

16 “(55) Exotic agents including hybrid orga-
17 nisms, genetically modified organisms, antibiotic-in-
18 duced toxins, autoimmune peptides, immune mim-
19 icry agents, binary bioweapons, stealth viruses, and
20 bioregulators and biomodulators.

21 “(c) REVISIONS.—The Secretary shall revise the list
22 developed under subsection (a) on at least an annual basis,
23 and make such list available, under the terms and limita-
24 tions described in this section, to potential manufacturers
25 of terror weapons countermeasures or to holders of ap-

1 proved certifications. Such terms and conditions shall be
2 consistent with the security interests of the United States.

3 “(d) NO JUDICIAL REVIEW.—Notwithstanding any
4 other provision of law, there shall be no judicial review
5 of the Secretary’s determinations regarding which agents,
6 toxins, or materials to include on the list, or revised list,
7 developed under this section or of a determination to ex-
8 empt information from public distribution under this sec-
9 tion.

10 “(e) PROCUREMENT.—

11 “(1) PURPOSE.—It is the purpose of this sub-
12 section to provide potential manufacturers of coun-
13 termeasures that are registered with the Department
14 under section 1812 with sufficient information to en-
15 able that manufacturer to structure and manage its
16 research and development of a terror weapons coun-
17 termeasure and to determine when the manufacturer
18 has successfully developed such a countermeasure
19 and therefore becomes entitled to the procurement,
20 intellectual property, and liability incentives provided
21 for under this title (or an amendment made by the
22 Biological, Chemical, and Radiological Weapons
23 Countermeasures Research Act).

24 “(2) FEDERAL GOVERNMENT SUCCESS AND
25 MARKET DETERMINATION.—Not later than 180 days

1 after the development of the list, or revised list,
2 under subsection (a), the Secretary, in consultation
3 with the Food and Drug Administration, shall, with
4 respect to each agent, toxin, or material on the list,
5 determine—

6 “(A) the type of countermeasure to be de-
7 veloped, including whether such countermeasure
8 is a diagnostic, vaccine, biological, drug, or
9 other countermeasure;

10 “(B) the testing and clinical trial stand-
11 ards that will be required with respect to the
12 countermeasure, in order for the manufacturer
13 to become entitled to procurement, intellectual
14 property, and liability provisions of this title (or
15 an amendment made by the Biological, Chem-
16 ical, and Radiological Weapons Counter-
17 measures Research Act), including the terms of
18 review of the countermeasure by the Food and
19 Drug Administration and whether the approval
20 of such Administration is required;

21 “(C) the safety and efficacy profile of the
22 countermeasure;

23 “(D) the projected utilization of such coun-
24 termeasure in combination;

1 “(E) the Federal procurement market that
2 will be available to the manufacturer of such
3 countermeasure, including the minimum num-
4 ber of dosages or units that will be purchased,
5 the minimum price per dose or unit, and the
6 timing and minimum number of years projected
7 for such purchases;

8 “(F) the advance, partial, progress, mile-
9 stone or other payments that may be available
10 to the manufacturer under section 1822, and
11 the terms and conditions for the adjustment of
12 any such payments for uncontrollable factors;
13 and

14 “(G) such other information as the manu-
15 facturer may reasonably request to enable the
16 manufacturer to structure and manage research
17 and development activities and determine when
18 a countermeasure has been successfully devel-
19 oped therefore entitling the manufacturer to the
20 procurement, intellectual property, and liability
21 provisions of this title (or an amendment made
22 by the Biological, Chemical, and Radiological
23 Weapons Countermeasures Research Act).

24 “(3) DETERMINATIONS.—

1 “(A) IN GENERAL.—The Secretary shall
2 make determinations with respect to the suc-
3 cessful development of countermeasures under
4 section 1812(d)(3).

5 “(B) TESTING AND CLINICAL TRIALS.—
6 The determination by the Secretary under para-
7 graph (2)(B) with respect to the testing and
8 clinical trial standards that will be required
9 shall apply only to the entitlement of the manu-
10 facturer to the procurement, intellectual prop-
11 erty, and liability provisions of this title (or an
12 amendment made by the Biological, Chemical,
13 and Radiological Weapons Countermeasures
14 Research Act). Nothing in this title shall be
15 construed otherwise to alter or affect the au-
16 thority of the Food and Drug Administration
17 with respect to the testing, clinical trial, or
18 other regulatory standards applicable to the
19 countermeasure involved.

20 “(C) NO JUDICIAL REVIEW.—Notwith-
21 standing any other provision of law, there shall
22 be no judicial review of determinations made by
23 the Secretary under this subsection.

24 “(4) REVISIONS.—The Secretary is authorized
25 to—

1 “(A) revise upward determinations under
2 subparagraphs (E) and (G) of paragraph (2)
3 with respect to minimum number of dosages
4 that will be purchased and minimum price per
5 dose and the advance, partial, progress, mile-
6 stone or other payments that may be available
7 to the manufacturer upon a determination that
8 such revision is necessary to protect the na-
9 tional security interests of the United States
10 and provide an effective incentive to entities de-
11 veloping countermeasures; and

12 “(B) revise determinations under para-
13 graph (2)(C) to reduce the requirements of
14 safety and efficacy profiles for purposes of the
15 successful development determination pursuant
16 to paragraph (3) upon a determination that
17 such a revision is in the best interests of the
18 United States.

19 **“SEC. 1812. RESEARCH REGISTRATION REQUIREMENTS.**

20 “(a) IN GENERAL.—On or before December 31 of
21 each year each entity that operates any private sector es-
22 tablishment in any State that seeks to be eligible for the
23 tax, procurement, intellectual property, and liability provi-
24 sions in subtitle B (and the amendments made by sections
25 4 through 9 of the Biological, Chemical, and Radiological

1 Weapons Countermeasures Research Act), and that is en-
2 gaged in the conduct of research to develop counter-
3 measures, detections equipment (as provided for in section
4 1813), diagnostics (as provided for in section 1814), or
5 research tools (as provided for in section 1815) shall reg-
6 ister with the Department. Such registration shall con-
7 tain—

8 “(1) the name and address of the entity;

9 “(2) the name and address of the establishment
10 at which the research is being conducted;

11 “(3) the name of the agent, toxin, or material
12 with respect to which the entity seeks to develop
13 countermeasures, detection equipment, diagnostics
14 or research tools;

15 “(4) a description of the research that is being,
16 or that will be, conducted to develop counter-
17 measures to, or detection equipment, diagnostic or
18 research tools with respect to, such agent, toxin, or
19 material;

20 “(5) a description of the capability of the enti-
21 ty, including its technology and personnel, to develop
22 countermeasures to such agents, toxins, or material
23 that meet the safety and efficacy profiles specified
24 by the Secretary;

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

3 “(7) the procedures that the entity will follow
4 to ensure that the security interests of the United
5 States are met; and

6 “(8) any other information required under reg-
7 ulations promulgated by the Secretary, including ad-
8 ditions and corrections to the information required
9 under this subsection as may be required by the Sec-
10 retary through regulation.

11 “(b) AVAILABILITY OF INFORMATION.—

12 “(1) IN GENERAL.—Not later than 90 days
13 after the date of enactment of this title, the Sec-
14 retary shall promulgate regulations with respect to
15 the availability of information under this subsection.

16 “(2) INSPECTIONS.—Subject to regulations pro-
17 mulgated under paragraph (1), the Department shall
18 make available for inspection, to any person so re-
19 questing, any registration filed pursuant to sub-
20 section (a), except as provided in paragraph (3).

21 “(3) CERTAIN INFORMATION NOT AVAIL-
22 ABLE.—The Secretary shall promulgate regulations
23 to exempt certain information from disclosure under
24 paragraph (2). Such regulations shall exempt from
25 publication and disclosure trade secret and commer-

1 cial or financial information which is exempt from
2 disclosure to the public under section 552(b)(4) of
3 title 5, United States Code, national security infor-
4 mation, and information affecting the security of re-
5 search and other facilities.

6 “(4) NO JUDICIAL REVIEW.—Notwithstanding
7 any other provision of law, there shall be no judicial
8 review of determinations made by the Secretary to
9 exempt information under paragraph (3), except
10 that this paragraph shall not apply to judicial review
11 of the failure to exempt from publication and disclo-
12 sure trade secret and commercial or financial infor-
13 mation, national security information, and informa-
14 tion affecting the security of research and other fa-
15 cilities.

16 “(c) REPORTS.—

17 “(1) IN GENERAL.—The Secretary shall pro-
18 mulgate regulations that prescribe the reports that
19 each establishment that is registered with the De-
20 partment under this section shall be required to file
21 with the Secretary. Such regulations shall limit such
22 reports to those necessary to enable the Secretary
23 to—

24 “(A) ensure that the capital derived by the
25 utilization of the tax incentives provided for in

1 subtitle B (and the amendments made by sec-
2 tion 4 and 5 of the Biological, Chemical, and
3 Radiological Weapons Countermeasures Re-
4 search Act) is used to fund the research that is
5 the subject of the registration and certification
6 under this section;

7 “(B) determine the status of the research
8 involved; and

9 “(C) determine the outlook for United
10 States preparedness for a biological, chemical,
11 or radiological attack.

12 “(2) NO PUBLIC DISCLOSURE.—Notwith-
13 standing any other provision of law, reports under
14 this subsection, and the contents of such reports,
15 shall be exempt from disclosure to the public. The
16 submission of the reports required under this sub-
17 section to the Federal Government shall not con-
18 stitute public disclosure or public use of the reports,
19 or the information contained therein, and shall not
20 vest any intellectual property rights relating to dis-
21 coveries or inventions derived from such information,
22 or any intellectual property rights in such informa-
23 tion, in the United States or any person or entity.

24 “(d) CERTIFICATION.—

1 “(1) IN GENERAL.—With respect to each entity
2 that registers with the Department under this sec-
3 tion, the Secretary, in consultation with the Sec-
4 retary of Health and Human Services, shall deter-
5 mine—

6 “(A) whether the research to be conducted
7 under such registration is directed to lead to
8 the development of a—

9 “(i) countermeasure with respect to a
10 biological or chemical agent or radiological
11 material on the list under section 1811;

12 “(ii) detection equipment with re-
13 spect to the list developed under section
14 1813;

15 “(iii) diagnostic with respect to the
16 list developed under section 1814; or

17 “(iv) research tool with respect to the
18 list developed under section 1815;

19 “(B) whether the entity is qualified to con-
20 duct research to develop the countermeasure
21 with respect to which the entity seeks certifi-
22 cation, and, with respect to such determination,
23 the Secretary shall not presume that the entity
24 is unqualified because the entity has not pre-
25 viously secured approval of the Food and Drug

1 Administration of a device, drug, or biologic,
2 nor shall the Secretary presume that the entity
3 is unqualified because the entity itself lacks re-
4 search laboratories, testing facilities, or manu-
5 facturing facilities as research, testing, and
6 manufacturing services are reasonably available
7 through contracts with third parties and col-
8 laborative agreements; and

9 “(C) whether the procedures of the entity
10 will ensure compliance with section 351A of the
11 Public Health Service Act (as added by section
12 201 of the Public Health Security and Bioter-
13 rorism Preparedness and Response Act of 2002.

14 “(2) INSPECTION.—The Department shall be
15 authorized to require the inspection of an entity
16 seeking certification as a precondition to such cer-
17 tification to the extent necessary to enable the Sec-
18 retary to make the determinations required under
19 subparagraphs (A) through (C) of paragraph (1)
20 pursuant to regulations promulgated by the Sec-
21 retary.

22 “(3) DETERMINATION.—If the Secretary makes
23 an affirmative determination under paragraph (1)
24 with respect to an entity—

1 “(A) the Secretary shall certify the entity
2 as being entitled to utilize the tax incentive pro-
3 visions described in section 1821 (and the
4 amendments made by section 4 of the Biologi-
5 cal, Chemical, and Radiological Weapons Coun-
6 termeasures Research Act); and

7 “(B) the Secretary shall enter into a writ-
8 ten agreement with the entity setting forth the
9 agreement of the parties to the contract with
10 respect to the issues raised as a result of the
11 determinations made under section 1811(e)(2)
12 and the terms and conditions to be offered by
13 the Secretary pursuant to subsection (e)(2)
14 upon the Secretary’s determination pursuant to
15 such subsection (e) that the entity successfully
16 has developed the countermeasure, detection
17 equipment, diagnostic, or research tool, includ-
18 ing the Secretary’s agreement regarding the
19 availability of the liability protections provided
20 for under section 1824.

21 The execution by the parties of the agreement de-
22 scribed in subparagraph (B) shall create vested con-
23 tractual rights in the certified entity, including with
24 respect to procurement by the government upon suc-

1 successful development of the relevant countermeasure,
2 detection equipment, diagnostic, or research tool.

3 “(e) SUCCESSFUL DEVELOPMENT.—Not later than
4 90 days after the date on which a certified entity submits
5 to the Secretary an application for a determination that
6 the entity has successfully developed a terror weapons
7 countermeasure in accordance with section 1811(e)(2), de-
8 tectations equipment in accordance with section 1813, diag-
9 nostic in accordance with section 1814, or research tool
10 in accordance with section 1815, and the terms of the
11 agreement of the parties pursuant to subsection (d)(3)(B),
12 the Secretary shall notify the entity—

13 “(1) of such determination; and

14 “(2) in the case of an affirmative determination
15 by the Secretary with respect to the countermeasure,
16 detection equipment, diagnostic, or research tool in-
17 volved, that the entity shall be entitled to—

18 “(A) procurement of the countermeasure,
19 detection equipment, diagnostic, or research
20 tool under the terms and conditions of the par-
21 ties agreement pursuant to subsection
22 (d)(3)(B), upon the Secretary’s execution of a
23 contract consistent with such agreement, or
24 based on such other terms more favorable to
25 the entity as shall be deemed by the Secretary

1 to be in the interests of national security and
2 agreed to by the entity;

3 “(B) the patent restoration and extension
4 protection under section 156a or 158 of title
5 35, United States Code, as added by section 5
6 of the Biological, Chemical, and Radiological
7 Weapons Countermeasures Research Act;

8 “(C) the market exclusivity provisions of
9 sections 505(e)(3)(D) and 505(j)(4)(D) of the
10 Federal Food, Drug, and Cosmetic Act (as
11 amended by section 505B); and

12 “(D) the liability protections provided for
13 under section 1824 to the extent that the Sec-
14 retary agreed to such protections in the parties
15 agreement pursuant to subsection (d)(3)(B) or
16 determines that the provision of such protec-
17 tions is in the national interests.

