

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 3148

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

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IN THE SENATE OF THE UNITED STATES

OCTOBER 17, 2002

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

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## A BILL

To provide incentives to increase research by private sector entities to develop antivirals, antibiotics and other drugs, vaccines, microbicides, 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 of 2002”.

1 (b) IN HONOR.—This Act is enacted in honor of Rob-  
 2 ert Stevens, Thomas Morris Jr., Joseph Curseen, Kathy  
 3 Nguyen, Otilie 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. Definitions.

#### TITLE I—STRATEGY FOR THE DEVELOPMENT OF COUNTERMEASURES

- Sec. 101. Biological, chemical and radiological agent, toxin, and material countermeasure research priority list.
- Sec. 102. Research registration requirements.
- Sec. 103. Diagnostics incentives.
- Sec. 104. Research tools incentives.

#### TITLE II—INCENTIVES FOR THE DEVELOPMENT OF COUNTERMEASURES

##### Subtitle A—Primary Incentives

- Sec. 201. Federal tax incentives.
- Sec. 202. Terror Weapon Countermeasure Purchase Fund.
- Sec. 203. Patent term protection and exclusive marketing.
- Sec. 204. Liability and indemnification.

##### Subtitle B—Other Incentives

- Sec. 211. Accelerated approval of countermeasures.
- Sec. 212. Approvals of certain drugs based on animal trials.
- Sec. 213. Limited antitrust exemption.
- Sec. 214. Biologics manufacturing capacity incentives.
- Sec. 215. Biologics manufacturing efficiency incentives.
- Sec. 216. Construction of biosafety level 3-4 research facilities.
- Sec. 217. National Institutes of Health countermeasures partnership challenge grants.
- Sec. 218. Human clinical trials and drugs for rare diseases and conditions.
- Sec. 219. Use of adjuvants in vaccine production.
- Sec. 220. Annual report.
- Sec. 221. International conference on research to develop countermeasures.

## 7 **SEC. 2. FINDINGS.**

8 Congress makes the following findings:

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

7           (2) The threat of biological and chemical weap-  
8 ons is real.

9           (A) Members of the cult Aum Shinrikyo  
10 were responsible for chemical weapons attacks  
11 in Japan that killed 12 people and injured over  
12 5,000 on March 20, 1995. In this attack, ter-  
13 rorists placed plastic bags of diluted sarin, a le-  
14 thal nerve agent, on crowded subway trains  
15 during the morning rush-hour. It was found  
16 that sect members had legally stockpiled sodium  
17 cyanide and hundreds of tons of chemicals used  
18 to make sarin, including sodium fluoride, phos-  
19 phorous trichloride, isopropyl alcohol, and ace-  
20 tonitrile. Aum Shinrikyo concealed its sarin  
21 manufacturing plant in a shrine to a sect god-  
22 dess. Investigators also found a biological weap-  
23 ons research lab on the cult's compound. The  
24 facility contained an incubator, an electron mi-  
25 croscope, a growth medium for fermenting or

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

23 (B) Before the 2001 anthrax attacks, the  
24 most recent successful biological attack in the  
25 United States, which was not recognized as

1 such at the time, was with salmonella. Fol-  
2 lowers of Bhagwan Shree Rajneesh put the bac-  
3 teria in salad bars in restaurants in Dalles, Or-  
4 egon, in 1984, sickening 750 people.

5 (C) There is a long and sordid history of  
6 chemical and biological weapons, including use  
7 during the First and Second World Wars, an  
8 accidental release of anthrax spores in 1979  
9 from a Soviet military microbiological facility,  
10 use of mustard gas, tabun, and hydrogen cya-  
11 nide by Iraq in the Iran-Iraq War and against  
12 the Kurds, and development by Iraq of an of-  
13 fensive biological weapons capability including  
14 anthrax and botulinum toxin.

15 (D) The United States bioterror weapons  
16 program focused on anthrax, botulinum toxin,  
17 brucellosis, tularemia, psittacosis, plague, Ven-  
18 zuelan equine encephalitis, Q fever, cholera,  
19 dengue, shigellosis dysentery, glanders, and  
20 Rocky Mountain spotted fever. The United  
21 States Army concocted a botulinum toxin that  
22 was so toxic that a pound, if expertly dispersed,  
23 could kill 1,000,000,000 people. Botulinum  
24 toxin is 15,000 times more toxic than VX and  
25 10,000 times more toxic than Sarin. The Soviet

1 bioterror program involved 47 laboratories and  
2 65,000 people. It focused on 52 different patho-  
3 gens, including smallpox, anthrax, plague,  
4 Ebola and Marburg hemorrhagic fevers, yellow  
5 fever, tularemia, brucellosis, Q fever, botulinum  
6 toxin, and Venezuelan equine encephalitis. It  
7 created 2,000 strains of anthrax with 7,000 em-  
8 ployees working on nothing but anthrax. It pro-  
9 duced 20 tons of smallpox virus each year, cre-  
10 ated antibiotic resistant strains, strains with  
11 odd systems to confuse diagnosis, plague bac-  
12 teria that secreted diphtheria toxin and resisted  
13 antibiotics, and some Venezuelan equine en-  
14 cephalitis. The Iraqi bioterror program focused  
15 on anthrax, botulinum toxin, cholera, plague,  
16 gas gangrene, Salmonella, ricin, staphylococcal  
17 enterotoxin, camelpox, cancer-causing molds  
18 called aflatoxins, rotavirus, and hemorrhagic  
19 conjunctivitis.

20 (E) A Central Intelligence Agency report  
21 concluded that “clandestine production of chem-  
22 ical and biological weapons for multiple casualty  
23 attacks raises no greater technical obstacles  
24 than does the clandestine production of chem-  
25 ical narcotics or heroin”. One of the aspects

1           which makes chemical and biological agents  
2           such an attractive weapon for a terrorist is the  
3           high shock value of these weapons.

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

11          (3) The threat of terrorism using radiological  
12          weapons is real.

13          (A) In April 2000, customs officers from  
14          Uzbekistan discovered 10 lead-lined containers  
15          at a remote border crossing with Kazakhstan.  
16          These containers were filled with enough radio-  
17          active material to make dozens of crude weap-  
18          ons, each capable of contaminating a large area  
19          for many years. The consignment was ad-  
20          dressed to a company in Quetta, Pakistan,  
21          called Ahmadjan Haji Mohammed. Quetta,  
22          where border controls are virtually non-existent,  
23          is the main Pakistani crossing into southern Af-  
24          ghanistan and only a 6 hour drive from  
25          Kandahar.

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

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

14           (D) The International Atomic Energy  
15 Agency, a Vienna-based division of the United  
16 Nations, has documented almost 400 cases of  
17 trafficking in nuclear or radiological materials  
18 since 1993. Many such supplies are subject to  
19 few controls or are poorly guarded, particularly  
20 in the former Soviet Union. Reports also have  
21 cited weak protection of spent fuel at nuclear  
22 facilities in the United States. Other experts  
23 worry about the security of the nuclear facilities  
24 in Pakistan, India, and other developing coun-  
25 tries. An estimated 1300 kilograms of highly

1 enriched uranium and 180,000 kilograms of  
2 plutonium, the main fuels for a nuclear device,  
3 exists in civilian nuclear facilities around the  
4 world. There are nearly 450 nuclear power  
5 plants, nearly 300 nuclear research reactors,  
6 and 250 nuclear fuel cycle plants around the  
7 world.

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

15 (F) A crude but deadly radiation dispersal  
16 device (RDD) fashioned from stolen nuclear  
17 material (from a nuclear waster processor, a  
18 nuclear power plant, a university research facil-  
19 ity, a medical radiotherapy clinic, or an indus-  
20 trial complex) and a few sticks of dynamite  
21 could spread radioactive material across an area  
22 without a nuclear detonation. Such a weapon  
23 could kill many, contaminate a square mile for  
24 10 years or more, and cause widespread panic.  
25 The Chernobyl nuclear reactor meltdown in

1 1986 resulted in the uninhabitability of a 6 mile  
2 belt around the reactor. That area is still un-  
3 inhabitable today. It released about 400 times  
4 as much radioactivity at the Hiroshima bomb.  
5 Half of the atoms in a sample of cobalt-60 will  
6 disintegrate over a 5 year period, but it takes  
7 430 years for half of the atoms in a sample of  
8 Americium-241 to decay.

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

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

20 (I) Such a device or bomb can cause expo-  
21 sure to a variety of radioactive materials, in-  
22 cluding Plutonium, enriched or depleted Ura-  
23 nium, Radium, Cesium, Strontium, Cobalt, Io-  
24 dine, Americium, etc.

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

17           (K) Medical responses currently available  
18 with respect to exposure to radioactive mate-  
19 rials are rather limited and can include use of  
20 chelation agents to speed secretion of radio-  
21 active metals from the body if radioactive mate-  
22 rial was swallowed or inhaled, preventive block-  
23 ing of thyroid uptake of radioactive iodine by  
24 use of potassium iodine tablets, and use of In-  
25 vestigational New Drugs like Prussian Blue.

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

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

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

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

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

11          (7) Vaccines exist for some of the biological  
12          agents that might be used by terrorists and others,  
13          but these vaccines need substantial additional devel-  
14          opment. The current United States vaccine against  
15          anthrax was formulated in the 1960s and licensed in  
16          1970. Before and subsequent to the licensing of this  
17          vaccine in the United States, additional preclinical  
18          and clinical studies have been conducted to confirm  
19          its safety and efficacy. The current Food and Drug  
20          Administration-licensed immunization schedule for  
21          the anthrax vaccine involves 6 doses over 18 months  
22          followed by yearly boosters. Since this is a cum-  
23          bersome schedule for immunizing both military per-  
24          sonnel and civilian laboratory workers and first re-  
25          sponders at occupational risk of exposure to the bio-

1 threat from an anthrax attack, the Centers for Dis-  
2 ease Control and Prevention has initiated multi-cen-  
3 ter studies to develop the next generation of the an-  
4 thrax vaccine by reducing the number of doses and  
5 changing its route of administration. Additional  
6 early development phase studies of experimental re-  
7 combinant and live attenuated anthrax vaccines are  
8 underway to determine their suitability, safety and  
9 efficacy.

10 (8) Treatments for those who are not protected  
11 by vaccines are often not effective. Inhalation an-  
12 thrax (woolsorters' disease) results from inhaling an-  
13 thrax spores disseminated from either a natural  
14 source or a biological attack and, if untreated, it is  
15 considered to be 99 percent fatal. Antibiotics and  
16 standard interventions provided after symptoms have  
17 developed rarely prevent a fatal outcome.

18 (9) The United States does not currently have  
19 available the diagnostics, drugs, and vaccines needed  
20 in the event of a bioterror attack. It has been esti-  
21 mated by the Defense Science Board that the United  
22 States is adequately protected with respect to only  
23 13 of the top 50 pathogens that might be  
24 weaponized. For example, while the United States  
25 has a vaccine for smallpox, that vaccine has side ef-

1       fects and is one that cannot be well tolerated by  
2       many, and for those who are infected, the United  
3       States has no effective treatment. The United States  
4       has a treatment for early stage inhalation anthrax,  
5       but those treatments are ineffective when there are  
6       delays in diagnosis. The United States has very few  
7       products that are effective against viruses. The  
8       United States is not well protected with broad-spec-  
9       trum antibiotics that are needed to deal with patho-  
10      gens that have been modified or selected for anti-  
11      biotic resistance. It takes more than 24 hours to di-  
12      agnose many of the most dangerous pathogens.

13           (10) A ring vaccination strategy may well be  
14      impossible to implement given the mobility of Ameri-  
15      cans. Twenty-three million international airline pas-  
16      sengers embarked or disembarked at United States  
17      airports in the fourth quarter of 2001. Nearly  
18      500,000,000 people crossed the United States-Can-  
19      ada and United States-Mexico borders by land in  
20      2000. Tens of millions of people each day cross from  
21      one metropolitan area to another. For the same rea-  
22      sons, it may not be possible to enforce a quarantine.  
23      If, however, the United States has safe and effective  
24      treatments to deploy, there will be less need to at-

1       tempt to implement a ring vaccination strategy or  
2       quarantine.

3               (11) Vaccines and treatments for exposure to  
4       nerve toxins and radiological materials do not exist  
5       or are ineffective.

6               (12) The United States Government is directly  
7       funding biomedical research on vaccines and treat-  
8       ments for biological and chemical agents and radio-  
9       logical materials. These funding efforts could be  
10      matched many-fold if the 1,500 biotechnology com-  
11      panies, 100 pharmaceutical companies, medical de-  
12      vice and research tool companies, and research insti-  
13      tutions were able to secure the funding from private  
14      investors, or justify the investment of retained earn-  
15      ings, to conduct this research.

16              (13) The enactment of tax, procurement, pat-  
17      ent, liability, and other incentives will enable the bio-  
18      technology, pharmaceutical, device, and research tool  
19      industries to raise equity and other capital from in-  
20      vestors to fund research on countermeasures for bio-  
21      logical, chemical, and radiological attacks. This will  
22      supplement direct Federal funding for this research  
23      and speed development of life saving technologies.  
24      The existence of these technologies will reassure the

1 public that if attacks occur, effective medical treat-  
2 ments are available and there is no reason for panic.

3 (14) Past efforts by agencies of the Federal  
4 Government to contract for the development and  
5 manufacture of countermeasures have been, and  
6 likely will continue to be, ineffective. These efforts  
7 have been under-funded, too complex, financially re-  
8 strictive, and unreliable and therefore have failed to  
9 attract the commitment of capital and research-in-  
10 tensive biotechnology, pharmaceutical, medical de-  
11 vice, and research tool companies. These short-  
12 comings are likely to be even more apparent and se-  
13 vere with respect to proposals to use Federal tax-  
14 payer dollars for Federal Government construction,  
15 ownership, and operation of research and develop-  
16 ment and manufacturing facilities for the production  
17 of vaccines for military and civilian use (GOGOs and  
18 GOCOs) or for the establishment of a National Vac-  
19 cine Authority for the research and development and  
20 production of vaccines for the protection of civilians  
21 against bioterrorist attacks. These federalized pro-  
22 posals will result in significantly higher costs for  
23 taxpayers, add significant additional layers of Fed-  
24 eral bureaucracy, and delay the availability of need-  
25 ed countermeasures.