18 “(f) REQUIRED AFFIRMATIVE DETERMINATION.—
19 The Secretary shall make an affirmative determination
20 that an entity has successfully developed a terror weapons
21 countermeasure, detection equipment, diagnostic, or re-
22 search tool under this section if, with respect to the testing
23 and clinical trial standards and the safety and efficacy
24 profile of the countermeasure referred to in subparagraphs
25 (B) and (C) of section 1811(e)(2) and set forth in the

1 parties' agreement pursuant to subsection (d)(3)(B), such
2 countermeasure, detection equipment, diagnostic, or re-
3 search tool—

4 “(1) has been authorized under the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
6 seq.) and the Public Health Service Act (42 U.S.C.
7 201 et seq.) for introduction or distribution into
8 commerce;

9 “(2) has not been authorized for such introduc-
10 tion or distribution into commerce under subpara-
11 graph (A) but has been authorized for investigation
12 or compassionate use as a terror weapons counter-
13 measure, detection equipment, diagnostic, or re-
14 search tool under such Acts and the Secretary deter-
15 mines that significant quantities of the counter-
16 measure, detection equipment, diagnostic, or re-
17 search tool have been manufactured by or on behalf
18 of the entity and are available for such investiga-
19 tional or compassionate use; or

20 “(3) is not required by the parties' agreement
21 to be authorized for introduction or distribution in
22 commerce or investigational use under such Acts,
23 but otherwise complies with the requirements set
24 forth in the agreement of the parties.

1 “(g) DISCRETIONARY AFFIRMATIVE DETERMINA-
2 TION.—The Secretary is authorized to make an affirma-
3 tive determination that an entity has successfully devel-
4 oped a terror weapons countermeasure, detection equip-
5 ment, diagnostic, or research tool within the meaning of
6 subsection (e) upon a determination that such a finding
7 is in the national interest.

8 “(h) JUDICIAL REVIEW.—An adverse determination
9 by the Secretary under subsection (f) with respect to the
10 development by a manufacturer of a terror weapons coun-
11 termeasure, detection equipment, diagnostic, or research
12 tool within the meaning of this title, or the refusal or fail-
13 ure of the Secretary to enter into a contract with the man-
14 ufacturer pursuant to subsection (e)(2)(A), shall be con-
15 sidered a final decision of the agency with the meaning
16 of section 702 of title 5, United States Code, and shall
17 be subject to appropriate judicial review. A plaintiff who
18 is successful in challenging an adverse determination by
19 the Secretary under subsection (f) may be awarded rea-
20 sonable and ordinary attorneys fees.

21 “(i) ELIGIBILITY OF ENTITIES WITH MORE THAN
22 \$750,000,000 IN AGGREGATE GROSS ASSETS, ETC.—

23 “(1) AUTHORITY OF SECRETARY TO WAIVE AG-
24 GREGATE GROSS ASSETS LIMITATION.—Within 60
25 days of the request of an entity for a certification

1 under subsection (d)(1) or a determination under
2 subsection (d)(3), and upon a finding by the Sec-
3 retary that it is in the public interest, the Secretary
4 may extend the entitlement to utilize the tax incen-
5 tives described in section 1821 (and the amendments
6 made by section 4 of the Biological, Chemical, and
7 Radiological Weapons Countermeasures Research
8 Act) and the patent restoration and extension pro-
9 tection described in section 1823 (and the amend-
10 ments made by section 5 of the Biological, Chemical,
11 and Radiological Weapons Countermeasures Re-
12 search Act), to such an entity with aggregate gross
13 assets exceeding \$750,000,000 (as defined in section
14 1202(d)(2) of the Internal Revenue Code of 1986).

15 “(2) WAIVER WITH REGARD TO ENTITIES WITH
16 NET OPERATING LOSSES.—Any entity obtaining a
17 certification or determination described in paragraph
18 (1) shall be entitled to utilize the tax incentives de-
19 scribed in paragraphs (1), (2), and (3) of section
20 1821(b) and the patent restoration and extension
21 protection described in section 158 of title 35,
22 United States Code, as added by section 5 of the Bi-
23 ological, Chemical, and Radiological Weapons Coun-
24 termeasures Research Act, if such entity’s tax status
25 in no fewer than 3 of the 5 taxable years preceding

1 such certification or determination is that of an enti-
2 ty with net operating losses (as defined in section
3 172(c) of the Internal Revenue Code of 1986).

4 “(3) IMPLEMENTING RULES.—The Secretary
5 shall publish appropriate rules to implement this
6 subsection taking into account the need to encourage
7 participation by entities which have not yet become
8 profitable on a sustainable basis.

9 “(4) NO JUDICIAL REVIEW.—Notwithstanding
10 any other provision of law, there shall be no judicial
11 review of determinations made by the Secretary with
12 respect to waivers under this subsection.

13 “(j) RULE OF CONSTRUCTION.—Nothing in this sec-
14 tion shall be construed to prohibit—

15 “(1) a private sector establishment from filing
16 more than 1 registration concerning research and
17 from obtaining more than 1 certification of eligibility
18 under this section;

19 “(2) a consortium, partnership, or joint venture
20 of more than one private sector establishment from
21 filing one or more registrations concerning research
22 and obtaining one or more certification of eligibility
23 under this section; and

24 “(3) a private sector establishment from receiv-
25 ing Federal grants, contracts, or cooperative agree-

1 ments for research, investigations, experiments,
2 demonstrations, and studies in addition to the incen-
3 tives provided for under this title (and the amend-
4 ments made by the Biological, Chemical, and Radio-
5 logical Weapons Countermeasures Research Act).

6 “(k) PRIORITY ACCESS TO CERTAIN RESEARCH RE-
7 SULTS.—An entity that is certified under this section shall
8 be given priority access to the results of research related
9 to the epidemiology and pathogenesis of agents, the
10 genomes and other DNA analysis, or other comparative
11 analysis of agents, and other relevant research conducted
12 under subparagraphs (A), (B), and (C) of section
13 391F(h)(1) of the Public Health Service Act (as added
14 by section 125 of the Public Health Security and Bioter-
15 rorism Preparedness and Response Act of 2002.

16 “(l) ACCELERATED APPROVAL.—An entity that is
17 certified under this section shall be eligible for accelerated
18 approval of a countermeasure as described in section 1831
19 and as provided for in section 122 of the Public Health
20 Security and Bioterrorism Preparedness and Response
21 Act of 2002.

22 “(m) PRIORITY FOR TECHNICAL AND OTHER ASSIST-
23 ANCE.—An entity that is certified under this section shall
24 be given priority for receiving technical and other assist-
25 ance to provide security for their personnel and facilities

1 that conduct development, production, distribution, or
2 storage of countermeasures under section 319K of the
3 Public Health Service Act (as added by section 124 of the
4 Public Health Security and Bioterrorism Preparedness
5 and Response Act of 2002).

6 **“SEC. 1813. DETECTORS INCENTIVES.**

7 “(a) FINDINGS.—Congress finds that—

8 “(1) early detection of a terrorist attack using
9 a terror weapon is critical in maximizing the ability
10 of governments and first responders to limit and
11 manage the consequences;

12 “(2) with early detection, first responders can
13 be quickly deployed, containment areas can be estab-
14 lished, and evacuation plans can be implemented;

15 “(3) medical treatment is often more effective
16 immediately after an attack than it is at later stages
17 of a disease;

18 “(4) detector systems must be integrated into
19 comprehensive response plans, including medical
20 diagnostics and other countermeasures;

21 “(5) such technology facilitates the determina-
22 tion of when and where an attack has occurred, the
23 identification of what type of terror weapon has been
24 utilized, and the extent and dispersal of the agent,

1 and must do so with a minimum of false negative or
2 false positive reports;

3 “(6) early detection is also critical in appre-
4 hending the terrorists who have unleashed the terror
5 weapon; and

6 “(7) a suite of detection devices, with different
7 sensitivities, is best capable of providing the timeli-
8 ness, range, and depth of information needed to de-
9 tect and respond to an attack.

10 “(b) IDENTIFICATION.—

11 “(1) IN GENERAL.—Not later than 180 days
12 after the date of enactment of this title, the Sec-
13 retary shall develop and make available to potential
14 manufacturers, a list of agents to be detected as well
15 as the standards and regulations under which detec-
16 tion equipment will be evaluated and approved. The
17 detection targets shall include chemical or biological
18 agents or toxins or nuclear or radiological materials.

19 “(2) AVAILABILITY OF INFORMATION.—The
20 Secretary shall provide such information as the Sec-
21 retary determines to be necessary to enable the po-
22 tential manufacturers of terror weapons detection
23 equipment to structure and focus their research and
24 development programs for the development of such
25 equipment.

1 “(3) REVISIONS.—The Secretary shall revise
2 the list developed under paragraph (1) on at least an
3 annual basis, and make such list available to poten-
4 tial manufacturers of terror weapons detections
5 equipment under terms and conditions consistent
6 with the security interests of the United States.

7 “(4) NO JUDICIAL REVIEW.—Notwithstanding
8 any other provision of law, there shall be no judicial
9 review of the Secretary’s determinations regarding
10 which agents, toxins, or materials to include on the
11 list, or revised list, developed under this subsection.

12 **“SEC. 1814. DIAGNOSTICS INCENTIVES.**

13 “(a) FINDINGS.—Congress finds that—

14 “(1) in the case of a bioterrorist attack, the
15 United States public health authorities need the ca-
16 pacity to quickly and accurately diagnose the agent,
17 toxin, or material involved so that appropriate med-
18 ical intervention can be implemented;

19 “(2) public health authorities need information
20 on which vaccines and drugs will be effective in pre-
21 venting infection, or in treating those who are in-
22 fected, as a result of a terrorist attack, and whether
23 there are any existing vaccines or drugs that are ef-
24 fective;

1 “(3) there is a lack of information on the com-
2 plications involved in administering vaccines and
3 drugs via the use of diagnostic devices to portions of
4 society that are known or unknown to carry contra-
5 indication diseases or conditions;

6 “(4) few diagnostics for agents, toxins, or mate-
7 rials that could be used in a terror attack are cur-
8 rently available;

9 “(5) the current structure and management of
10 patients in both the emergency room and outpatient
11 clinical settings is not conducive to rapid recognition
12 of infectious disease agents, which may in fact be
13 biothreat agents or chemical agents, which may re-
14 quire immediate appropriate treatment to prevent
15 permanent injury and loss of life;

16 “(6) financial inducements to conduct screening
17 tests for infectious diseases are nonexistent or re-
18 quire substantial justification before a health care
19 provider will order a specific test to diagnose an in-
20 fectious disease;

21 “(7) cultures, the gold standard currently for
22 infectious disease agents, can require 48 hours to
23 many days or weeks to provide a definitive diagnosis
24 while new molecular level tests can reduce that time
25 to hours;

1 “(8) the clinical presentation of many condi-
2 tions, including biothreat agents, is a very common
3 and nonspecific pattern of symptoms and doctors, in
4 general, will not order a test unless they happen to
5 think of a particular disease in their presumptive
6 differential diagnosis;

7 “(9) it is often easier to prescribe an antibiotic
8 rather than to determine the underlying causative
9 organism;

10 “(10) both screening and more specific tests to
11 diagnose infectious diseases need to be available to
12 physicians; and

13 “(11) screening particularly needs to be part of
14 the routine way physicians practice medicine, and
15 this means the ready availability of tests in emer-
16 gency room settings, the ability to rapidly provide a
17 definitive diagnosis, and the ability to report out
18 electronically to local public health agencies and hos-
19 pital infection control monitors results of these tests.

20 “(b) IDENTIFICATION.—Not later than 180 days
21 after the date of enactment of this title, the Secretary
22 shall develop and make available to potential manufactur-
23 ers, a list of the diagnostics and diagnostics for
24 contraindicators to vaccines or drugs that need to be de-
25 veloped to prepare the United States for a terrorist attack

1 with a biological or chemical agent or toxin or nuclear or
2 radiological materials. The Secretary shall provide such in-
3 formation as the Secretary determines to be necessary to
4 enable such potential manufacturers to structure and
5 focus their research and development programs for the de-
6 velopment of such research tools.

7 “(c) REVISIONS.—The Secretary shall revise the list
8 developed under subsection (b) on at least an annual basis,
9 and make such list available to potential manufacturers
10 of diagnostics under terms and conditions consistent with
11 the security interests of the United States.

12 “(d) DEVELOPMENT OF CERTAIN DIAGNOSTICS.—

13 “(1) IN GENERAL.—The Secretary shall develop
14 and implement a strategy for the development of in-
15 fectionous disease multiplexed molecular level tech-
16 nologies and the building of an integrated informa-
17 tion system linking the local, State, and Federal
18 public health systems for reporting automated lab-
19 oratory results for all infectious diseases.

20 “(2) STRATEGY.—The strategy developed and
21 implemented pursuant to paragraph (1) shall—

22 “(A) include the development of confirm-
23 atory laboratory tests to back up presumptive
24 results available from initial screening;

1 “(B) recognize the importance and the
2 need for advancement in the field of
3 bioinformatics which will accelerate the dis-
4 covery of countermeasures, using advanced
5 mathematical, computing, and image processing
6 technologies to solve complex problems includ-
7 ing pattern recognition methods, lossless digital
8 data compression for storage and transmission
9 of biomedical images, and the ability to analyze
10 massive amounts of data; and

11 “(C) promote the advancement of
12 bioinformatics through the use of incentives, the
13 procurement and rapid development of new de-
14 vices, and the development of a robust informa-
15 tion infrastructure for carrying out medical sur-
16 veillance tasks.

17 “(3) TECHNOLOGY.—The specific screening and
18 diagnostics technology used to implement the strat-
19 egy described in paragraph (1) may consist of multi-
20 plexed devices that screen for routinely encountered
21 common infectious diseases and have biothreat agent
22 detection algorithms embedded in the devices with
23 automatic reporting features such that the results
24 can be rapidly added and saved into the public

1 health system databases and put into the public
2 health system quickly.

3 “(e) UTILIZATION OF DIAGNOSTICS BY HEALTH
4 CARE PROVIDERS.—

5 “(1) IN GENERAL.—The Secretary shall develop
6 and implement a strategy that recognizes the need
7 to provide the right incentives to the health care in-
8 dustry to allow them to utilize the new diagnostic
9 tools that will be made available through research
10 and allow for routine screening for infectious dis-
11 eases.

12 “(2) REIMBURSEMENT.—The strategy shall in-
13 clude appropriate incentives to allow for reimburse-
14 ment to hospitals, clinics, and other providers who
15 perform routine laboratory screening utilizing newer
16 molecular level tests that rapidly detect infectious
17 diseases.

18 “(3) GUIDELINES.—The Secretary shall estab-
19 lish similar guidelines for States to utilize to pro-
20 mote infectious disease screening, including testing
21 for the rapid identification of potential biothreat
22 agents.

23 “(f) NO JUDICIAL REVIEW.—Notwithstanding any
24 other provision of law, there shall be no judicial review

1 of the list, or revised list, developed by the Secretary under
2 this section.

3 **“SEC. 1815. RESEARCH TOOLS INCENTIVES.**

4 “(a) FINDINGS.—Congress finds that—

5 “(1) it may not be possible for the United
6 States to anticipate the biological or chemical agent
7 or toxin or nuclear or radiological material that
8 might be utilized in a terrorist attack against the
9 United States;

10 “(2) terrorists may develop a biological or
11 chemical agent or toxin or nuclear or radiological
12 material that the United States has not anticipated
13 would be weaponized;

14 “(3) terrorists may be able to genetically mod-
15 ify an organism or manufacture a novel biological or
16 chemical agent or toxin or nuclear or radiological
17 material so that available diagnostics, vaccines, and
18 drugs are not effective;

19 “(4) in such cases, the United States needs the
20 capacity to develop and deploy, in the middle of an
21 epidemic or attack, effective diagnostics, vaccines,
22 drugs, and research tools;

23 “(5) the ability of terrorists to deploy novel
24 weapons of mass destruction far exceeds the power
25 of existing research tools;

1 “(6) to be prepared, the United States needs to
2 provide incentives for the development of new and
3 more powerful research tools; and

4 “(7) the Defense Science Board has found ‘Ef-
5 fective biodefense measures for treatment or
6 proactive vaccination against engineered agents in-
7 troduces an additional element of technical com-
8 plexity that would demand just-in-time R&D initia-
9 tives on a case-by-case basis to address the specific
10 technical manipulation used in producing the engi-
11 neered agent’.