1           (15) Efforts by the Department of Defense to  
2           acquire drugs and vaccines for bioterror agents have  
3           been ineffective. The Defense Science Board has  
4           found that “DOD has failed to implement a  
5           proactive strategy for engagement of the private sec-  
6           tor in gaining access to new technologies relevant to  
7           biodefense . . . (There are) significant obstacles to  
8           engagement of the private sector. Neither the DOD  
9           nor the nation can achieve a robust biodefense with-  
10          out engagement of private sector R&D and leading  
11          scientists in academia and closer ties to industry  
12          . . . A program of longer-term investment in new  
13          R&D initiatives to address major gaps in drug and  
14          vaccine coverage is crucial but it will take 10 to 15  
15          years to bring such investments to fruition.”

16          (16) The Defense Science Board has noted the  
17          “private sector’s declared lack of interest in seeking  
18          Government R&DE contracts.” It has found that the  
19          “medical-related industry differs from traditional de-  
20          fense industries. The financial disincentives inherent  
21          in producing products for limited markets (i.e. DOD  
22          only) with no commitment to longterm supply in the  
23          face of massive capitalization needs and the long,  
24          multi-year lead times to build new manufacturing fa-  
25          cilities for drugs and vaccines are considerable.

1       Nonetheless, it is difficult to see how DOD or the  
2       nation can pursue a successful biodefense strategy if  
3       they do not engage leading companies and top sci-  
4       entists from outside the physics/engineering circles  
5       of traditional defense contractors.”

6               (17) This Act is premised on the belief that the  
7       most effective strategy is to capitalize on the experi-  
8       ence and entrepreneurship of America’s world pre-  
9       eminent biotechnology, pharmaceutical, medical de-  
10      vice, research tool companies, and research institu-  
11      tions engaged in this research, development, and  
12      manufacturing at their own risk, their own expense,  
13      for their own good business reasons.

14 **SEC. 3. DEFINITIONS.**

15       In this Act:

16               (1) BIOLOGICAL OR CHEMICAL AGENT; TOXIN;  
17      NUCLEAR OR RADIOLOGICAL MATERIAL; TERROR  
18      WEAPON.—The term—

19               (A) “biological agent”, “biological toxin”,  
20               “chemical agent”, or “chemical toxin”, or any  
21               variation of any such term, means any micro-  
22               organism, virus, infectious substance, biological  
23               product, toxic or poisonous chemical, or pre-  
24               cursor of a toxic or poisonous chemical, that  
25               may be used in a manner that is intended to

1 cause widespread death or serious bodily injury,  
2 including biological agents and toxins described  
3 in paragraphs (1) and (2) of section 178 of title  
4 18, United States Code;

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

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

14 (2) COUNTERMEASURES.—The term “counter-  
15 measures” means—

16 (A) a vaccine and related delivery system,  
17 antiviral, microbicide, diagnostic technology,  
18 drug, or other technology that can be used to  
19 diagnose, treat, or prevent infection with or  
20 bodily harm from, or the spread of, a biological  
21 agent or toxin on the list described in section  
22 101, and that is subject to applicable provisions  
23 of the Federal Food, Drug, and Cosmetic Act  
24 (21 U.S.C. 301 et seq.), the Public Health  
25 Service Act (42 U.S.C. 201 et seq.), and the

1 Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.);  
2 and

3 (B) a therapy or diagnostic that may be  
4 used to detect, treat, or prevent bodily harm  
5 that may be caused by the use of nuclear or ra-  
6 diological material as a terror weapon.

7 (3) DEPARTMENT.—The term “Department”  
8 means the Department of Homeland Security.

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

15 (5) DIAGNOSTICS.—The term “diagnostics” in-  
16 cludes products, devices, and technologies to detect,  
17 identify, or analyze, the potential presence or ab-  
18 sence of 1 or more biological agents or toxins in pa-  
19 tient samples, environmental samples, or field sam-  
20 ples.

21 (6) RESEARCH TOOL.—The term “research  
22 tool” includes the full range of tools that scientists  
23 may use in the laboratory, including cell lines,  
24 monoclonal antibodies, reagents, animal models,  
25 growth factors, combinatorial chemistry and DNA li-

1       braries, clones and cloning tools (such as PCR),  
2       methods, laboratory equipment and machines, data-  
3       bases, and other technologies that enable the rapid  
4       and effective development of countermeasures, in-  
5       cluding diagnostics, vaccines, and drugs.

6               (7) SECRETARY.—The term “Secretary” means  
7       the Secretary of the Department of Homeland Secu-  
8       rity.

9       **TITLE I—STRATEGY FOR THE**  
10       **DEVELOPMENT OF COUNTER-**  
11       **MEASURES**

12       **SEC. 101. BIOLOGICAL, CHEMICAL AND RADIOLOGICAL**  
13               **AGENT, TOXIN, AND MATERIAL COUNTER-**  
14               **MEASURE RESEARCH PRIORITY LIST.**

15       (a) DEVELOPMENT.—

16               (1) IN GENERAL.—Not later than 180 days  
17       after the date of enactment of this Act, the Sec-  
18       retary, in consultation with the Secretary of Defense  
19       and the Secretary of Health and Human Services,  
20       shall develop and make available to potential manu-  
21       facturers of terror weapons countermeasures and,  
22       except as provided in paragraph (5) publish, a list  
23       of biological and chemical agents and toxins and nu-  
24       clear and radiological materials that may be used as  
25       weapons of mass destruction with respect to which

1 the Secretary finds that research to develop counter-  
2 measures is in the national security interest of the  
3 United States.

4 (2) REQUIREMENTS.—

5 (A) IN GENERAL.—The Secretary shall  
6 only include on the list developed under para-  
7 graph (1) agents, toxins, and materials—

8 (i) that pose a significant security or  
9 medical threat to the United States mili-  
10 tary and intelligence personnel, govern-  
11 ment officials, or civilians;

12 (ii) that are more likely to be subject  
13 to a countermeasure that is developed as a  
14 result of the availability of the tax, pro-  
15 curement, intellectual property, liability,  
16 and other provisions of this Act (and the  
17 amendment made by this Act); and

18 (iii) with respect to which safe and ef-  
19 fective countermeasures are not available  
20 or with respect to which the development  
21 of safer and more effective counter-  
22 measures, or countermeasures that may be  
23 deployed more safely or effectively, is in  
24 the public interest.

1 (B) CERTAIN DETERMINATIONS.—For pur-  
2 poses of subparagraph (A)(ii), in determining  
3 whether the agents, toxins, and materials are  
4 more likely to be subject to a countermeasure,  
5 the Secretary shall consider—

6 (i) the status of existing public and  
7 private sector research to develop such  
8 countermeasure;

9 (ii) the status of public and private  
10 sector research that could be adapted or  
11 redirected to develop such countermeasure;

12 (iii) the availability of products that  
13 could be utilized as countermeasures;

14 (iv) the extent to which such counter-  
15 measures may be utilized for purposes  
16 other than as a countermeasure for a bio-  
17 logical agent or toxin or radiological mate-  
18 rial on the list developed under this sec-  
19 tion;

20 (v) the extent to which market-based  
21 reimbursement is available for uses of the  
22 countermeasure other than as a counter-  
23 measure for a biological agent or toxin or  
24 radiological material on the list developed  
25 under this section; and

1 (vi) the most effective strategy for ex-  
2 pediting development of such counter-  
3 measure, including reliance on Government  
4 contracts, grants and cooperative research  
5 agreements and utilization of the incen-  
6 tives provided for in this Act (and the  
7 amendments made by this Act).

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

18 (4) INFORMATION AND DETERMINATIONS RE-  
19 LATING TO POTENTIAL MANUFACTURERS.—With re-  
20 spect to the list developed under paragraph (1), the  
21 Secretary shall—

22 (A) provide such information regarding  
23 such weapons of mass destruction as the Sec-  
24 retary determines to be necessary to enable  
25 such potential manufacturers to structure and

1 manage their research and development pro-  
2 grams for the development of terror weapons  
3 countermeasures; and

4 (B) determine when such a manufacturer  
5 has successfully developed a countermeasure  
6 and therefore becomes entitled to the procure-  
7 ment, intellectual property, and liability provi-  
8 sions of this Act (or an amendment made by  
9 this Act).

10 (5) EXEMPTION.—

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

21 (B) SUFFICIENCY OF INFORMATION.—In  
22 developing the procedures described in subpara-  
23 graph (A), the Secretary shall ensure that the  
24 information provided to potential manufacturers  
25 of countermeasures is sufficient to enable the

1 Federal Government and the manufacturer to  
2 determine when such a manufacturer has suc-  
3 cessfully developed a countermeasure and there-  
4 fore becomes entitled to the procurement, intel-  
5 lectual property, and liability provisions of this  
6 Act (or an amendment made by this Act).

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

12 (1) Variola major (confluent, flat, and hemor-  
13 rhagic smallpox).

14 (2) Bacillus anthracis (anthrax).

15 (3) Clostridium botulinum (botulism).

16 (4) Francisella tularensis (tularemia).

17 (5) Yersina pestis (Black Death/bubonic  
18 plague).

19 (6) Ebola hemorrhagic fever.

20 (7) Marbug hemorrhagic fever.

21 (8) Lassa fever.

22 (9) Junin (Argentine hemmorrhagic fever).

23 (10) Crimean-Congo Hemmorrhagic Fever.

24 (11) Coxiella burnetti (Q fever).

- 1           (12) *Coccidioidomycosis* (San Joaquin Valley or  
2           desert fever).
- 3           (13) *Clostridium perfringens*.
- 4           (14) *Chalydia psittaci* (parrot fever).
- 5           (15) Rift Valley Fever.
- 6           (16) Rocky Mountain Spotted Fever.
- 7           (17) *Brucella* species (brucellosis).
- 8           (18) *Burkholderia mallei* (glanders).
- 9           (19) Venezuelan encephalomyelitis.
- 10          (20)     Eastern     and     Western     equine  
11          encephalomyelitis.
- 12          (21) Ricin toxin from *ricinus communis* (castor  
13          beans).
- 14          (22) Trichothecene Mycotoxins (Yellow Rain).
- 15          (23) Paralytic Shellfish Toxin.
- 16          (24) Aflatoxins.
- 17          (25) Epsilon toxin of *clostridium perfringens*.
- 18          (26) *Staphylococcus enterotoxin B*.
- 19          (27) *Salmonella* species.
- 20          (28) *Salmonella Typhi* (typhoid fever).
- 21          (29) *Shigella dysenteriae*.
- 22          (30) *Escherichia coli* 0157:H7.
- 23          (31) *Vibrio cholerae* (colera).
- 24          (32) *Cryptosporidium parvum*.
- 25          (33) Nipah virus.

- 1 (34) Hantaviruses.
- 2 (35) Tickborne hemorrhagic fever viruses.
- 3 (36) Tickborne encephalitis virus.
- 4 (37) Yellow fever.
- 5 (38) Malaria.
- 6 (39) Typhus.
- 7 (40) Antibiotic resistant tuberculosis.
- 8 (41) *Entamoeba histolytica*.
- 9 (42) Bacillary dysentery.
- 10 (43) Giardiasis.
- 11 (44) Trichomoniasis.
- 12 (45) Trypanosomiasis.
- 13 (46) Visceral leishmaniasis (black fever).
- 14 (47) Nerve agents (including tabun, sarin,  
15 soman, GF, and VX).
- 16 (48) Blood agents (including hydrogen cyanide  
17 and cyanogen chloride).
- 18 (49) Blister agents (including lewisite, nitrogen  
19 and sulfur mustards).
- 20 (50) Heavy metals (including arsenic, lead, and  
21 mercury).
- 22 (51) Volatile toxins (including benzene, chloro-  
23 form, and trihalomethanes).
- 24 (52) Pulmonary agents (including phosgene and  
25 chlorine vinyl chloride).

1           (53) Incapacitating agents (including BZ).

2           (54) Nuclear and radiological materials.

3           (c) REVISIONS.—The Secretary shall revise the list  
4 developed under subsection (a) on at least an annual basis,  
5 and make such list available, under the terms and limita-  
6 tions described in this section, to potential manufacturers  
7 of terror weapons countermeasures or to holders of ap-  
8 proved certifications. Such terms and conditions shall be  
9 consistent with the security interests of the United States.

10          (d) NO JUDICIAL REVIEW.—Notwithstanding any  
11 other provision of law, there shall be no judicial review  
12 of the Secretary's determinations regarding which agents,  
13 toxins, or materials to include on the list, or revised list,  
14 developed under this section or of a determination to ex-  
15 empt information from public distribution under this sec-  
16 tion.

17          (e) PROCUREMENT.—

18           (1) PURPOSE.—It is the purpose of this sub-  
19 section to provide potential manufacturers of coun-  
20 termeasures that are registered with the Department  
21 under section 102 with sufficient information to en-  
22 able that manufacturer to structure and manage its  
23 research and development of a terror weapons coun-  
24 termeasure and to determine when the manufacturer  
25 has successfully developed such a countermeasure

1 and therefore becomes entitled to the procurement,  
2 intellectual property, and liability incentives provided  
3 for under this Act (or an amendment made by this  
4 Act).

5 (2) FEDERAL GOVERNMENT SUCCESS AND MAR-  
6 KET DETERMINATION.—Not later than 180 days  
7 after the development of the list, or revised list,  
8 under subsection (a), the Secretary shall, with re-  
9 spect to each agent, toxin, or material on the list,  
10 determine—

11 (A) the type of countermeasure to be de-  
12 veloped, including whether such countermeasure  
13 is a diagnostic, vaccine, biological, drug, or  
14 other countermeasure;

15 (B) the testing and clinical trial standards  
16 that will be required with respect to the coun-  
17 termeasure, in order for the manufacturer to  
18 become entitled to procurement, intellectual  
19 property, and liability provisions of this Act (or  
20 an amendment made by this Act), including the  
21 terms of review of the countermeasure by the  
22 Food and Drug Administration and whether the  
23 approval of such Administration is required;

24 (C) the safety and efficacy profile of the  
25 countermeasure;

1 (D) the projected utilization of such coun-  
2 termeasure in combination;

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

10 (F) with respect to a developer of a coun-  
11 termeasure that contracts with another entity  
12 for the manufacturer of such countermeasure,  
13 or with respect to a developer that is one of sev-  
14 eral manufacturers of such countermeasure, the  
15 Federal Government market that will be avail-  
16 able to the developer of such countermeasure;

17 (G) the advance, partial, progress, mile-  
18 stone or other payments that may be available  
19 to the manufacturer under section 202, and the  
20 terms and conditions for the adjustment of any  
21 such payments for uncontrollable factors; and

22 (H) such other information as the manu-  
23 facturer may reasonably request to enable the  
24 manufacturer to structure and manage research  
25 and development activities and determine when

1 a countermeasure has been successfully devel-  
2 oped therefore entitling the manufacturer to the  
3 procurement, intellectual property, and liability  
4 provisions of this Act (or an amendment made  
5 by this Act).