12 “(b) IDENTIFICATION.—Not later than 180 days
13 after the date of enactment of this title, the Secretary
14 shall develop and make available to potential manufactur-
15 ers, a list of the research tools that need to be developed
16 to prepare the United States for a terrorist attack with
17 a biological or chemical agent or toxin or nuclear or radio-
18 logical materials. The list developed by the Secretary shall
19 include research tools for which there is a need for devel-
20 opment in order to understand why certain counter-
21 measures may cause adverse events, how to minimize such
22 adverse events, and how to treat such adverse events. The
23 Secretary shall provide such information as the Secretary
24 determines to be necessary to enable such potential manu-

1 facturers to structure and focus their research and devel-
2 opment programs for the development of such diagnostics.

3 “(c) REVISIONS.—The Secretary shall revise the list
4 developed under subsection (b) on at least an annual basis,
5 and make such list available to potential manufacturers
6 of research tools under terms and conditions consistent
7 with the security interests of the United States.

8 “(d) NO JUDICIAL REVIEW.—Notwithstanding any
9 other provision of law, there shall be no judicial review
10 of the list, or revised list, developed by the Secretary under
11 this section.

12 “(e) UTILIZATION AND AVAILABILITY.—

13 “(1) IN GENERAL.—Entities with respect to
14 which an affirmative determination is made under
15 subsection (f) or (g) of section 1812 shall maximize
16 the utilization of the research tools involved for the
17 development of countermeasures, including making
18 such tools available on commercially reasonable
19 terms to other entities certified under section 1812
20 to develop countermeasures.

21 “(2) RULE OF CONSTRUCTION.—Nothing in
22 this title or chapter 18 of title 35, United States
23 Code, shall be construed to restrict the right of an
24 entity described in paragraph (1) to—

1 “(A) secure and enforce patents with re-
2 gard to research tools;

3 “(B) enter into exclusive, revocable, and
4 nontransferable licenses of such research tools;

5 or

6 “(C) impose limits on royalty-reach-
7 through agreements, option rights, or product
8 reach-through rights concerning such research
9 tools.

10 **“Subtitle B—Incentives for the**
11 **Development of Countermeasures**

12 **“CHAPTER 1—PRIMARY INCENTIVES**

13 **“SEC. 1821. FEDERAL TAX INCENTIVES.**

14 “(a) FINDINGS AND PURPOSE.—

15 “(1) FINDINGS.—Congress makes the following
16 findings:

17 “(A) Most biotechnology companies, and
18 many device and research tool companies, are
19 early stage research ventures with no revenue
20 from product sales to finance their medical re-
21 search. Most biotechnology companies must rely
22 on repeated and large infusions of investor cap-
23 ital to fund this research. To conduct research
24 on countermeasures to biological agents and
25 other toxins or any other type of research, these

1 companies must persuade venture capitalists
2 and other investors that funding this research
3 may lead to a rate of return commensurate with
4 the risk and comparable to the rate of return
5 available to other, comparable investment op-
6 portunities.

7 “(B) Biotechnology companies are justifi-
8 ably reluctant to modify their ongoing research
9 priorities and devote scarce management and
10 scientific talent to new and risky projects. Their
11 first priority and obligation is and must be to
12 secure approval to market a product that will
13 generate revenue sufficient to reduce the de-
14 pendence of the company on continued infu-
15 sions of investor capital and to provide a long-
16 awaited return to patient investors.

17 “(C) Biotechnology companies tend to
18 focus on breakthrough research to develop med-
19 ical treatments for diseases where no effective
20 treatments are currently available. They often
21 specialize in research and development on rare
22 diseases and they are parties in the vast major-
23 ity of the collaborations in the United States
24 between private industry and academic medical
25 centers and the National Institutes of Health.

1 Many biotechnology companies do not have ap-
2 proval to market products with respect to which
3 they might develop minor improvements to
4 maintain a market advantage.

5 “(D) No type of industrial research is as
6 costly as biotechnology research. Successful re-
7 search and development of countermeasures will
8 necessitate breakthroughs in virology, immu-
9 nology, biochemistry, antibiotics, genetic engi-
10 neering, and many other disciplines in biology.

11 “(E) Many biotechnology companies have
12 no tax liability with respect to which to claim
13 a tax credit. Many of the tax incentives in the
14 income tax system of the United States have no
15 value to a company with no current revenue or
16 tax liability. Large pharmaceutical companies
17 can utilize tax credits as an incentive for re-
18 search.

19 “(F) The provision of tax incentives will
20 help in enabling biotechnology companies to
21 form the capital needed to conduct research to
22 develop countermeasures. Such incentives lower
23 the cost of capital, induce investors to fund re-
24 search, and enable biotechnology companies to
25 justify the investment of retained earnings.

1 Without such capital, research on counter-
2 measures is not likely to go forward. Tax incen-
3 tives are less costly than direct Federal Govern-
4 ment funding of the research and tend to shift
5 some of the risk of failure to the companies.

6 “(2) PURPOSE.—It is the purpose of this sec-
7 tion to provide tax incentives to enable bio-
8 technology, pharmaceutical, diagnostics, and re-
9 search tool companies to form capital to conduct re-
10 search to develop countermeasures.

11 “(b) IN GENERAL.—Any entity certified as entitled
12 to the provisions described in this section for any taxable
13 year under section 1812(d) may irrevocably elect 1 of the
14 following Federal tax incentives to fund research with re-
15 spect to each certification to develop countermeasures, de-
16 tection equipment, diagnostics, or medical research tools:

17 “(1) RESEARCH AND DEVELOPMENT LIMITED
18 PARTNERSHIPS TO FUND COUNTERMEASURE RE-
19 SEARCH.—The entity may establish a limited part-
20 nership for the certified countermeasures, detection
21 equipment, diagnostics, or research tools research,
22 but only if such entity is a qualified small business
23 as determined under section 1202(d) of the Internal
24 Revenue Code of 1986, by substituting
25 ‘\$750,000,000’ for ‘\$50,000,000’ each place it ap-

1 appears. For purposes of the Internal Revenue Code of
2 1986, section 469 of such Code shall not apply with
3 respect to a limited partnership established under
4 this paragraph.

5 “(2) CAPITAL GAINS EXCLUSION FOR INVES-
6 TORS TO FUND COUNTERMEASURE RESEARCH.—The
7 entity may issue a class of stock for the certified
8 countermeasures, detection equipment, diagnostics,
9 or research tools research under section 1202 of the
10 Internal Revenue Code of 1986 with the following
11 modifications:

12 “(A) INCREASED EXCLUSION FOR NONCOR-
13 PORATE TAXPAYERS.—Subsection (a) of section
14 1202 of such Code shall be applied by sub-
15 stituting ‘100 percent’ for ‘50 percent’.

16 “(B) APPLICATION TO CORPORATE TAX-
17 PAYERS.—Subsection (a) of section 1202 of
18 such Code shall be applied without regard to
19 the phrase ‘other than a corporation’.

20 “(C) STOCK OF LARGER BUSINESSES ELI-
21 GIBLE 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 it
25 appears.

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

5 “(E) NONAPPLICATION OF PER-ISSUER
6 LIMITATION.—Section 1202 of such Code shall
7 be applied without regard to subsection (b) (re-
8 lating to per-issuer limitations on taxpayer’s eli-
9 gible gain).

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

21 “(3) TAX CREDIT TO FUND COUNTERMEASURE
22 RESEARCH.—The entity may be eligible for the tax
23 credits provided for in the amendments made by sec-
24 tion 4 of the Biological, Chemical, and Radiological
25 Weapons Countermeasures Research Act.

1 “(c) REPORTING; RECAPTURE.—

2 “(1) REPORTING.—Each certified entity under
3 subsection (b) shall submit to the Secretary and the
4 Secretary of the Treasury such information regard-
5 ing its election of any tax incentive under this sec-
6 tion for the purpose certified under section 1812(d)
7 as the Director and the Secretary determine nec-
8 essary to carry out the enforcement provisions pre-
9 scribed under paragraph (2).

10 “(2) RECAPTURE.—The Secretary of the Treas-
11 ury, in consultation with the Secretary, shall provide
12 for the recapture of any tax benefits resulting from
13 any elected tax incentive under this section if the re-
14 sulting research is for a purpose other than that cer-
15 tified under section 1811(e).

16 “(d) EFFECTIVE DATE.—The provisions of this sec-
17 tion shall apply to taxable years beginning after December
18 31, 2002.

19 **“SEC. 1822. TERROR WEAPON COUNTERMEASURE PUR-**
20 **CHASE FUND.**

21 “(a) FINDINGS AND PURPOSE.—

22 “(1) FINDINGS.—Congress finds that—

23 “(A) the market for countermeasures is
24 uncertain at best and it is not possible for pri-
25 vate, for-profit entities to determine the pros-

1 pects for a reasonable rate of return on their
2 research and development investments relating
3 to such countermeasures;

4 “(B) such entities and their investors have
5 reasonable concerns that they will not realize a
6 reasonable rate of return in a market where the
7 Federal Government has monopoly or oligopoly
8 purchasing power;

9 “(C) such entities need to know in ad-
10 vance, prior to undertaking the research nec-
11 essary to develop a countermeasure, the nature,
12 size, duration, and terms of the market that is
13 available if it is successful in such development;
14 and

15 “(D) the market and rate of return that
16 the Federal Government guarantees for a coun-
17 termeasure must be comparable to a market
18 and rate of return that would be available to
19 the entity and investors for non-countermeasure
20 research.

21 “(2) PURPOSE.—It is the purpose of this sec-
22 tion to—

23 “(A) establish the guaranteed market and
24 a long-term commitment for private sector re-
25 search that leads to the successful development

1 of countermeasures to respond to an attack
2 with biological and chemical agents or toxins or
3 nuclear and radiological materials, or detection
4 equipment, diagnostics or research tools with
5 respect to such agents, toxins or materials; and

6 “(B) provide advance, partial, progress or
7 other payments to manufacturers of counter-
8 measures, detection equipment, diagnostics, or
9 research tools described in subparagraph (A).

10 “(3) LIMITATION.—Private sector entities are
11 entitled to the procurement incentives provided for
12 in this title (and the amendments made by the Bio-
13 logical, Chemical, and Radiological Weapons Coun-
14 termeasures Research Act) only when such entities
15 successfully develop a countermeasure that meets
16 the specifications prescribed by the Secretary.

17 “(b) DEFINITIONS.—In this section:

18 “(1) ELIGIBLE COUNTERMEASURE, DETECTION
19 EQUIPMENT, DIAGNOSTIC, OR RESEARCH TOOL.—
20 The term ‘eligible countermeasure, detection equip-
21 ment, diagnostic, or research tool’ means a counter-
22 measure (as defined in section 1802(1)), detection
23 equipment (developed under section 1813), diag-
24 nostic (developed under section 1814), or research
25 tool (developed under section 1815)—

1 “(A) that is developed by an entity that
2 has been certified under section 1812(d);

3 “(B) in the case of a countermeasure, that
4 the Secretary has determined is successful pur-
5 suant to subsection (f) or (g) of section 1812;
6 and

7 “(C) with respect to which an affirmative
8 notice has been provided under section 1812(d).

9 “(2) FUND.—The term ‘Fund’ means the Ter-
10 ror Weapon Countermeasure Purchase Fund estab-
11 lished under subsection (c).

12 “(c) ESTABLISHMENT OF FUND.—There is estab-
13 lished in the Treasury of the United States a fund to be
14 known as the ‘Terror Weapon Countermeasure Purchase
15 Fund’ consisting of amounts appropriated under sub-
16 section (f).

17 “(d) INVESTMENT OF FUND.—Amounts in the Fund
18 shall be invested in accordance with section 9702 of title
19 31, United States Code, and any interest on, and proceeds
20 from any such investment shall be credited to and become
21 part of the Fund.

22 “(e) USE OF FUND.—

23 “(1) IN GENERAL.—The Secretary of the
24 Treasury shall expend amounts in the Fund—

1 “(A) for the purchase of eligible counter-
2 measures, detection equipment, diagnostics, or
3 research tools with respect to which the Sec-
4 retary has made an affirmative determination
5 as provided for in subsection (f) or (g) of sec-
6 tion 1812 which shall be made available to the
7 Secretary and distributed as the Secretary, in
8 consultation with the Secretary of Health and
9 Human Services and the Secretary of Defense,
10 determines appropriate; and

11 “(B) to provide advance, partial, progress
12 or other payments, in accordance with para-
13 graph (4), to an entity pursuant to an agree-
14 ment reached under section 1812(d)(3)(B), or
15 pursuant to a contract under section 1812(e),
16 to manufacturers of eligible countermeasures,
17 detection equipment, diagnostics, or research
18 tools with respect to which the Secretary has
19 made an affirmative determination as provided
20 for in such section 1812.

21 “(2) PURCHASE.—Countermeasures, detection
22 equipment, diagnostics, or research tools shall be
23 purchased by the Fund—

24 “(A) in the case of a countermeasure, in
25 the amount and at the per dosage price as de-

1 scribed in the notice received by the entity
2 under section 1812(d)(3) unless superceded by
3 the contract between the parties pursuant to
4 section 1812(e); or

5 “(B) in the case of detection equipment,
6 diagnostics, or research tools, at the price and
7 under the terms negotiated by the Secretary
8 and the manufacturer.

9 “(3) CONDITIONS FOR PURCHASE.—Payments
10 made for purchases under paragraph (1)(A) shall be
11 made under such terms and conditions as are set
12 forth in the contract between the parties pursuant to
13 section 1812(e), including the provision by the man-
14 ufacturer of adequate security for such payments if
15 applicable. If such security is in the form of a lien
16 on property or equipment in favor of the United
17 States, such lien shall be paramount to all other
18 liens on such property or equipment and shall be ef-
19 fective immediately upon the first payment, without
20 filing, notice, or other action by the United States.

21 “(4) ADVANCE, PARTIAL, PROGRESS OR OTHER
22 PAYMENTS.—

23 “(A) IN GENERAL.—The Secretary of the
24 Treasury may make payments under paragraph
25 (1)(B) to manufacturers of eligible counter-

1 measures, detection equipment, diagnostics, or
2 research tools prior to the final purchase of
3 such countermeasure, equipment, diagnostic, or
4 research tool.