6 (3) DETERMINATIONS.—

7 (A) IN GENERAL.—The Secretary shall  
8 make determinations under this subsection with  
9 respect to the successful development of coun-  
10 termeasures in accordance with section  
11 102(e)(3).

12 (B) TESTING AND CLINICAL TRIALS.—The  
13 determination by the Secretary under para-  
14 graph (2)(B) with respect to the testing and  
15 clinical trial standards that will be required  
16 shall apply only to the entitlement of the manu-  
17 facturer to the procurement, intellectual prop-  
18 erty, and liability provisions of this Act (or an  
19 amendment made by this Act). Nothing in this  
20 Act shall be construed to alter or affect the au-  
21 thority of the Food and Drug Administration  
22 with respect to the testing, clinical trial, or  
23 other regulatory standards applicable to the  
24 countermeasure involved.

1           (C) NO JUDICIAL REVIEW.—Notwith-  
2           standing any other provision of law, there shall  
3           be no judicial review of determinations made by  
4           the Secretary under this subsection.

5           (4) REVISIONS.—The Secretary is authorized to  
6           revise upward determinations under subparagraphs  
7           (E) and (G) of paragraph (2) with respect to min-  
8           imum number of dosages that will be purchased and  
9           minimum price per dose and the advance, partial,  
10          progress, milestone or other payments that may be  
11          available to the manufacturer upon a determination  
12          that such revision is necessary to protect the na-  
13          tional security interests of the United States and  
14          provide an effective incentive to entities developing  
15          countermeasures.

16 **SEC. 102. RESEARCH REGISTRATION REQUIREMENTS.**

17          (a) IN GENERAL.—On or before December 31 of each  
18          year each entity that operates any private sector establish-  
19          ment in any State that seeks to be eligible for the tax,  
20          procurement, intellectual property, and liability provisions  
21          in title II (and the amendments made by such title), and  
22          that is engaged in the conduct of research to develop coun-  
23          termeasures, diagnostics (as provided for in section 103),  
24          or research tools (as provided for in section 104) shall reg-

1 ister with the Department. Such registration shall con-  
2 tain—

3 (1) the name and address of the entity;

4 (2) the name and address of the establishment  
5 at which the research is being conducted;

6 (3) the name of the agent, toxin, or material  
7 with respect to which the entity seeks to develop  
8 countermeasures, diagnostics or research tools;

9 (4) a description of the research that is being,  
10 or that will be, conducted to develop counter-  
11 measures to, or diagnostic or research tools with re-  
12 spect to, such agent, toxin, or material;

13 (5) a description of the capability of the entity,  
14 including its technology and personnel, to develop  
15 countermeasures to such agents, toxins, or material  
16 that meet the safety and efficacy profiles specified  
17 by the Secretary;

18 (6) the name of each individual who is con-  
19 ducting the research involved;

20 (7) the procedures that the entity will follow to  
21 ensure that the security interests of the United  
22 States are met; and

23 (8) any other information required under regu-  
24 lations promulgated by the Secretary, including ad-  
25 ditions and corrections to the information required

1 under this subsection as may be required by the Sec-  
2 retary through regulation.

3 (b) AVAILABILITY OF INFORMATION.—

4 (1) IN GENERAL.—Not later than 90 days after  
5 the date of enactment of this Act, the Secretary  
6 shall promulgate regulations with respect to the  
7 availability of information under this subsection.

8 (2) INSPECTIONS.—Subject to regulations pro-  
9 mulgated under paragraph (1), the Department shall  
10 make available for inspection, to any person so re-  
11 questing, any registration filed pursuant to sub-  
12 section (a), except as provided in paragraph (3).

13 (3) CERTAIN INFORMATION NOT AVAILABLE.—  
14 The Secretary shall promulgate regulations to ex-  
15 empt certain information from disclosure under  
16 paragraph (2). Such regulations shall exempt from  
17 publication and disclosure trade secret and commer-  
18 cial or financial information which is exempt from  
19 disclosure to the public under section 552(b)(4) of  
20 title 5, United States Code, national security infor-  
21 mation, and information affecting the security of re-  
22 search and other facilities.

23 (4) NO JUDICIAL REVIEW.—Notwithstanding  
24 any other provision of law, there shall be no judicial  
25 review of determinations made by the Secretary to

1 exempt information under paragraph (3), except  
2 that this paragraph shall not apply to judicial review  
3 of the failure to exempt from publication and diselo-  
4 sure trade secret and commercial or financial infor-  
5 mation, national security information, and informa-  
6 tion affecting the security of research and other fa-  
7 cilities.

8 (c) INSPECTIONS.—Every establishment in any State  
9 registered with the Department pursuant to this section  
10 shall be subject to inspection, limited to such information  
11 as may be necessary relating to the development of coun-  
12 termeasures, diagnostics, or research tools and facility se-  
13 curity, pursuant to regulations promulgated by the Sec-  
14 retary.

15 (d) REPORTS.—The Secretary shall promulgate regu-  
16 lations that prescribe the reports that each establishment  
17 that is registered with the Department under this section  
18 shall be required to file with the Secretary. Such regula-  
19 tions shall limit such reports to those necessary to enable  
20 the Secretary to—

21 (1) ensure that the capital derived by the utili-  
22 zation of the tax incentives provided for in title II  
23 (and the amendments made by such title) is used to  
24 fund the research that is the subject of the registra-  
25 tion and certification under this section;

1           (2) determine the status of the research in-  
2           volved; and

3           (3) determine the outlook for United States  
4           preparedness for a biological, chemical, or radio-  
5           logical attack.

6           (e) CERTIFICATION.—

7           (1) IN GENERAL.—With respect to each entity  
8           that registers with the Department under this sec-  
9           tion, the Secretary, in consultation with the Sec-  
10          retary of Health and Human Services, shall deter-  
11          mine—

12                   (A) whether the research to be conducted  
13                   under such registration is directed to lead to  
14                   the development of a—

15                           (i) countermeasure with respect to a  
16                           biological or chemical agency or radio-  
17                           logical material on the list under section  
18                           101;

19                           (ii) diagnostic with respect to the list  
20                           developed under section 103; or

21                           (iii) research tool with respect to the  
22                           list developed under section 104;

23                   (B) whether the entity is qualified to con-  
24                   duct research to develop the countermeasure  
25                   with respect to which the entity seeks certifi-

1 cation, and, with respect to such determination,  
2 the Secretary shall not presume that the entity  
3 is unqualified because the entity has not pre-  
4 viously secured approval of the Food and Drug  
5 Administration of a device, drug, or biologic;  
6 and

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

12 (2) DETERMINATION.—If the Secretary makes  
13 an affirmative determination under paragraph (1)  
14 with respect to an entity, the Secretary shall certify  
15 the entity as being entitled to utilize the tax incen-  
16 tive provisions described in section 201 (and the  
17 amendments made by such section).