5 “(B) BASIS FOR PAYMENTS.—Payments
6 under this paragraph shall be based on—

7 “(i) the performance of the manufac-
8 turer involved as measured by the Sec-
9 retary of the Treasury using objective,
10 quantifiable methods (such as delivery of
11 acceptable items, work measurement, or
12 statistical process controls) established by
13 the Secretary of the Treasury in consulta-
14 tion with the Secretary;

15 “(ii) the accomplishment of events as
16 defined in a program management plan
17 that is developed by the manufacturer and
18 submitted to the Secretary of the Treas-
19 ury; or

20 “(iii) other quantifiable measures of
21 results determined appropriate by the Sec-
22 retary of the Treasury, in consultation
23 with the Secretary.

24 “(C) NUMBER, TIME, AND AMOUNT OF
25 PAYMENTS.—

1 “(i) IN GENERAL.—The Secretary of
2 the Treasury, in consultation with the Sec-
3 retary, shall, with respect to a manufac-
4 turer of an eligible countermeasure, detec-
5 tion equipment, diagnostic, or research
6 tool, determine the number payments to be
7 made, the timing of such payments, and
8 subject to clause (ii), the amount of each
9 such payment.

10 “(ii) LIMITATION.—The amount of
11 any payment made to a manufacturer
12 under this paragraph shall not exceed the
13 amount of the final purchase price (de-
14 scribed in paragraph (2)(A)) for the coun-
15 termeasure, detection equipment, diag-
16 nostic, or research tool involved that re-
17 mains unpaid as of the date of the pay-
18 ment involved.

19 “(D) CONDITIONS FOR PAYMENT.—The
20 Secretary of the Treasury, in consultation with
21 the Secretary, shall ensure that any payment to
22 which this paragraph applies is commensurate
23 with the actions taken by the manufacturer and
24 the progress made in achieving the performance
25 measures under subparagraph (B)(i) through

1 the time of such payment. The manufacturer
2 shall provide such information and evidence as
3 the Secretary of the Treasury and the Secretary
4 determine is necessary to determine compliance
5 with the preceding sentence.

6 “(E) SECURITY.—The provisions of para-
7 graph (3) relating to security shall apply to
8 payments made under this paragraph.

9 “(5) DISTRIBUTION.—Eligible countermeasures,
10 detection equipment, diagnostics, or research tools
11 purchased by the Fund shall be distributed as pro-
12 vided for by the Secretary, in consultation with the
13 Secretary of Health and Human Services, deter-
14 mines appropriate after—

15 “(A) consideration of—

16 “(i) in the case of countermeasures,
17 the prevalence of the infection or exposure
18 to an agent, toxin, or material to be treat-
19 ed by the eligible countermeasure; or

20 “(ii) in the case of detection equip-
21 ment, diagnostics, or research tools, the
22 predicted demand for the use of such
23 equipment, diagnostics, or research tools;
24 and

1 “(B) consideration of the ability of the re-
2 cipient to effectively and safely deliver the coun-
3 termeasures, detection equipment, diagnostics,
4 or research tools.

5 “(6) PUSH PACKS.—The Secretary of the
6 Treasury may use amounts in the Fund for the pur-
7 chase of countermeasures to be included in Federal
8 or State government maintained PUSH Packs to be
9 used in the case of a terror attack using chemical,
10 biological, or radiologic toxins, agents or materials.

11 “(7) RULE OF CONSTRUCTION.—Nothing in
12 this subsection shall be construed to require that the
13 Fund purchase a countermeasure, detection equip-
14 ment, diagnostic, or research tool for each agent,
15 toxin, or material contained on the Biological and
16 Chemical Agent Priority List developed under sec-
17 tion 1811 from an entity that the Secretary has not
18 certified for development of that countermeasure, de-
19 tection equipment, diagnostic, or research tool under
20 section 1812(d).

21 “(8) REGULATIONS.—The Secretary shall pro-
22 mulgate such regulations as are necessary to carry
23 out the provisions of this subsection.

24 “(f) APPROPRIATIONS.—

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 there are appropriated out of any funds in the
3 Treasury not otherwise appropriated such sums as
4 may be necessary to carry out the purposes of the
5 Fund for each of 10 fiscal years beginning with the
6 first fiscal year after the date that the Secretary of
7 the Treasury determines that any eligible counter-
8 measure, detection equipment diagnostic, or research
9 tool is available for purchase by the Fund.

10 “(2) TRANSFER TO FUND.—The Secretary of
11 the Treasury shall transfer the amount appropriated
12 under paragraph (1) for a fiscal year to the Fund.

13 “(3) AVAILABILITY.—Amounts appropriated
14 under this section shall remain available until ex-
15 pended.

16 “(g) AUTHORITY TO CONTRACTS.—

17 “(1) IN GENERAL.—Notwithstanding any other
18 provision of law, including section 1341 of title 31,
19 United States Code, a multi-year contract may be
20 entered into by the Secretary under subsection
21 (d)(3) or (e) of section 1812, except that any such
22 contract shall be for a period of not to exceed 10
23 years.

24 “(2) FEDERAL ACQUISITION.—Notwithstanding
25 any other provision of law, a contract described in

1 paragraph (1) shall not be subject to the require-
2 ments of title III of the Federal Property and Ad-
3 ministrative Services Act of 1949 (41 U.S.C. 251 et
4 seq.) or Federal regulations relating to acquisitions.

5 “(h) RULE OF CONSTRUCTION.—Nothing in this sec-
6 tion shall be construed to limit in any manner, the sale
7 or terms of sale of an eligible countermeasure, detection
8 equipment, diagnostic, or research tool to any other entity
9 or individual in any public or private sector market.

10 **“SEC. 1823. PATENT TERM PROTECTION AND EXCLUSIVE**
11 **MARKETING.**

12 “(a) FINDINGS.—Congress makes the following find-
13 ings:

14 “(1) Patents are necessary to protect the inven-
15 tions of entrepreneurial firms. Without patents, the
16 inventions of these companies can be expropriated by
17 competitors and investors’ expectations of a reason-
18 able rate of return on their investment are frus-
19 trated. In return for a limited term of protection
20 from competitors, inventors are required to publish
21 a detailed description of the invention for which the
22 patent has been granted.

23 “(2) The 20 year term of a patent is measured
24 from the date of the patent application. The effective
25 term of a patent, however, is the term remaining

1 after an invention has been approved for sale by
2 Government regulators. Erosion of the term of pat-
3 ents for biotechnology and pharmaceutical firms,
4 which cannot market a product until it has been ap-
5 proved, is common and increasing. Protection
6 against such erosion, due to delays caused by Gov-
7 ernment regulatory review, will ensure that the full
8 term of the patent granted by the Patent and Trade-
9 mark Office is available to the inventor to recoup
10 their investment. Such protections maintain the full
11 term of the patent.

12 “(3) As an incentive for capital formation to
13 fund research to develop countermeasures, compa-
14 nies and investors will respond to the prospect of
15 being able to extend other patents in their portfolio.

16 “(4) Biotechnology and pharmaceutical compa-
17 nies and their investors are sensitive to any possi-
18 bility that successful completion of breakthrough re-
19 search leading to the approval for the sale of a prod-
20 uct, including a countermeasure, will lead to chal-
21 lenges to their patents.

22 “(b) REFERENCE TO OTHER LAW.—For provisions
23 relating to patent term protection and exclusive marketing
24 incentives, see section 5 of the Biological, Chemical, and
25 Radiological Weapons Countermeasures Research Act.

1 **“SEC. 1824. LIABILITY AND INDEMNIFICATION.**

2 “(a) FINDINGS AND PURPOSE.—

3 “(1) FINDINGS.—Congress makes the following
4 findings:

5 “(A) Many countermeasures to terror
6 agents, toxins, and materials will be deployed
7 with a minimum of human clinical trials, which
8 are either impractical or unethical. In other
9 cases, when countermeasures are deployed in an
10 emergency, no human clinical trials may have
11 been conducted.

12 “(B) Companies are justifiably reluctant to
13 permit deployment of a countermeasure where
14 so little clinical testing is possible. They need
15 reassurance that they will not be held liable for
16 claims that may arise related to the safety and
17 efficacy of countermeasures, especially from
18 vaccines as well as prophylactically adminis-
19 tered countermeasures that they develop.

20 “(C) The United States faces dire public
21 health consequences if agents, toxins, and mate-
22 rials are used in an attack for which no coun-
23 termeasures are available. The United States
24 has enemies who will not hesitate to use these
25 agents in an attack. Our national security re-
26 quires that we ensure that these counter-

1 measures are developed and the most effective
2 available research and development expertise
3 lies with biotechnology and pharmaceutical com-
4 panies.

5 “(2) PURPOSE.—It is the purpose of this sec-
6 tion to provide liability protections to encourage
7 companies to conduct research to develop and
8 produce countermeasures.

9 “(b) REFERENCE TO OTHER PROVISION.—For provi-
10 sions relating to liability provisions for manufacturers,
11 distributors, and other entities involved with counter-
12 measures developed under this title see section 224(p) of
13 the Public Health Service Act.

14 **“CHAPTER 2—OTHER INCENTIVES**

15 **“SEC. 1831. ACCELERATED APPROVAL OF COUNTER-** 16 **MEASURES.**

17 “(a) IN GENERAL.—The Secretary of Health and
18 Human Services may designate a countermeasure as a
19 fast-track product pursuant to section 506 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 356) or as a
21 device granted priority review pursuant to section
22 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a des-
23 ignation may be made prior to the submission of—

24 “(1) a request for designation by the sponsor or
25 applicant; or

1 “(2) an application for the investigation of the
2 drug under section 505(i) of such Act or section
3 351(a)(3) of the Public Health Service Act.

4 Nothing in this subsection shall be construed to prohibit
5 a sponsor or applicant from declining such a designation.

6 “(b) USE OF ANIMAL TRIALS.—A drug for which ap-
7 proval is sought under section 505(d) of the Federal Food,
8 Drug, and Cosmetic Act or section 351 of the Public
9 Health Service Act on the basis of evidence of effectiveness
10 that is derived from animal studies under section 1832
11 may be designated as a fast track product for purposes
12 of this section.

13 “(c) PRIORITY REVIEW.—

14 “(1) IN GENERAL.—A countermeasure that is a
15 drug or biological product shall be subject to the
16 performance goals established by the Commissioner
17 of Food and Drugs for priority drugs or biological
18 products.

19 “(2) DEFINITION.—In this subsection the term
20 ‘priority drugs or biological products’ means a drug
21 or biological product that is the subject of a drug
22 application referred to in section 101(4) of the Food
23 and Drug Administration Modernization Act of
24 1997.

1 **“SEC. 1832. BIOLOGICS MANUFACTURING CAPACITY INCEN-**
2 **TIVES.**

3 “(a) FINDINGS.—Congress makes the following find-
4 ings:

5 “(1) When the United States develops new bio-
6 logically derived materials, including vaccines,
7 monoclonal antibodies, and recombinant proteins,
8 plant compounds, and blood products to prevent in-
9 fection by bioterrorist agents or toxins or to treat
10 those infected in bioterrorist attacks or to protect or
11 treat those exposed to chemical agents, a shortage of
12 manufacturing facilities for biologics may delay or
13 prevent the production and stockpiling of such mate-
14 rials.

15 “(2) There is a severe shortage of manufac-
16 turing capacity to produce such materials. There are
17 nearly 100 biologics in clinical trials, and current
18 manufacturing capacity is 475,000 liters, virtually
19 all of which is utilized. An additional 1,100,000 li-
20 ters of capacity will come online by the end of 2006,
21 but civilian demand will continue to outstrip capac-
22 ity. There is little or no available capacity to produce
23 such biologically derived materials to treat those who
24 might be infected by bioterror agents.

25 “(3) The Defense Science Board has found
26 ‘Any bioterrorism attack that created the need to

1 treat more than 50,000 people with an extended
2 course of antibiotic therapy . . . or to immunize
3 more than 1 to 3 million people with a vaccine would
4 completely overwhelm the total production capacity
5 of the industry.’ The Federal Government ‘must es-
6 tablish a proactive long-term plan to address these
7 inventory and production shortfalls’.

8 “(4) A typical manufacturing facility costs be-
9 tween \$200,000,000 and \$400,000,000 to build, and
10 there is no incentive for companies to build these fa-
11 cilities until a product has been developed and ap-
12 proved. On average, a plant takes 4 years to build,
13 considering the intricacies of the process and the
14 necessary Food and Drug Administration proce-
15 dures.

16 “(5) Biotechnology and pharmaceutical compa-
17 nies have no reason to fund the construction of bio-
18 logics manufacturing facilities unless and until there
19 is a market demand for the facilities.

20 “(6) The incentives provided under this title,
21 and the tax, procurement, intellectual property, and
22 liability provisions in subtitle B (and the amend-
23 ments made by the Biological, Chemical, and Radio-
24 logical Weapons Countermeasures Research Act),
25 should lead to the development of new biologically

1 derived materials to prevent and treat bioterrorist
2 attacks and decisions to purchase, stockpile and per-
3 haps deploy such materials.

4 “(7) It is in the national interest for the United
5 States to provide incentives for the construction of
6 sufficient biologics manufacturing facilities so that
7 there will be no delay in the production of bio-
8 logically active materials once such materials are de-
9 veloped.

10 “(b) SURVEY AND PLAN.—Not later than 90 days
11 after the date of enactment of this title, the Secretary
12 shall—

13 “(1) conduct a survey of the biologics manufac-
14 turing facilities, including those for the production
15 of monoclonal antibodies, recombinant proteins, and
16 plant compounds using cell culture methods as well
17 as those for the production of antibodies and other
18 blood products from human blood, operating in the
19 United States and determine whether additional
20 manufacturing facilities that will be needed (and if
21 so the number of such facilities) to manufacture and
22 stockpile biologically active materials for bioterrorist
23 attacks; and

24 “(2) develop a plan to ensure that sufficient
25 biologics manufacturing facilities are available in the

1 United States when they are needed, including an
2 analysis of the feasibility of the Federal Government
3 contracting for the construction of such facilities or
4 of providing tax and other incentives for the con-
5 struction of such facilities by private sector entities.

6 “(c) SUBMISSION TO CONGRESS.—The Secretary
7 shall submit the plan developed under subsection (b)(2)
8 to Congress together with recommendations concerning
9 the manner in which to ensure that the needed biologics
10 manufacturing facilities available for the production of
11 countermeasures under this title are constructed and
12 available, including the siting, design and certification
13 costs, costs of training and recruitment of expert staff,
14 and other costs associated with such facilities.

15 “(d) INCENTIVES FOR THE CONSTRUCTION OF BIO-
16 LOGICS MANUFACTURING FACILITIES AVAILABLE FOR
17 THE PRODUCTION OF COUNTERMEASURES.—The Sec-
18 retary shall issue regulations regarding the selection of an
19 entity that agrees to operate as a biologics manufacturing
20 facility available for the production of countermeasures
21 under this title in accordance with the plan developed
22 under subsection (b)(2) for the investment tax credit pro-
23 vided under section 8 of the Biological, Chemical, and Ra-
24 diological Weapons Countermeasures Research Act. Such
25 regulations shall state when such an entity shall be avail-

1 able and the terms for the use for the production of such
2 countermeasures. If an entity is constructed to produce
3 such countermeasures, such entity shall provide notice
4 that such entity is available to produce such counter-
5 measures.

6 **“SEC. 1833. BIOLOGICS MANUFACTURING EFFICIENCY IN-**
7 **CENTIVES.**

8 “(a) FINDINGS.—Congress finds that—

9 “(1) the manufacturing of biologics, which are
10 derived from living organisms, is an art as well as
11 a science;

12 “(2) the efficiency of the biologics manufac-
13 turing process determines the output capacity, pu-
14 rity, and manufacturing cost of vaccines, recom-
15 binant proteins, plant compounds, and blood prod-
16 ucts;

17 “(3) technical advances in manufacturing
18 sciences for biologics can increase the capacity of the
19 Federal Government to ensure that vaccines, recom-
20 binant proteins, plant compounds, and blood prod-
21 ucts are available as part of a bioterror plan and to
22 reduce the cost of manufacturing and stockpiling
23 these vaccines, recombinant proteins, plant com-
24 pounds, and blood products; and

1 “(4) the subjects of research relating to the
2 manufacturing of biologics may include the develop-
3 ment of—

4 “(A) additional well characterized cell lines
5 for vaccine, recombinant proteins, plant com-
6 pounds, and monoclonal antibody production;

7 “(B) new biologic and chemical standards
8 for use in product testing, including testing of
9 potency and purity;

10 “(C) improved preservatives for vaccines or
11 other biologics to prolong shelf-life;

12 “(D) adjuvants that enhance the immune
13 response to a vaccine or antigen;

14 “(E) tests to determine contamination with
15 human or animal viruses or prions;

16 “(F) improved tests of potency and purity
17 during the manufacturing process, not just for
18 the final product;

19 “(G) improved characterization of biologics
20 at the macro-molecular level;

21 “(H) processes that enhance the yield and
22 quality of biologics;

23 “(I) improved methods that enhance dis-
24 infection and sterilization of material and facili-
25 ties;

1 “(J) new methods to improve output, man-
2 ufacturing costs, and product quality with a
3 particular emphasis on downstream processing
4 (separation and purification) where particular
5 bottlenecks occur with much lost product, com-
6 plexity and very high costs; and

7 “(K) improved methods for decontamina-
8 tion of production of facilities to enable switch-
9 ing from one product to another.

10 “(b) SURVEY AND PLAN.—Not later than 90 days
11 after the date of enactment of this title, the Secretary
12 shall—

13 “(1) conduct a survey of existing biologics man-
14 ufacturing sciences and determine whether technical
15 advances in such sciences might increase the bio-
16 logics output capacity and purity, and lower the
17 manufacturing cost of vaccines, recombinant pro-
18 teins, plant compounds, and blood products; and

19 “(2) develop a plan to provide incentives to en-
20 hance scientific research to develop new technologies
21 identified under the survey conducted under para-
22 graph (1), including a list of the possible tech-
23 nologies that may be developed and the possible in-
24 centives that may lead to their development.

1 “(c) SUBMISSION TO CONGRESS.—The Secretary
2 shall submit the plan developed under subsection (b)(2)
3 to Congress together with recommendations concerning
4 the provision of funding or incentives for the conduct of
5 scientific research to develop new technologies relating to
6 biologics manufacturing sciences.

7 “(d) INCENTIVES.—The Secretary shall establish a
8 program under which entities that agree to develop new
9 technologies in accordance with the plan developed under
10 subsection (b)(2) are eligible for the tax incentives pro-
11 vided for under the amendments made by section 4 of the
12 Biological, Chemical, and Radiological Weapons Counter-
13 measures Research Act.

14 **“SEC. 1834. CONSTRUCTION OF BIOSAFETY LEVEL 3-4 RE-**
15 **SEARCH FACILITIES.**

16 “(a) FINDINGS.—Congress finds that—

17 “(1) research to develop countermeasures re-
18 quires the use of special facilities where biological
19 agents and chemical agents can be handled safely
20 both for laboratory research as well as research and
21 efficacy tests in animals;

22 “(2) very few companies can capitalize the con-
23 struction of these special facilities; and

1 “(3) the Federal Government can facilitate re-
2 search and development of countermeasures by fi-
3 nancing the construction of these special facilities.

4 “(b) GRANTS AUTHORIZED.—

5 “(1) IN GENERAL.—The Secretary is authorized
6 to award grants and contracts to grantees to con-
7 struct, maintain, and manage (including funding for
8 staff and staff training) biosafety level 3–4 facilities.

9 “(2) REQUIREMENTS.—To be eligible for a
10 grant under paragraph (1) an entity shall—

11 “(A) allow use of the facility involved by
12 only those researchers who meet qualifications
13 set by the Secretary;

14 “(B) give priority for the use of the facility
15 involved to those entities that have been reg-
16 istered and certified by the Secretary to develop
17 countermeasures; and

18 “(C) allow the National Institutes of
19 Health to inspect the facility involved at any
20 time.

21 “(3) NUMBER OF GRANTS.—The Secretary of
22 the Department of Homeland Security shall deter-
23 mine the number of facilities that need to be con-
24 structed under this section, not to exceed 10 such

1 facilities nationwide, and the Secretary shall award
2 grants based on such determination.

3 “(c) APPLICATION.—

4 “(1) IN GENERAL.—To be eligible to receive a
5 grant under this section an entity shall submit to
6 the Secretary an application at such time, in such
7 form and containing such information, as the Sec-
8 retary may require.

9 “(2) CONTENTS.—Each application submitted
10 pursuant to paragraph (1) shall—

11 “(A) provide detailed information on the
12 technical specifications of proposed facilities;

13 “(B) propose a design that includes offices
14 for personnel, visiting researchers, and facilities
15 for research and laboratory materials;

16 “(C) provide assurances that the facilities
17 shall be available on a fee-for-service or other
18 basis to companies and academic researchers;
19 and

20 “(D) provide assurances that the facilities
21 will be constructed as secure facilities.

22 “(d) DEFINITIONS.—For the purposes of this sec-
23 tion—

1 “(1) unless otherwise specifically identified, the
2 term ‘Director’ means the Director of the National
3 Institutes of Health; and

4 “(2) a ‘biosafety level 3–4 facility’ means a fa-
5 cility for research on indigenous, exotic, or dan-
6 gerous agents with the potential for aerosol trans-
7 mission of disease that may have serious or lethal
8 consequences or that pose a high risk of life-threat-
9 ening disease, aerosol-transmitted laboratory infec-
10 tions, or related agents with unknown risk of trans-
11 mission.

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated such sums as may be
14 necessary to carry out this section.

15 **“SEC. 1835. NATIONAL INSTITUTES OF HEALTH COUNTER-**
16 **MEASURES PARTNERSHIP CHALLENGE**
17 **GRANTS.**

18 “(a) GRANTS AUTHORIZED.—The Director of the
19 National Institutes of Health (in this section referred to
20 as the ‘Director’) is authorized to award partnership chal-
21 lenge grants to promote joint ventures between the Na-
22 tional Institutes of Health, its grantees, and for-profit bio-
23 technology, pharmaceutical, and medical device industries
24 for the development of countermeasures and research
25 tools.

1 “(b) REGULATIONS.—The Director shall issue regu-
2 lations within 90 days of the date of enactment of this
3 section to implement the awarding of grants under sub-
4 section (a).

5 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
6 tion shall be construed to preclude an entity that receives
7 a partnership challenge grant under this section from also
8 being certified as being eligible for incentives under this
9 title (and the amendments made by tax, procurement, in-
10 tellectual property, and liability provisions in subtitle B
11 (and the amendments made by the Biological, Chemical,
12 and Radiological Weapons Countermeasures Research
13 Act).

14 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated \$200,000,000 for each
16 of fiscal years 2004, 2005, 2006, 2007, and 2008 for the
17 purpose of carrying out this section.

18 **“Subtitle C—Administrative**
19 **Provisions**

20 **“SEC. 1841. ANNUAL REPORT.**

21 “(a) IN GENERAL.—Not later than January 1, 2005,
22 and each January 1 thereafter, the Secretary shall prepare
23 and submit to the appropriate committees of Congress and
24 make available to the public, a report concerning the im-
25 plementation of this title (and the amendment made by

1 the Biological, Chemical, and Radiological Weapons Coun-
2 termeasures Research Act). Such reports shall include—

3 “(1) an assessment of whether the incentives
4 provided for in this title are sufficient, as deter-
5 mined by the Secretary, to induce the biotechnology,
6 pharmaceutical, device, and research tools industries
7 to modify their ongoing research priorities and de-
8 vote scarce management and scientific talent to re-
9 search to develop terror weapons countermeasures;

10 “(2) an assessment of whether such incentives
11 are sufficient, as determined by the Secretary, to ad-
12 dress the sensitivity of such industries to the possi-
13 bility of challenges to their prices and patents and
14 the terms of sales that may arise when the Federal
15 Government is an oligopoly or monopoly purchaser;

16 “(3) an assessment of whether such incentives
17 are likely to lead to the development of counter-
18 measures to prepare the United States in the event
19 of the use of biological, chemical, and radiological
20 weapons by terrorists and others against both mili-
21 tary or intelligence, government, and civilian per-
22 sonnel;

23 “(4) an assessment of whether such incentives
24 will lead to the development of research tools;

1 measures to biological, chemical and nuclear terror at-
2 tacks.

3 “(b) FOCUS OF CONFERENCE.—Each conference
4 convened under subsection (a) shall focus on one or more
5 of the following:

6 “(1) An assessment of the biological, chemical,
7 or radiological threats that may arise and the coun-
8 termeasures that may be needed.

9 “(2) The status of research to develop counter-
10 measures, including research tools.

11 “(3) The need for and effectiveness of incen-
12 tives for such research by private sector entities, in-
13 cluding tax, procurement, intellectual property, and
14 liability incentives.

15 “(4) Mechanisms that will improve coordination
16 among public and private sector entities conducting
17 such research and development.

18 “(5) The potential benefits and applications of
19 such research for the prevention and treatment of
20 tropical and other diseases.

21 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated, such sums as be nec-
23 essary in each fiscal year to carry out this section.”.

1 **SEC. 4. TAX INCENTIVES.**

2 (a) AMENDMENTS TO THE INTERNAL REVENUE
3 CODE.—

4 (1) TAX CREDIT TO FUND COUNTERMEASURE
5 RESEARCH.—

6 (A) IN GENERAL.—Subpart D of part IV
7 of subchapter A of chapter 1 of the Internal
8 Revenue Code of 1986 (relating to business re-
9 lated credits) is amended by adding at the end
10 the following new section:

11 **“SEC. 45G. CREDIT FOR MEDICAL RESEARCH RELATED TO**
12 **DEVELOPING COUNTERMEASURES.**

13 “(a) GENERAL RULE.—For purposes of section 38,
14 in the case of any certified entity under section 1812(d)
15 of the Biological, Chemical, and Radiological Weapons
16 Countermeasures Research Act of 2003 which makes an
17 election under section 1821(b) of such Act to apply this
18 section, the countermeasures research credit determined
19 under this section for the taxable year is an amount equal
20 to 35 percent of the qualified countermeasures research
21 expenses for the taxable year.

22 “(b) QUALIFIED COUNTERMEASURES RESEARCH EX-
23 PENSES.—For purposes of this section—

24 “(1) QUALIFIED COUNTERMEASURES RE-
25 SEARCH EXPENSES.—

1 “(A) IN GENERAL.—Except as otherwise
2 provided in this paragraph, the term ‘qualified
3 countermeasures research expenses’ means the
4 amounts which are paid or incurred by the tax-
5 payer during the taxable year which would be
6 described in subsection (b) of section 41 if such
7 subsection were applied with the modifications
8 set forth in subparagraph (B).

9 “(B) MODIFICATIONS; INCREASED INCEN-
10 TIVE FOR CONTRACT RESEARCH PAYMENTS.—
11 For purposes of subparagraph (A), subsection
12 (b) of section 41 shall be applied—

13 “(i) by substituting ‘qualified counter-
14 measures research’ for ‘qualified research’
15 each place it appears in paragraphs (2)
16 and (3) of such subsection, and

17 “(ii) by substituting ‘100 percent’ for
18 ‘65 percent’ in paragraph (3)(A) of such
19 subsection.

20 “(C) EXCLUSION FOR AMOUNTS FUNDED
21 BY GRANTS, ETC.—The term ‘qualified counter-
22 measures research expenses’ shall not include
23 any amount to the extent such amount is fund-
24 ed by any grant, contract, or otherwise by an-
25 other person (or any governmental entity).

1 “(2) COUNTERMEASURES RESEARCH.—The
2 term ‘countermeasures research’ means certified
3 countermeasures research for any biological or chem-
4 ical agent or toxin or nuclear or radiological material
5 on the list described in section 1811 of the Biologi-
6 cal, Chemical, and Radiological Weapons Counter-
7 measures Research Act of 2003.

8 “(c) COORDINATION WITH CREDIT FOR INCREASING
9 RESEARCH EXPENDITURES.—

10 “(1) IN GENERAL.—Except as provided in para-
11 graph (2), any qualified countermeasures research
12 expenses for a taxable year to which an election
13 under this section applies shall not be taken into ac-
14 count for purposes of determining the credit allow-
15 able under section 41 for such taxable year.

16 “(2) EXPENSES INCLUDED IN DETERMINING
17 BASE PERIOD RESEARCH EXPENSES.—Any qualified
18 countermeasures research expenses for any taxable
19 year which are qualified research expenses (within
20 the meaning of section 41(b)) shall be taken into ac-
21 count in determining base period research expenses
22 for purposes of applying section 41 to subsequent
23 taxable years.

24 “(d) SPECIAL RULES.—

1 “(1) PRE-CLINICAL RESEARCH.—No credit shall
2 be allowed under this section for pre-clinical re-
3 search unless such research is pursuant to a re-
4 search plan an abstract of which has been filed with
5 the Director of the Office of Homeland Security be-
6 fore the beginning of such year. This paragraph
7 shall be waived for any research that is pursuant to
8 a research plan or abstract that has been filed with
9 the Secretary of Homeland Security not later than
10 270 days after the date of enactment of this section.
11 The Director of the Office of Homeland Security, in
12 consultation with the Secretary of Health and
13 Human Services, shall prescribe regulations speci-
14 fying the requirements for such plans and proce-
15 dures for filing under this paragraph.

16 “(2) CERTAIN RULES MADE APPLICABLE.—
17 Rules similar to the rules of paragraphs (1) and (2)
18 of section 41(f) shall apply for purposes of this sec-
19 tion.

20 “(3) COORDINATION WITH CREDIT FOR CLIN-
21 ICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR
22 RARE DISEASES.—Any qualified countermeasures re-
23 search expense for a taxable year shall not be taken
24 into account for purposes of determining the credit
25 allowable under section 45C for such taxable year.”.

1 (B) INCLUSION IN GENERAL BUSINESS
2 CREDIT.—

3 (i) IN GENERAL.—Section 38(b) of
4 such Code is amended by striking “plus”
5 at the end of paragraph (14), by striking
6 the period at the end of paragraph (15)
7 and inserting “, plus”, and by adding at
8 the end the following new paragraph:

9 “(16) the countermeasures research credit de-
10 termined under section 45G.”.