18 (3) SUCCESSFUL DEVELOPMENT.—Not later  
19 than 90 days after the date on which a certified en-  
20 tity submits to the Secretary an application for a de-  
21 termination that the entity has successfully devel-  
22 oped a terror weapons countermeasure in accordance  
23 with section 101(e)(2), diagnostic in accordance with  
24 section 103, or research tool in accordance with sec-  
25 tion 104, the Secretary shall notify the entity—

1 (A) of such determination; and

2 (B) in the case of an affirmative deter-  
3 mination by the Secretary with respect to the  
4 countermeasure, diagnostic, or research tool in-  
5 volved, that the entity shall be entitled to—

6 (i) procurement of the counter-  
7 measure, diagnostic, or research tool under  
8 the terms and conditions described under  
9 such section 101(e)(2) (including the min-  
10 imum number of doses to be purchased,  
11 the timing and minimum number of years  
12 projected for such purchases, and the min-  
13 imum per dose price), in accordance with  
14 section 202, and upon the execution of a  
15 contract with the Secretary with respect to  
16 such procurement; and

17 (ii) the patent restoration and exten-  
18 sion protection under section 156a or 158  
19 of title 35, United States Code, as added  
20 by section 203; and

21 (iii) upon a determination by the Sec-  
22 retary that it is the national security inter-  
23 est of the United States, the liability pro-  
24 tections provided for under the amendment  
25 made by section 204.

1           (4) REQUIRED AFFIRMATIVE DETERMINA-  
2           TION.—The Secretary shall make an affirmative de-  
3           termination that an entity has successfully developed  
4           a terror weapons countermeasure, diagnostic, or re-  
5           search tool under this subsection if such counter-  
6           measure, diagnostic, or research tool—

7                   (A) has been authorized under the Federal  
8           Food, Drug, and Cosmetic Act (21 U.S.C. 301  
9           et seq.) and the Public Health Service Act (42  
10          U.S.C. 201 et seq.) for introduction or distribu-  
11          tion into commerce;

12                   (B) has not been authorized for such intro-  
13          duction or distribution into commerce under  
14          subparagraph (A) but has been authorized for  
15          investigation or compassionate use as a terror  
16          weapons countermeasure, diagnostic, or re-  
17          search tool under such Acts and the Secretary  
18          determines that significant quantities of the  
19          countermeasure, diagnostic, or research tool  
20          have been manufactured by the entity and are  
21          available for such investigational or compas-  
22          sionate use; or

23                   (C) is not required to be authorized for in-  
24          troduction or distribution in commerce or inves-  
25          tigational use under such Acts under subpara-

1           graphs (A) or (B) but the Secretary determines  
2           that significant quantities of it have been man-  
3           ufactured by an entity for use as a terror weap-  
4           ons countermeasure, diagnostic, or research tool  
5           and are available for such use.

6           (5) JUDICIAL REVIEW.—An adverse determina-  
7           tion by the Secretary with respect to the develop-  
8           ment by a manufacturer of a terror weapons coun-  
9           termeasure in accordance with section 101(e)(2), di-  
10          agnostic in accordance with section 103, or research  
11          tool in accordance with section 104, shall be subject  
12          to appropriate judicial review.

13          (f) ELIGIBILITY OF ENTITIES WITH MORE THAN  
14          \$750,000,000 IN AGGREGATE GROSS ASSETS, ETC.—

15                 (1) AUTHORITY OF SECRETARY TO WAIVE AG-  
16                 GREGATE GROSS ASSETS LIMITATION.—Within 60  
17                 days of the request of an entity for a certification  
18                 under subsection (e)(1) or a determination under  
19                 subsection (e)(3), and upon a finding by the Sec-  
20                 retary that it is in the public interest, the Secretary  
21                 may extend the entitlement to utilize the tax incen-  
22                 tives described in the amendments made by section  
23                 201 and the patent restoration and extension protec-  
24                 tion described in the amendments made by section  
25                 203, to such an entity with aggregate gross assets

1 exceeding \$750,000,000 (as defined in section  
2 1202(d)(2) of the Internal Revenue Code of 1986).

3 (2) WAIVER WITH REGARD TO ENTITIES WITH  
4 NET OPERATING LOSSES.—Any entity obtaining a  
5 certification or determination described in paragraph  
6 (1) shall be entitled to utilize the tax incentives de-  
7 scribed in paragraphs (1), (2), and (3) of section  
8 201 and the patent restoration and extension protec-  
9 tion described in section 158 of title 35, United  
10 States Code, as added by section 203(b), if such en-  
11 tity's tax status in no fewer than 3 of the 5 taxable  
12 years preceding such certification or determination  
13 is that of an entity with net operating losses (as de-  
14 fined in section 172(c) of the Internal Revenue Code  
15 of 1986).

16 (3) IMPLEMENTING RULES.—The Secretary  
17 shall publish appropriate rules to implement this  
18 subsection taking into account the need to encourage  
19 participation by entities which have not yet become  
20 profitable on a sustainable basis.

21 (4) NO JUDICIAL REVIEW.—Notwithstanding  
22 any other provision of law, there shall be no judicial  
23 review of determinations made by the Secretary with  
24 respect to waivers under this subsection.

1 (g) RULE OF CONSTRUCTION.—Nothing in this sec-  
2 tion shall be construed to prohibit—

3 (1) a private sector establishment from filing  
4 more than 1 registration concerning research and  
5 from obtaining more than 1 certification of eligibility  
6 under this section;

7 (2) a consortium, partnership, or joint venture  
8 of more than one private sector establishment from  
9 filing one or more registrations concerning research  
10 and obtaining one or more certification of eligibility  
11 under this section; and

12 (3) a private sector establishment from receiv-  
13 ing Federal grants, contracts, or cooperative agree-  
14 ments for research, investigations, experiments,  
15 demonstrations, and studies in addition to the incen-  
16 tives provided for under this Act (and the amend-  
17 ments made by this Act).

18 (h) PRIORITY ACCESS TO CERTAIN RESEARCH RE-  
19 SULTS.—An entity that is certified under this section shall  
20 be given priority access to the results of research related  
21 to the epidemiology and pathogenesis of agents, the  
22 genomes and other DNA analysis, or other comparative  
23 analysis of agents, and other relevant research conducted  
24 under subparagraphs (A), (b), and (C) of section  
25 391F(h)(1) of the Public Health Service Act (as added

1 by section 125 of the Public Health Security and Bioter-  
2 rorism Preparedness and Response Act of 2002.

3 (i) ACCELERATED APPROVAL.—An entity that is cer-  
4 tified under this section shall be eligible for accelerated  
5 approval of a countermeasure as described in section 211  
6 and as provided for in section 122 of the Public Health  
7 Security and Bioterrorism Preparedness and Response  
8 Act of 2002.

9 (j) PRIORITY FOR TECHNICAL AND OTHER ASSIST-  
10 ANCE.—An entity that is certified under this section shall  
11 be given priority for receiving technical and other assist-  
12 ance to provide security for their personnel and facilities  
13 that conduct development, production, distribution, or  
14 storage of countermeasures under section 319K of the  
15 Public Health Service Act (as added by section 124 of the  
16 Public Health Security and Bioterrorism Preparedness  
17 and Response Act of 2002).