11 (ii) TRANSITION RULE.—Section
12 39(d) of such Code is amended by adding
13 at the end the following new paragraph:

14 “(11) NO CARRYBACK OF SECTION 45G CREDIT
15 BEFORE ENACTMENT.—No portion of the unused
16 business credit for any taxable year which is attrib-
17 utable to the countermeasures research credit deter-
18 mined under section 45G may be carried back to a
19 taxable year beginning before January 1, 2003.”.

20 (C) DENIAL OF DOUBLE BENEFIT.—Sec-
21 tion 280C of such Code is amended by adding
22 at the end the following new subsection:

23 “(d) CREDIT FOR QUALIFIED COUNTERMEASURES
24 RESEARCH EXPENSES.—

1 “(1) IN GENERAL.—No deduction shall be al-
2 lowed for that portion of the qualified counter-
3 measures research expenses (as defined in section
4 45G(b)) otherwise allowable as a deduction for the
5 taxable year which is equal to the amount of the
6 credit determined for such taxable year under sec-
7 tion 45G(a).

8 “(2) CERTAIN RULES TO APPLY.—Rules similar
9 to the rules of paragraphs (2), (3), and (4) of sub-
10 section (c) shall apply for purposes of this sub-
11 section.”.

12 (D) DEDUCTION FOR UNUSED PORTION OF
13 CREDIT.—Section 196(c) of such Code (defining
14 qualified business credits) is amended by strik-
15 ing “and” at the end of paragraph (9), by
16 striking the period at the end of paragraph (10)
17 and inserting “, and”, and by adding at the end
18 the following new paragraph:

19 “(11) the countermeasures research credit de-
20 termined under section 45G(a) (other than such
21 credit determined under the rules of section
22 280C(d)(2)).”.

23 (E) TECHNICAL AMENDMENT.—The table
24 of sections for subpart D of part IV of sub-

1 chapter A of chapter 1 of such Code is amended
 2 by adding at the end the following new item:

“Sec. 45G. Credit for medical research related to developing countermeasures.”.

3 (2) TAX CREDIT TO FUND COUNTERMEASURE
 4 RESEARCH AT CERTAIN QUALIFIED NON-PROFIT AND
 5 ACADEMIC INSTITUTIONS INCLUDING TEACHING
 6 HOSPITALS.—

7 (A) IN GENERAL.—Subpart D of part IV
 8 of subchapter A of chapter 1 of the Internal
 9 Revenue Code of 1986 (relating to business re-
 10 lated credits) is amended by inserting after sec-
 11 tion 41 the following:

12 **“SEC. 41A. CREDIT FOR COUNTERMEASURES RESEARCH**
 13 **EXPENSES.**

14 “(a) GENERAL RULE.—For purposes of section 38,
 15 in the case of any certified entity under section 1812(d)
 16 of the Biological, Chemical, and Radiological Weapons
 17 Countermeasures Research Act of 2003 which makes an
 18 election under section 1821(b) of such Act to apply this
 19 section, the countermeasures research credit determined
 20 under this section for the taxable year shall be an amount
 21 equal to 35 percent of the excess (if any) of—

22 “(1) the qualified countermeasures research ex-
 23 penses for the taxable year, over

24 “(2) the countermeasures base period amount.

1 “(b) QUALIFIED COUNTERMEASURES RESEARCH EX-
2 PENSES.—For purposes of this section—

3 “(1) IN GENERAL.—The term ‘qualified coun-
4 termeasures research expenses’ means the amounts
5 which are paid or incurred by the taxpayer during
6 the taxable year directly or indirectly to any quali-
7 fied non-profit or academic institution for counter-
8 measures research activities certified under section
9 1812(d) of such Act.

10 “(2) COUNTERMEASURES RESEARCH ACTIVI-
11 TIES.—

12 “(A) IN GENERAL.—The term ‘counter-
13 measures research activities’ means research to
14 develop countermeasures, detection equipment,
15 diagnostics, or research tools conducted at any
16 qualified non-profit or academic institution in
17 the development of any product, which occurs
18 before—

19 “(i) the date on which an application
20 with respect to such product is approved
21 under section 505(b), 506, or 507 of the
22 Federal Food, Drug, and Cosmetic Act,

23 “(ii) the date on which a license for
24 such product is issued under section 351 of
25 the Public Health Service Act, or

1 “(iii) the date classification or ap-
2 proval of such product which is a device in-
3 tended for human use is given under sec-
4 tion 513, 514, or 515 of the Federal Food,
5 Drug, and Cosmetic Act.

6 “(B) DEFINITIONS.—

7 “(i) COUNTERMEASURES; DETECTION
8 EQUIPMENT; DIAGNOSTICS; RESEARCH
9 TOOLS.—The terms ‘countermeasures’, ‘de-
10 tection equipment’, ‘diagnostics’, and ‘re-
11 search tools’ have the meanings given such
12 terms by section 1802 of the Biological,
13 Chemical, and Radiological Weapons Coun-
14 termeasures Research Act of 2003.

15 “(ii) PRODUCT.—The term ‘product’
16 means any drug, biologic, medical device,
17 or research tool.

18 “(3) QUALIFIED NON-PROFIT OR ACADEMIC IN-
19 STITUTION.—The term ‘qualified non-profit or aca-
20 demic institution’ means any of the following institu-
21 tions:

22 “(A) EDUCATIONAL INSTITUTION.—A
23 qualified organization described in section
24 170(b)(1)(A)(iii) which is owned or affiliated

1 with an institution of higher education as de-
2 scribed in section 3304(f).

3 “(B) TEACHING HOSPITAL.—A teaching
4 hospital which—

5 “(i) is publicly supported or owned by
6 an organization described in section
7 501(c)(3), and

8 “(ii) is affiliated with an organization
9 meeting the requirements of subparagraph
10 (A).

11 “(C) FOUNDATION.—A medical research
12 organization described in section 501(c)(3)
13 (other than a private foundation) which is affili-
14 ated with, or owned by—

15 “(i) an organization meeting the re-
16 quirements of subparagraph (A), or

17 “(ii) a teaching hospital meeting the
18 requirements of subparagraph (B).

19 “(D) CHARITABLE RESEARCH HOS-
20 PITAL.—A hospital that is designated as a can-
21 cer center by the National Cancer Institute.

22 “(E) OTHER INSTITUTIONS.—A qualified
23 organization (as defined in section 41(e)(6)).

24 “(4) EXCLUSION FOR AMOUNTS FUNDED BY
25 GRANTS, ETC.—The term ‘qualified countermeasures

1 research expenses' shall not include any amount to
2 the extent such amount is funded by any grant, con-
3 tract, or otherwise by another person (or any gov-
4 ernmental entity).

5 “(c) COUNTERMEASURES RESEARCH BASE PERIOD
6 AMOUNT.—For purposes of this section, the term ‘coun-
7 termeasures research base period amount’ means the aver-
8 age annual qualified countermeasures research expenses
9 paid by the taxpayer during the 3-taxable year period end-
10 ing with the taxable year immediately preceding the first
11 taxable year of the taxpayer beginning after December 31,
12 2002.

13 “(d) SPECIAL RULES.—

14 “(1) CERTAIN RULES MADE APPLICABLE.—
15 Rules similar to the rules of subsections (f) and (g)
16 of section 41 shall apply for purposes of this section.

17 “(2) COORDINATION WITH CREDIT FOR IN-
18 CREASING RESEARCH EXPENDITURES AND WITH
19 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER-
20 TAIN DRUGS FOR RARE DISEASES.—Any qualified
21 countermeasures research expense for a taxable year
22 shall not be taken into account for purposes of de-
23 termining the credit allowable under section 41 or
24 45C for such taxable year.

1 “(3) QUALIFIED COUNTERMEASURES RE-
2 SEARCH EXPENSES NOT TREATED AS UNRELATED
3 BUSINESS TAXABLE INCOME.—For purposes of sec-
4 tion 511, qualified countermeasures research ex-
5 penses paid or incurred by the taxpayer directly or
6 indirectly to any qualified non-profit or academic in-
7 stitution shall not be considered unrelated business
8 taxable income of such institution.”.

9 (B) CREDIT TO BE PART OF GENERAL
10 BUSINESS CREDIT.—

11 (i) IN GENERAL.—Section 38(b) of
12 such Code (relating to current year busi-
13 ness credits), as amended by this section,
14 is amended by striking “plus” at the end
15 of paragraph (15), by striking the period
16 at the end of paragraph (16) and inserting
17 “, plus”, and by adding at the end the fol-
18 lowing:

19 “(17) the countermeasures research credit de-
20 termined under section 41A(a).”.

21 (ii) TRANSITION RULE.—Section
22 39(d) of such Code, as amended by this
23 section, is amended by adding at the end
24 the following new paragraph:

1 “(12) NO CARRYBACK OF SECTION 41A CREDIT
2 BEFORE ENACTMENT.—No portion of the unused
3 business credit for any taxable year which is attrib-
4 utable to the countermeasures research credit deter-
5 mined under section 41A may be carried back to a
6 taxable year beginning before January 1, 2003.”.

7 (C) DENIAL OF DOUBLE BENEFIT.—Sec-
8 tion 280C of such Code, as amended by this
9 section, is amended by adding at the end the
10 following new subsection:

11 “(e) CREDIT FOR COUNTERMEASURES RESEARCH
12 EXPENSES.—

13 “(1) IN GENERAL.—No deduction shall be al-
14 lowed for that portion of the qualified counter-
15 measures research expenses (as defined in section
16 41A(b)) otherwise allowable as a deduction for the
17 taxable year which is equal to the amount of the
18 credit determined for such taxable year under sec-
19 tion 41A(a).

20 “(2) CERTAIN RULES TO APPLY.—Rules similar
21 to the rules of paragraphs (2), (3), and (4) of sub-
22 section (c) shall apply for purposes of this sub-
23 section.”.

24 (D) DEDUCTION FOR UNUSED PORTION OF
25 CREDIT.—Section 196(c) of such Code (defining

1 qualified business credits), as amended by this
2 section, is amended by striking “and” at the
3 end of paragraph (10), by striking the period at
4 the end of paragraph (11) and inserting “,
5 and”, and by adding at the end the following
6 new paragraph:

7 “(5) the countermeasures research expenses
8 credit determined under section 41A(a) (other than
9 such credit determined under the rules of section
10 280C(e)(2)),”.

11 (E) CLERICAL AMENDMENT.—The table of
12 sections for subpart D of part IV of subchapter
13 A of chapter 1 of such Code is amended by
14 adding after the item relating to section 41 the
15 following:

“Sec. 41A. Credit for countermeasures research expenses.”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 this section shall apply to taxable years beginning after
18 December 31, 2002.

19 **SEC. 5. PATENT TERM PROTECTION AND EXCLUSIVE MAR-**
20 **KETING.**

21 (a) PURPOSE.—The purpose of this section is to pro-
22 vide patent incentives to protect inventions from expro-
23 priation by competitors and to provide an incentive for
24 capital formation to fund countermeasures research.

1 (b) LIMITATION.—Private sector entities are entitled
 2 to the intellectual property and marketing exclusivity in-
 3 centives provided for in this Act (and the amendments
 4 made by this Act) only when such entities successfully de-
 5 velop a countermeasure that meets the specifications of
 6 the Director and upon execution of a contract with the
 7 Secretary with respect to procurement of the counter-
 8 measure in accordance with section 1822 of the Biological,
 9 Chemical, and Radiological Weapons Countermeasures
 10 Research Act of 2003.

11 (c) RESTORATION OF PATENT TERMS RELATING TO
 12 COUNTERMEASURES FOR CERTAIN BIOLOGICAL OR
 13 CHEMICAL AGENTS OR TOXINS OR RADIOLOGICAL MATE-
 14 RIALS.—

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

18 **“§ 156a. Restoration of patent terms relating to coun-**
 19 **termeasures for certain biological or**
 20 **chemical agents or toxins**

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

22 “(1) ‘product’ means a new drug, antibiotic
 23 drug, or human biological product (as those terms
 24 are used in the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 301 et seq.) and the Public Health
2 Service Act (42 U.S.C. 201 et seq.);

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

4 “(A) the period beginning on the date a
5 patent is issued through the date of the first fil-
6 ing of an application relating to human clinical
7 trials for the subject of that patent with the
8 Food and Drug Administration under the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 301 et seq.) or the Public Health Service Act
11 (42 U.S.C. 201 et seq.), and includes any pe-
12 riod prior to such issuance during which the
13 Food and Drug Administration is reviewing
14 such application;

15 “(B) the period beginning on the date an
16 exemption under section 505(i) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 355(i)) became effective for the approved prod-
19 uct and ending on the date an application was
20 initially submitted for such product under sec-
21 tion 351 of the Public Health Service Act (42
22 U.S.C. 262) or section 505 of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 355); and

1 “(C) the period beginning on the date the
2 application was initially submitted for the ap-
3 proved product under section 351 of the Public
4 Health Service Act (42 U.S.C. 262) or section
5 505 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355) and ending on the date
7 such application was approved under the appli-
8 cable section; and

9 “(3) ‘Research Act’ means the Biological,
10 Chemical, and Radiological Weapons Counter-
11 measures Research Act of 2003.

12 “(b) PATENT.—A patent referred to under subsection
13 (c) or (d) is any patent that—

14 “(1) encompasses within its scope a composition
15 of matter, a method of using such composition, a
16 method of manufacturing such composition, or a
17 process for using such composition relating to a
18 product;

19 “(2) is for an eligible countermeasure as de-
20 fined under section 1822(b)(1) of the Research Act;
21 and

22 “(3) is held by an entity (or is exclusively li-
23 censed to an entity by a not-for-profit organization
24 or is exclusively licensed to an entity under section
25 209(e) of this title or section 12(b)(7) of the Steven-

1 son-Wyldler Technology Innovation Act of 1980 (15
2 U.S.C. 3710a(b)(1)(7)) that has entered into a con-
3 tract for sale of that countermeasure under section
4 1812(d)(3)(B)(i) of the Research Act.

5 “(c) CERTAIN ACTION NOT NECESSARY.—With re-
6 spect to the owner of record of a patent described under
7 subsection (b), it shall be presumed that no action under
8 this section is necessary to effect the policies and objec-
9 tives of title 18.

10 “(d) 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 “(e) 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 the agent of the owner
22 shall submit an application to the Patent and Trade-
23 mark Office.

24 “(2) CONTENT.—The application shall con-
25 tain—

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 1822(b)(1) of the Research Act; and

9 “(D) such patent or other information as
10 the Office may require.

11 “(3) SUBMISSION OF APPLICATION.—An appli-
12 cation may only be submitted within the 60-day pe-
13 riod beginning on the date the product became eligi-
14 ble for purchase under section 1822 of the Research
15 Act. The submission of an application under this
16 section is an irrevocable election of the application of
17 this section to a patent consistent with paragraph
18 (4).

19 “(4) EXCLUSIVE APPLICATION.—Sections 156
20 and 158 shall not apply to any patent for which an
21 application is filed under this section. This section
22 shall not apply to any patent the term of which has
23 been extended under section 156.

24 “(5) RULE OF CONSTRUCTION.—Nothing in
25 this section shall be construed to prohibit an exten-

1 sion of the term of patent relating to a product that,
2 before the effective date of this section—

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

5 “(B) was approved for commercial mar-
6 keting.”.