18 **SEC. 103. DIAGNOSTICS INCENTIVES.**

19 (a) FINDINGS.—Congress finds that—

20 (1) in the case of a bioterrorist attack, the  
21 United States public health authorities need the ca-  
22 pacity to quickly and accurately diagnose the agent,  
23 toxin, or material involved so that appropriate med-  
24 ical intervention can be implemented;

1           (2) public health authorities need information  
2           on which vaccines and drugs will be effective in pre-  
3           venting infection, or in treating those who are in-  
4           fected, as a result of a terrorist attack, and whether  
5           there are any existing vaccines or drugs that are ef-  
6           fective;

7           (3) there is a lack of information on the com-  
8           plications involved in administering vaccines and  
9           drugs via the use of diagnostic devices to portions of  
10          society that are known or unknown to carry contra-  
11          indication diseases or conditions;

12          (4) few diagnostics for agents, toxins, or mate-  
13          rials that could be used in a terror attack are cur-  
14          rently available;

15          (5) the current structure and management of  
16          patients in both the emergency room and outpatient  
17          clinical settings is not conducive to rapid recognition  
18          of infectious disease agents, which may in fact be  
19          biothreat agents;

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

1           (7) cultures, the gold standard currently, can  
2           require 48 hours to many days or weeks to provide  
3           a definitive diagnosis while new molecular level tests  
4           can reduce that time to hours;

5           (8) the clinical presentation of many conditions,  
6           including biothreat agents, is a very common and  
7           nonspecific pattern of symptoms and doctors, in gen-  
8           eral, will not order a test unless they happen to  
9           think of a particular disease in their presumptive  
10          differential diagnosis;

11          (9) it is often easier to prescribe an antibiotic  
12          rather than to determine the underlying causative  
13          organism;

14          (10) both screening and more specific tests to  
15          diagnose infectious diseases need to be available to  
16          physicians; and

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

24          (b) IDENTIFICATION.—Not later than 180 days after  
25          the date of enactment of this Act, the Secretary shall de-

1 velop and make available to potential manufacturers, a list  
2 of the diagnostics and diagnostics for contraindicators to  
3 vaccines or drugs that need to be developed to prepare  
4 the United States for a terrorist attack with a biological  
5 or chemical agent or toxin or nuclear or radiological mate-  
6 rials. The Secretary shall provide such information as the  
7 Secretary determines to be necessary to enable such poten-  
8 tial manufacturers to structure and focus their research  
9 and development programs for the development of such  
10 diagnostics.

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

16 (d) DEVELOPMENT OF CERTAIN DIAGNOSTICS.—

17 (1) IN GENERAL.—The Secretary shall develop  
18 and implement a strategy for the creation of infec-  
19 tious disease multiplexed molecular level technologies  
20 and the building of a system linking the local, State,  
21 and Federal public health systems through auto-  
22 mated laboratory results reporting for all infectious  
23 diseases.

24 (2) STRATEGY.—The strategy developed and  
25 implemented pursuant to paragraph (1) shall—

1 (A) include the development of confirm-  
2 atory laboratory tests to back up presumptive  
3 results available from initial screening;

4 (B) recognize the need for advancement in  
5 the field of bioinformatics to accelerate the dis-  
6 covery of countermeasures using advanced  
7 mathematical techniques for pattern recogni-  
8 tion, lossless digital data compression for stor-  
9 age and transmission of biomedical images, and  
10 the ability to analyze massive amounts of data;  
11 and

12 (C) promote the advancement of  
13 bioinformatics through the use of incentives, the  
14 procurement and rapid development of new de-  
15 vices, and the linkage of information systems  
16 into a medical surveillance infrastructure.

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 embedded in the devices capable of  
23 autoreporting results electronically, so results can be  
24 put into the public health system quickly.

1 (e) UTILIZATION OF DIAGNOSTICS BY HEALTH CARE  
2 PROVIDERS.—

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

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

16 (3) GUIDELINES.—The Secretary shall establish  
17 similar guidelines for States to utilize to promote in-  
18 fectionous disease screening, including testing for the  
19 rapid identification of potential biothreat agents.

20 (f) NO JUDICIAL REVIEW.—Notwithstanding any  
21 other provision of law, there shall be no judicial review  
22 of the list, or revised list, developed by the Secretary under  
23 this section.

24 (g) INCENTIVES.—Not later than 90 days after the  
25 date on which a certified entity submits to the Secretary

1 an application for a determination that the entity has suc-  
2 cessfully developed a terror weapons diagnostic in accord-  
3 ance with this section and section 102, the Secretary shall  
4 notify the entity—

5 (1) of such determination; and

6 (2) in the case of an affirmative determination  
7 by the Secretary with respect to the diagnostic in-  
8 volved, that the entity shall be entitled to—

9 (A) the tax incentives described in section  
10 201; and

11 (B) after the successful development of the  
12 diagnostic involved—

13 (i) procurement of the diagnostic;

14 (ii) the patent restoration and exten-  
15 sion protection under section 156a or 158  
16 of title 35, United States Code, as added  
17 by section 203; and

18 (iii) the liability protections provided  
19 for under the amendment made by section  
20 204.

21 (g) JUDICIAL REVIEW.—An adverse determination by  
22 the Secretary with respect to the development by a manu-  
23 facturer of a terror weapons diagnostic in accordance with  
24 this section, shall be subject to appropriate judicial review.

1 **SEC. 104. RESEARCH TOOLS INCENTIVES.**

2 (a) FINDINGS.—Congress finds that—

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

8 (2) terrorists may develop a biological or chem-  
9 ical agent or toxin or nuclear or radiological material  
10 that the United States has not anticipated would be  
11 weaponized;

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

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

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

24 (6) to be prepared, the United States needs to  
25 provide incentives for the development of new and  
26 more powerful research tools; and

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

9       (b) IDENTIFICATION.—Not later than 180 days after  
10   the date of enactment of this Act, the Secretary shall de-  
11   velop and make available to potential manufacturers, a list  
12   of the research tools that need to be developed to prepare  
13   the United States for a terrorist attack with a biological  
14   or chemical agent or toxin or nuclear or radiological mate-  
15   rials. The list developed by the Secretary shall include re-  
16   search tools for which there is a need for development in  
17   order to understand why certain countermeasures may  
18   cause adverse events, how to minimize such adverse  
19   events, and how to treat such adverse events. The Sec-  
20   retary shall provide such information as the Secretary de-  
21   termines to be necessary to enable such potential manufac-  
22   turers to structure and focus their research and develop-  
23   ment programs for the development of such diagnostics.

24       (c) REVISIONS.—The Secretary shall revise the list  
25   developed under subsection (b) on at least an annual basis,

1 and make such list available to potential manufacturers  
2 of research tools under terms and conditions consistent  
3 with the security interests of the United States.

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

8 (e) INCENTIVES.—Not later than 90 days after the  
9 date on which a certified entity submits to the Secretary  
10 an application for a determination that the entity has suc-  
11 cessfully developed a terror weapons research tool in ac-  
12 cordance with this section and section 102, the Secretary  
13 shall notify the entity—

14 (1) of such determination; and

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

18 (A) the tax incentives described in section  
19 201; and

20 (B) after the successful development of the  
21 research tool involved—

22 (i) procurement of the research tool;

23 (ii) the patent restoration and exten-  
24 sion protection under section 156a or 158

1 of title 35, United States Code, as added  
2 by section 203; and

3 (iii) the liability protections provided  
4 for under the amendment made by section  
5 204.

6 (f) JUDICIAL REVIEW.—An adverse determination by  
7 the Secretary with respect to the development by a manu-  
8 facturer of a terror weapons research tool in accordance  
9 with this section, shall be subject to appropriate judicial  
10 review.

11 (g) UTILIZATION AND AVAILABILITY.—

12 (1) IN GENERAL.—Entities with respect to  
13 which an affirmative determination is made under  
14 subsection (e) shall maximize the utilization of the  
15 research tools involved for the development of coun-  
16 termeasures, including making such tools available  
17 on commercially reasonable terms to other entities  
18 certified under section 102 to develop counter-  
19 measures.