7 (2) TECHNICAL AND CONFORMING AMEND-
8 MENT.—The table of sections for chapter 14 of title
9 35, United States Code, is amended by inserting
10 after the item relating to section 156 the following:

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

11 (d) GENERAL EXTENSION OF CERTAIN PATENT
12 TERMS FOR PATENTS HELD BY ENTITIES THAT HAVE
13 SUCCESSFULLY DEVELOPED COUNTERMEASURES.—

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

17 **“§ 158. Patent term for patents held by entities with
18 certain research certifications**

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

20 “(1) ‘product’ means a new drug, antibiotic
21 drug, or human biological product (as those terms
22 are used in the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 301 et seq.) and the Public Health
24 Service Act (42 U.S.C. 201 et seq.)); and

1 “(2) ‘Research Act’ means the Biological,
2 Chemical, and Radiological Weapons Counter-
3 measures Research Act of 2003.

4 “(b) PATENT TERM.—The term of a patent described
5 under subsection (c) shall be for a period of 2 years in
6 addition to the term which would otherwise apply except
7 for this section.

8 “(c) PATENT.—

9 “(1) IN GENERAL.—A patent referred to under
10 subsection (b) or (d) is any patent that—

11 “(A) is held by an entity (or is exclusively
12 licensed to an entity by a not-for-profit organi-
13 zation or is exclusively licensed to an entity
14 under section 209(e) of this title or section
15 12(b)(7) of the Stevenson-Wydler Technology
16 Innovation Act of 1980 (15 U.S.C.
17 3710a(b)(1)(7)) that—

18 “(i) holds a certification under section
19 1812(d) of the Research Act with respect
20 to a product, a method of manufacturing
21 such product, or a method of using such
22 product;

23 “(ii) has entered into a contract for
24 the sale of that product or method under

1 section 1812(d)(3)(B) of the Research Act;
2 and

3 “(iii) is a qualified small business as
4 determined under section 1202(d) of the
5 Internal Revenue Code of 1986, by sub-
6 stituting ‘\$750,000,000’ for ‘\$50,000,000’
7 each place it appears;

8 “(B) subject to subsections (d) and (e), is
9 designated by that entity as the patent to which
10 this section applies.

11 “(2) WAIVER.—The Secretary of Health and
12 Human Services may waive the requirement of para-
13 graph (1)(A)(iii).

14 “(d) CERTAIN ACTION NOT NECESSARY.—With re-
15 spect to the owner of record of a patent described under
16 subsection (c)(1), it shall be presumed that no action
17 under this section is necessary to effect the policies and
18 objectives of title 18.

19 “(e) LIMITATIONS AND CONDITIONS.—In the admin-
20 istration of this section—

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

23 “(2) no redesignation of another patent may be
24 made; and

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

1 “(A) shall be issued before the date of a
2 filing of an application under subsection (e);

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

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

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

12 “(f) APPLICATION.—

13 “(1) IN GENERAL.—An entity that holds a cer-
14 tification under section 1812(d) of the Research Act,
15 may file an application with the Patent and Trade-
16 mark Office under this section.

17 “(2) CONTENT.—The application shall con-
18 tain—

19 “(A) a copy of the certification under sec-
20 tion 1812(d) of the Research Act;

21 “(B) a copy of any waiver granted under
22 subsection (c)(2); and

23 “(C) a designation of the patent to which
24 this section applies.

1 “(3) SUBMISSION OF APPLICATION.—An appli-
 2 cation may only be submitted within the 60-day pe-
 3 riod beginning on the date that the applicable prod-
 4 uct is eligible for purchase under section 1822 of the
 5 Research Act.

6 “(4) IRREVOCABLE AND EXCLUSIVE.—

7 “(A) IRREVOCABLE ELECTION.—A filing of
 8 an application under this section is an irrev-
 9 ocable election of the application of this section
 10 to a patent consistent with subparagraph (B).

11 “(B) EXCLUSIVE.—Sections 156 and 156a
 12 shall not apply to any patent for which there is
 13 a filing under this section. This section shall
 14 not apply to any patent the term of which has
 15 been extended under section 156.”.

16 (2) TECHNICAL AND CONFORMING AMEND-
 17 MENT.—The table of sections for chapter 14 of title
 18 35, United States Code, is amended by adding at
 19 the end the following:

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

20 (e) EXCLUSIVE LICENSING.—

21 (1) IN GENERAL.—Notwithstanding sections
 22 200, 203, and 209 of title 35, United States Code,
 23 an entity that holds a certification under section
 24 1812(d) of the Biological, Chemical, and Radio-

1 logical Weapons Countermeasures Research Act of
2 2003 with respect to a product that is an eligible
3 countermeasure as defined under section 1822(b)(1)
4 of such Act may exclusively license such patented
5 product.

6 (2) **FEDERALLY OWNED INVENTIONS.**—Section
7 209 of title 35, United States Code, is amended—

8 (A) by redesignating subsections (e) and
9 (f) as subsections (f) and (g), respectively; and

10 (B) by inserting after subsection (d) the
11 following:

12 “(e) **TERMS AND CONDITIONS OF EXCLUSIVE LI-**
13 **CENSE.**—Each exclusive license granted under section
14 207(a)(2) shall include a provision that, at the discretion
15 of the licensee, the licensee may act as the agent for the
16 licensor with respect to any patent for the licensed inven-
17 tion for purposes of extending a patent under section 156a
18 or 158.”.

19 (3) **COOPERATIVE RESEARCH AND DEVELOP-**
20 **MENT AGREEMENTS.**—Section 12(b) of the Steven-
21 son-Wydler Technology Innovation Act of 1980 (15
22 U.S.C. 3710a(b)) is amended by adding at the end
23 the following:

24 “(7) Each exclusive license for a patent granted
25 under an agreement entered into under subsection

1 (a)(1) shall include a provision that, at the discre-
2 tion of the licensee, the licensee may act as the
3 agent for the licensor with respect to that patent for
4 purposes of extending a patent under section 156a
5 or 158 of title 35, United States Code.”.

6 (4) APPLICABLE LICENSES.—The amendments
7 made by paragraphs (2) and (3) shall apply only to
8 exclusive licenses granted on or after 60 days after
9 the date of enactment of this Act.

10 (f) EXCLUSIVE MARKETING.—Subchapter A of chap-
11 ter V of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 351 et seq.) is amended by inserting after section
13 505A, the following:

14 **“SEC. 505B. MARKET EXCLUSIVITY FOR TERROR WEAPONS**
15 **COUNTERMEASURES.**

16 “(a) IN GENERAL.—If, prior to approval of an appli-
17 cation that is submitted under section 505(b)(1), the Sec-
18 retary determines that the new drug involved is a counter-
19 measure (as defined in section 1802(1) of the Biological,
20 Chemical, and Radiological Weapons Countermeasures
21 Research Act of 2003) that meets the requirements of
22 subparagraphs (A) through (C) of section 1822(b)(1) of
23 such Act, the provisions of subsection (b) shall apply.

24 “(b) EXCLUSIVITY.—With respect to a new drug de-
25 scribed in subsection (a)—

1 “(1)(A)(i) the period referred to in subsection
2 (c)(3)(D)(ii) of section 505, and in subsection
3 (j)(5)(D)(ii) of such section, is deemed to be 10
4 years rather than five years, and the references in
5 subsections (c)(3)(D)(ii) and (j)(5)(D)(ii) of such
6 section to four years, to forty-eight months, and to
7 seven and one-half years are deemed to be nine
8 years, 108 months, and nine years, respectively; or

9 “(ii) the period referred to in clauses (iii) and
10 (iv) of subsection (c)(3)(D) of such section, and in
11 clauses (iii) and (iv) of subsection (j)(5)(D) of such
12 section, is deemed to be 10 years rather than three
13 years; and

14 “(B) if the drug is designated under section
15 526 for a rare disease or condition, the period re-
16 ferred to in section 527(a) is deemed to be 10 years
17 rather than seven years; and

18 “(2)(A) if the drug is the subject of—

19 “(i) a listed patent for which a certification
20 has been submitted under subsection
21 (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505;
22 or

23 “(ii) a listed patent for which a certifi-
24 cation has been submitted under subsections

1 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section
2 505,

3 the period during which an application may not be
4 approved under section 505(c)(3) or section
5 505(j)(4)(B) shall be extended by a period of 5
6 years after the date the patent expires (including
7 any patent extensions); or

8 “(B) if the drug is the subject of a listed patent
9 for which a certification has been submitted under
10 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-
11 tion 505, and in the patent infringement litigation
12 resulting from the certification the court determines
13 that the patent is valid and would be infringed, the
14 period during which an application may not be ap-
15 proved under section 505(c)(3) or section
16 505(j)(4)(B) shall be extended by a period of 5
17 years after the date the patent expires (including
18 any patent extensions).”.

19 **SEC. 6. APPROVALS OF CERTAIN DRUGS BASED ON ANIMAL**
20 **TRIALS.**

21 (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
22 Section 505(d) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 355(d)) is amended by adding at the end
24 the following: “In the case of drugs and diagnostic devices
25 for use against lethal or permanently disabling toxic chem-

1 ical, biological, radiological, nuclear, or other substances,
2 when adequate and well-controlled studies of effectiveness
3 in humans cannot ethically be conducted because the stud-
4 ies would involve administering a potentially lethal or per-
5 manently disabling toxic substance or organism to healthy
6 human volunteers, and when adequate field trials assess-
7 ing use of the drug or diagnostic device (in situations such
8 as after accidental or hostile exposure to the substance)
9 have not been feasible or where adequate volumes of
10 human samples for diagnosis from previous exposures is
11 not available, the Secretary may grant approval based on
12 evidence of effectiveness derived from appropriate studies
13 in animals. The Secretary may promulgate regulations es-
14 tablishing standards, criteria, and procedures for use of
15 the authority contained in the preceding sentence.”.

16 (b) PUBLIC HEALTH SERVICE ACT.—Section 351 of
17 the Public Health Service Act (42 U.S.C. 262) is amended
18 by adding at the end the following:

19 “(k) APPROVAL OF CERTAIN PRODUCTS AND DIAG-
20 NOSTIC DEVICES BASED ON ANIMAL TRIALS.—In the
21 case of biological products and diagnostic devices for use
22 against lethal or permanently disabling toxic chemical, bio-
23 logical, radiological, nuclear, or other substances, when de-
24 finitive human effectiveness studies in humans cannot
25 ethically be conducted because the studies would involve

1 administering a potentially lethal or permanently disabling
2 toxic substance or organism to healthy human volunteers,
3 and when adequate field trials assessing use of the drug
4 (in situations such as after accidental or hostile exposure
5 to the substance) have not been feasible, the Secretary
6 may grant approval based on evidence of effectiveness de-
7 rived from appropriate studies in animals. The Secretary
8 may promulgate regulations establishing standards, cri-
9 teria, and procedures for use of the authority provided
10 under this subsection.”.

11 **SEC. 7. LIMITED ANTITRUST EXEMPTION.**

12 Section 2 of the Clayton Act (15 U.S.C. 13) is
13 amended by adding at the end the following:

14 “(g) LIMITED ANTITRUST EXEMPTION.—

15 “(1) COUNTERMEASURES DEVELOPMENT MEET-
16 INGS.—

17 “(A) COUNTERMEASURES DEVELOPMENT
18 MEETINGS AND CONSULTATIONS.—The Sec-
19 retary may conduct meetings and consultations
20 with parties involved in the development of
21 countermeasures for the purpose of the develop-
22 ment, manufacture, distribution, purchase, or
23 sale of countermeasures consistent with the
24 purposes of this title. The Secretary shall give
25 notice of such meetings and consultations to the

1 Attorney General and the Chairperson of the
2 Federal Trade Commission (referred to in this
3 subsection as the ‘Chairperson’).

4 “(B) MEETING AND CONSULTATION CON-
5 DITIONS.—A meeting or consultation conducted
6 under subparagraph (A) shall—

7 “(i) be chaired or, in the case of a
8 consultation, facilitated by the Secretary;

9 “(ii) be open to parties involved in the
10 development, manufacture, distribution,
11 purchase, or sale of countermeasures, as
12 determined by the Secretary;

13 “(iii) be open to the Attorney General
14 and the Chairperson;

15 “(iv) be limited to discussions involv-
16 ing the development, manufacture, dis-
17 tribution, or sale of countermeasures, con-
18 sistent with the purposes of this title; and

19 “(v) be conducted in such manner as
20 to ensure that national security, confiden-
21 tial, and proprietary information is not dis-
22 closed outside the meeting or consultation.

23 “(C) MINUTES.—The Secretary shall
24 maintain minutes of meetings and consultations
25 under this subsection, which shall not be dis-

1 closed under section 552 of title 5, United
2 States Code.

3 “(D) EXEMPTION.—The antitrust laws
4 shall not apply to meetings and consultations
5 under this paragraph, except that any agree-
6 ment or conduct that results from a meeting or
7 consultation and that does not receive an ex-
8 emption pursuant to this subsection shall be
9 subject to the antitrust laws.

10 “(2) WRITTEN AGREEMENTS.—The Secretary
11 shall file a written agreement regarding covered ac-
12 tivities, made pursuant to meetings or consultations
13 conducted under paragraph (1) and that is con-
14 sistent with this paragraph, with the Attorney Gen-
15 eral and the Chairperson for a determination of the
16 compliance of such agreement with antitrust laws.
17 In addition to the proposed agreement itself, any
18 such filing shall include—

19 “(A) an explanation of the intended pur-
20 pose of the agreement;

21 “(B) a specific statement of the substance
22 of the agreement;

23 “(C) a description of the methods that will
24 be utilized to achieve the objectives of the
25 agreement;

1 “(D) an explanation of the necessity of a
2 cooperative effort among the particular partici-
3 pating parties to achieve the objectives of the
4 agreement; and

5 “(E) any other relevant information deter-
6 mined necessary by the Secretary in consulta-
7 tion with the Attorney General and the Chair-
8 person.

9 “(3) DETERMINATION.—The Attorney General,
10 in consultation with the Chairperson, shall determine
11 whether an agreement regarding covered activities
12 referred to in paragraph (2) would likely—

13 “(A) be in compliance with the antitrust
14 laws, and so inform the Secretary and the par-
15 ticipating parties; or

16 “(B) violate the antitrust laws, in which
17 case, the filing shall be deemed to be a request
18 for an exemption from the antitrust laws, lim-
19 ited to the performance of the agreement con-
20 sistent with the purposes of this title.

21 “(4) ACTION ON REQUEST FOR EXEMPTION.—

22 “(A) IN GENERAL.—The Attorney General,
23 in consultation with the Chairperson, shall
24 grant, deny, grant in part and deny in part, or
25 propose modifications to a request for exemp-

1 tion from the antitrust laws under paragraph
2 (3) within 15 days of the receipt of such re-
3 quest.

4 “(B) EXTENSION.—The Attorney General
5 may extend the 15-day period referred to in
6 subparagraph (A) for an additional period of
7 not to exceed 10 days. Such additional period
8 may be further extended only by the United
9 States district court, upon an application by the
10 Attorney General after notice to the Secretary
11 and the parties involved.

12 “(C) DETERMINATION.—In granting an
13 exemption under this paragraph, the Attorney
14 General, in consultation with the Chairperson
15 and the Secretary—

16 “(i) must find—

17 “(I) that the agreement involved
18 is necessary to ensure the availability
19 of countermeasures;

20 “(II) that the exemption from
21 the antitrust laws would promote the
22 public interest; and

23 “(III) that there is no substantial
24 competitive impact to areas not di-

1 rectly related to the purposes of the
2 agreement; and

3 “(ii) may consider any other factors
4 determined relevant by the Attorney Gen-
5 eral and the Chairperson.

6 “(5) LIMITATION ON AND RENEWAL OF EXEMP-
7 TIONS.—An exemption granted under paragraph (4)
8 shall be limited to covered activities, and shall expire
9 on the date that is 3 years after the date on which
10 the exemption becomes effective (and at 3 year in-
11 tervals thereafter, if renewed) unless the Attorney
12 General in consultation with the Chairperson deter-
13 mines that the exemption should be renewed (with
14 modifications, as appropriate) considering the fac-
15 tors described in paragraph (4).

16 “(6) LIMITATION ON PARTIES.—The use of any
17 information acquired under an exempted agreement
18 by the parties to such an agreement for any pur-
19 poses other than those specified in the antitrust ex-
20 emption granted by the Attorney General shall be
21 subject to the antitrust laws and any other applica-
22 ble laws.

23 “(7) GUIDELINES.—The Attorney General and
24 the Chairperson may develop and issue guidelines to
25 implement this subsection.

1 “(8) REPORT.—Not later than 1 year after the
2 date of enactment of the Biological, Chemical, and
3 Radiological Weapons Countermeasures Research
4 Act of 2003, and annually thereafter, the Attorney
5 General and the Chairperson shall report to Con-
6 gress on the use and continuing need for the exemp-
7 tion from the antitrust laws provided by this sub-
8 section.

9 “(9) SUNSET.—The authority of the Attorney
10 General to grant or renew a limited antitrust exemp-
11 tion under this subsection shall expire at the end of
12 the 10-year period that begins on the date of enact-
13 ment of the Biological, Chemical, and Radiological
14 Weapons Countermeasures Research Act of 2003.

15 “(h) DEFINITIONS.—In this section:

16 “(1) ANTITRUST LAWS.—The term ‘antitrust
17 laws’—

18 “(A) has the meaning given such term in
19 subsection (a) of the first section of the Clayton
20 Act (15 U.S.C. 12(a)), except that such term
21 includes the Act of June 19, 1936 (15 U.S.C.
22 13 et seq.) commonly known as the Robinson-
23 Patman Act), and section 5 of the Federal
24 Trade Commission Act (15 U.S.C. 45) to the

1 extent such section 5 applies to unfair methods
2 of competition; and

3 “(B) includes any State law similar to the
4 laws referred to in subparagraph (A).

5 “(2) COUNTERMEASURE.—The term ‘counter-
6 measure’ has the meaning given such term in section
7 1802(2) of the Biological, Chemical, and Radio-
8 logical Weapons Countermeasures Research Act of
9 2003.

10 “(3) COVERED ACTIVITIES.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B), the term ‘covered activities’
13 means any group of activities or conduct, in-
14 cluding attempting to make, making, or per-
15 forming a contract or agreement or engaging in
16 other conduct, for the purpose of—

17 “(i) theoretical analysis, experimen-
18 tation, or the systematic study of phe-
19 nomena or observable facts necessary to
20 the development of countermeasures;

21 “(ii) the development or testing of
22 basic engineering techniques necessary to
23 the development of countermeasures;

24 “(iii) the extension of investigative
25 findings or theory of a scientific or tech-

1 nical nature into practical application for
2 experimental and demonstration purposes,
3 including the experimental production and
4 testing of models, prototypes, equipment,
5 materials, and processes necessary to the
6 development of countermeasures;

7 “(iv) the production, distribution, or
8 marketing of a product, process, or service
9 that is a countermeasures;

10 “(v) the testing in connection with the
11 production of a product, process, or serv-
12 ices necessary to the development of coun-
13 termeasures;

14 “(vi) the collection, exchange, and
15 analysis of research or production informa-
16 tion necessary to the development of coun-
17 termeasures; or

18 “(vii) any combination of the purposes
19 described in clauses (i) through (vi);

20 and such term may include the establishment
21 and operation of facilities for the conduct of
22 covered activities described in clauses (i)
23 through (vi), the conduct of such covered activi-
24 ties on a protracted and proprietary basis, and
25 the processing of applications for patents and

1 the granting of licenses for the results of such
2 covered activities.

3 “(B) EXCEPTION.—The term ‘covered ac-
4 tivities’ shall not include the following activities
5 involving 2 or more persons:

6 “(i) Exchanging information among
7 competitors relating to costs, sales, profit-
8 ability, prices, marketing, or distribution of
9 any product, process, or service if such in-
10 formation is not reasonably necessary to
11 carry out the purposes of covered activi-
12 ties.

13 “(ii) Entering into any agreement or
14 engaging in any other conduct—

15 “(I) to restrict or require the
16 sale, licensing, or sharing of inven-
17 tions, developments, products, proc-
18 esses, or services not developed
19 through, produced by, or distributed
20 or sold through such covered activi-
21 ties; or

22 “(II) to restrict or require par-
23 ticipation by any person who is a
24 party to such covered activities in
25 other research and development activi-

1 ties, that is not reasonably necessary
2 to prevent the misappropriation of
3 proprietary information contributed
4 by any person who is a party to such
5 covered activities or of the results of
6 such covered activities.

7 “(iii) Entering into any agreement or
8 engaging in any other conduct allocating a
9 market with a competitor that is not ex-
10 pressly exempted from the antitrust laws
11 by a determination under subsection (i)(4).

12 “(iv) Exchanging information among
13 competitors relating to production (other
14 than production by such covered activities)
15 of a product, process, or service if such in-
16 formation is not reasonably necessary to
17 carry out the purpose of such covered ac-
18 tivities.

19 “(v) Entering into any agreement or
20 engaging in any other conduct restricting,
21 requiring, or otherwise involving the pro-
22 duction of a product, process, or service
23 that is not so expressly exempted from the
24 antitrust laws by a determination under
25 subsection (i)(4).

1 “(vi) Except as otherwise provided in
2 this subsection, entering into any agree-
3 ment or engaging in any other conduct to
4 restrict or require participation by any per-
5 son who is a party to such activities, in
6 any unilateral or joint activity that is not
7 reasonably necessary to carry out the pur-
8 pose of such covered activities.

9 “(4) DEVELOPMENT.—The term ‘development’
10 includes the identification of suitable compounds or
11 biological materials, the conduct of preclinical and
12 clinical studies, the preparation of an application for
13 marketing approval, and any other actions related to
14 preparation of a countermeasure.

15 “(5) PERSON.—The term ‘person’ has the
16 meaning given such term in subsection (a) of the
17 first section of this Act.

18 “(6) SECRETARY.—The term ‘Secretary’ means
19 the Secretary of Health and Human Services.”.

20 **SEC. 8. INCENTIVES FOR THE CONSTRUCTION OF BIO-**
21 **LOGICS MANUFACTURING FACILITIES AVAIL-**
22 **ABLE FOR THE PRODUCTION OF COUNTER-**
23 **MEASURES.**

24 (a) BIOLOGICS MANUFACTURING FACILITIES IN-
25 VESTMENT TAX CREDIT.—

1 (1) ALLOWANCE OF CREDIT.—Section 46(a) of
2 the Internal Revenue Code of 1986 (relating to
3 amount of investment credit) is amended by striking
4 “and” at the end of paragraph (2), by striking the
5 period at the end of paragraph (3) and inserting “,
6 and”, and by adding at the end the following new
7 paragraph:

8 “(4) the biologics manufacturing facilities in-
9 vestment credit.”.

10 (2) AMOUNT OF CREDIT.—Section 48 of such
11 Code is amended by adding at the end the following
12 new subsection:

13 “(c) BIOLOGICS MANUFACTURING FACILITIES IN-
14 VESTMENT CREDIT.—

15 “(1) IN GENERAL.—For purposes of section 46,
16 in the case of any entity selected under section
17 1832(d) of the Biological, Chemical, and Radio-
18 logical Weapons Countermeasures Research Act of
19 2003, the biologics manufacturing facilities invest-
20 ment credit for any taxable year is an amount equal
21 to 20 percent of the qualified investment for such
22 taxable year.

23 “(2) QUALIFIED INVESTMENT.—For purposes
24 of paragraph (1), the qualified investment for any
25 taxable year is the basis of each biologics manufac-

1 turing facilities property placed in service by the tax-
2 payer during such taxable year.

3 “(3) BIOLOGICS MANUFACTURING FACILITIES
4 PROPERTY.—For purposes of this subsection, the
5 term ‘biologics manufacturing facilities property’
6 means real and tangible personal property—

7 “(A)(i) the original use of which com-
8 mences with the taxpayer, or

9 “(ii) which is acquired through purchase
10 (as defined by section 179(d)(2)),

11 “(B) which is depreciable under section
12 167, and

13 “(C) which is used for the manufacture,
14 distribution, or research and development of
15 vaccines and other biologics.

16 “(4) CERTAIN PROGRESS EXPENDITURE RULES
17 MADE APPLICABLE.—Rules similar to rules of sub-
18 section (c)(4) and (d) of section 46 (as in effect on
19 the day before the date of the enactment of the Rev-
20 enue Reconciliation Act of 1990) shall apply for pur-
21 poses of this subsection.”.

22 (3) TECHNICAL AMENDMENTS.—

23 (A) Subparagraph (C) of section 49(a)(1)
24 of such Code is amended by striking “and” at
25 the end of clause (ii), by striking the period at

1 the end of clause (iii) and inserting “, and”,
 2 and by adding at the end the following new
 3 clause:

4 “(iv) the basis of any biologics manu-
 5 facturing facilities property.”.

6 (B) Subparagraph (E) of section 50(a)(2)
 7 of such Code is amended by striking “section
 8 48(a)(5)(A)” and inserting “section 48(a)(5) or
 9 48(c)(4)”.

10 (C)(i) The section heading for section 48
 11 of such Code is amended to read as follows:

12 **“SEC. 48. OTHER CREDITS.”.**

13 (ii) The table of sections for subpart E of
 14 part IV of subchapter A of chapter 1 of such
 15 Code is amended by striking the item relating
 16 to section 48 and inserting the following:

“Sec. 48. Other Credits.”.

17 (b) **PREEMPTION OF ZONING LAWS FOR SITING OF**
 18 **BIOLOGICS MANUFACTURING FACILITIES.**—The provi-
 19 sions of this section relating to the operation and location
 20 of biologics manufacturing facilities, in accordance with
 21 the plan developed under section 1832(b)(2) of the Bio-
 22 logical, Chemical, and Radiological Weapons Counter-
 23 measures Research Act of 2003, shall preempt State and
 24 local laws relating to zoning. State and local laws relating
 25 to the construction and maintenance of such facilities shall

1 be preempted to the extent that such laws conflict with
2 such plan and the purposes of this section. Any action that
3 is commenced in any State relating to this subsection shall
4 be removed to the appropriate Federal district court.

5 **SEC. 9. HUMAN CLINICAL TRIALS AND DRUGS FOR RARE**
6 **DISEASES AND CONDITIONS.**

7 (a) EXPANDED HUMAN CLINICAL TRIALS QUALI-
8 FYING FOR ORPHAN DRUG CREDIT.—

9 (1) IN GENERAL.—Subclause (I) of section
10 45C(b)(2)(A)(ii) of the Internal Revenue Code of
11 1986 is amended to read as follows:

12 “(I) after the date that the appli-
13 cation is filed for designation under
14 such section 526, and”.

15 (2) CONFORMING AMENDMENT.—Clause (i) of
16 section 45C(b)(2)(A) of the Internal Revenue Code
17 of 1986 is amended by inserting “which is” before
18 “being” and by inserting before the comma at the
19 end “and which is designated under section 526 of
20 such Act”.

21 (3) EFFECTIVE DATE.—The amendments made
22 by this subsection shall apply to amounts paid or in-
23 curred after December 31, 2003.

24 (b) PUBLICATION OF FILING AND APPROVAL OF RE-
25 QUESTS FOR DESIGNATION OF DRUGS FOR RARE DIS-

1 EASES OR CONDITIONS.—Subsection (c) of section 526 of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 360bb) is amended to read as follows:

4 “(c) Not less than monthly, the Secretary shall pub-
5 lish in the Federal Register, and otherwise make available
6 to the public, notice of requests for designation of a drug
7 under subsection (a) and approvals of such requests. Such
8 notice shall include—

9 “(1) the name and address of the manufacturer
10 and the sponsor;

11 “(2) the date of the request for designation or
12 of the approval of such request;

13 “(3) the nonproprietary name of the drug and
14 the name of the drug under which an application is
15 filed under section 505(b) or section 351 of the Pub-
16 lic Health Service Act;

17 “(4) the rare disease or condition for which the
18 designation is requested or approved; and

19 “(5) the proposed indication for use of the
20 product.”.

21 **SEC. 10. LIABILITY.**

22 Section 224(p) of the Public Health Service Act (42
23 U.S.C. 233(p)) is amended by adding at the end the fol-
24 lowing:

1 “(8) APPLICATION OF PROVISION TO OTHER
2 COUNTERMEASURES.—

3 “(A) COVERED COUNTERMEASURES AND
4 ELIGIBLE PERSONS.—For purposes of this sub-
5 section—

6 “(i) the term ‘covered counter-
7 measure’ includes a countermeasure as de-
8 fined in section 1802(2) of the Biological,
9 Chemical, and Radiological Weapons Coun-
10 termeasures Research Act of 2003; and

11 “(ii) the term ‘eligible person’ includes
12 any individual or entity who—

13 “(I) is a manufacturer or dis-
14 tributor of a covered countermeasure
15 that is subject to indemnification from
16 the United States under a contract
17 between such manufacturer or dis-
18 tributor and the United States for
19 such covered countermeasure; or

20 “(II) is a health care entity
21 under whose auspices such a covered
22 countermeasure was administered.

23 “(B) APPLICATION OF PROVISION.—The
24 provisions of this subsection shall apply to eligi-
25 ble persons (as defined in subparagraph (A))

1 with respect to liability arising out of the use
2 or administration of a covered countermeasure
3 (as defined in subparagraph (A)), except that
4 the Secretary need not make a declaration with
5 respect to such a person or countermeasure
6 under paragraph (2)(A).

7 “(C) LIMITATION.—This paragraph shall
8 only apply to an eligible person (as defined in
9 subparagraph (A)) who has entered into a con-
10 tract with the Secretary of Homeland Security,
11 for procurement of the covered countermeasure
12 in accordance with section 1812 of the Biologi-
13 cal, Chemical, and Radiological Weapons Coun-
14 termeasures Research Act of 2003. Such con-
15 tracts and any protection under this subsection
16 against claims or civil actions shall apply only
17 to the administration or use of a counter-
18 measure, detection equipment, diagnostic, or re-
19 search tool by the Federal Government or an-
20 other entity with respect to a biological agent or
21 toxin or a nuclear or radiological material used
22 as a terror weapon and to products sold to the
23 Federal Government under a contract pursuant
24 to section 1812(e) of such Act.”.

○