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

24 (A) secure and enforce patents with regard  
25 to research tools;

1 (B) enter into exclusive, revocable, and  
2 nontransferable licenses of such research tools;  
3 or

4 (C) impose limits on royalty-reach-through  
5 agreements, option rights, or product reach-  
6 through rights concerning such research tools.

7 **TITLE II—INCENTIVES FOR THE**  
8 **DEVELOPMENT OF COUNTER-**  
9 **MEASURES**  
10 **Subtitle A—Primary Incentives**

11 **SEC. 201. FEDERAL TAX INCENTIVES.**

12 (a) FINDINGS AND PURPOSE.—

13 (1) FINDINGS.—Congress makes the following  
14 findings:

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

1           may lead to a rate of return commensurate with  
2           the risk and comparable to the rate of return  
3           available to other, comparable investment op-  
4           portunities.

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

15          (C) Biotechnology companies tend to focus  
16          on breakthrough research to develop medical  
17          treatments for diseases where no effective treat-  
18          ments are currently available. They often spe-  
19          cialize in research and development on rare dis-  
20          eases and they are parties in the vast majority  
21          of the collaborations in the United States be-  
22          tween private industry and academic medical  
23          centers and the National Institutes of Health.  
24          Many biotechnology companies do not have ap-  
25          proval to market products with respect to which

1 they might develop minor improvements to  
2 maintain a market advantage.

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

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

16 (F) The provision of tax incentives will  
17 help in enabling biotechnology companies to  
18 form the capital needed to conduct research to  
19 develop countermeasures. Such incentives lower  
20 the cost of capital, induce investors to fund re-  
21 search, and enable biotechnology companies to  
22 justify the investment of retained earnings.  
23 Without such capital, research on counter-  
24 measures is not likely to go forward. Tax incen-  
25 tives are less costly than direct Federal Govern-

1           ment funding of the research and tend to shift  
2           some of the risk of failure to the companies.

3           (2) PURPOSE.—It is the purpose of this section  
4           to provide tax incentives to enable biotechnology,  
5           pharmaceutical, diagnostics, and research tool com-  
6           panies to form capital to conduct research to develop  
7           countermeasures.

8           (b) IN GENERAL.—Any entity certified as entitled to  
9           the provisions described in this section for any taxable  
10          year under section 102(e) may irrevocably elect 1 of the  
11          following Federal tax incentives to fund research with re-  
12          spect to each certification to develop countermeasures,  
13          diagnostics, or medical research tools:

14           (1) RESEARCH AND DEVELOPMENT LIMITED  
15          PARTNERSHIPS TO FUND COUNTERMEASURE RE-  
16          SEARCH.—The entity may establish a limited part-  
17          nership for the certified countermeasures,  
18          diagnostics, or research tools research, but only if  
19          such entity is a qualified small business as deter-  
20          mined under section 1202(d) of the Internal Rev-  
21          enue Code of 1986, by substituting “\$750,000,000”  
22          for “\$50,000,000” each place it appears. For pur-  
23          poses of the Internal Revenue Code of 1986, section  
24          469 of such Code shall not apply with respect to a

1 limited partnership established under this para-  
2 graph.

3 (2) CAPITAL GAINS EXCLUSION FOR INVESTORS  
4 TO FUND COUNTERMEASURE RESEARCH.—The enti-  
5 ty may issue a class of stock for the certified coun-  
6 termeasures, diagnostics, or research tools research  
7 under section 1202 of the Internal Revenue Code of  
8 1986 with the following modifications:

9 (A) INCREASED EXCLUSION FOR NONCOR-  
10 PORATE TAXPAYERS.—Subsection (a) of section  
11 1202 of such Code shall be applied by sub-  
12 stituting “100 percent” for “50 percent”.

13 (B) APPLICATION TO CORPORATE TAX-  
14 PAYERS.—Subsection (a) of section 1202 of  
15 such Code shall be applied without regard to  
16 the phrase “other than a corporation”.

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

23 (D) REDUCTION IN HOLDING PERIOD.—  
24 Subsection (a) of section 1202 of such Code

1 shall be applied by substituting “3 years” for  
2 “5 years”.

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

8 (F) MODIFICATION OF WORKING CAPITAL  
9 LIMITATION.—Section 1202(e)(6) of such Code  
10 shall be applied—

11 (i) in subparagraph (B), by sub-  
12 stituting “5 years” for “2 years”, and

13 (ii) without regard to the last sen-  
14 tence.

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

19 (3) TAX CREDIT TO FUND COUNTERMEASURE  
20 RESEARCH.—

21 (A) IN GENERAL.—Subpart D of part IV  
22 of subchapter A of chapter 1 of the Internal  
23 Revenue Code of 1986 (relating to business re-  
24 lated credits) is amended by adding at the end  
25 the following new section:

1 **“SEC. 45G. CREDIT FOR MEDICAL RESEARCH RELATED TO**  
2 **DEVELOPING COUNTERMEASURES.**

3 “(a) GENERAL RULE.—For purposes of section 38,  
4 in the case of any certified entity under section 102(e)  
5 of the Biological, Chemical, and Radiological Weapons  
6 Countermeasures Research Act of 2002 which makes an  
7 election under section 201(b) of such Act to apply this  
8 section, the countermeasures research credit determined  
9 under this section for the taxable year is an amount equal  
10 to 35 percent of the qualified countermeasures research  
11 expenses for the taxable year.

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

14 “(1) QUALIFIED COUNTERMEASURES RE-  
15 SEARCH EXPENSES.—

16 “(A) IN GENERAL.—Except as otherwise  
17 provided in this paragraph, the term ‘qualified  
18 countermeasures research expenses’ means the  
19 amounts which are paid or incurred by the tax-  
20 payer during the taxable year which would be  
21 described in subsection (b) of section 41 if such  
22 subsection were applied with the modifications  
23 set forth in subparagraph (B).

24 “(B) MODIFICATIONS; INCREASED INCEN-  
25 TIVE FOR CONTRACT RESEARCH PAYMENTS.—

1 For purposes of subparagraph (A), subsection  
2 (b) of section 41 shall be applied—

3 “(i) by substituting ‘qualified counter-  
4 measures research’ for ‘qualified research’  
5 each place it appears in paragraphs (2)  
6 and (3) of such subsection, and

7 “(ii) by substituting ‘100 percent’ for  
8 ‘65 percent’ in paragraph (3)(A) of such  
9 subsection.

10 “(C) EXCLUSION FOR AMOUNTS FUNDED  
11 BY GRANTS, ETC.—The term ‘qualified counter-  
12 measures research expenses’ shall not include  
13 any amount to the extent such amount is fund-  
14 ed by any grant, contract, or otherwise by an-  
15 other person (or any governmental entity).

16 “(2) COUNTERMEASURES RESEARCH.—The  
17 term ‘countermeasures research’ means certified  
18 countermeasures research for any biological agent or  
19 toxin on the list described in section 101 of the Bio-  
20 logical, Chemical, and Radiological Weapons Coun-  
21 termeasures Research Act of 2002.

22 “(c) COORDINATION WITH CREDIT FOR INCREASING  
23 RESEARCH EXPENDITURES.—

24 “(1) IN GENERAL.—Except as provided in para-  
25 graph (2), any qualified countermeasures research

1 expenses for a taxable year to which an election  
2 under this section applies shall not be taken into ac-  
3 count for purposes of determining the credit allow-  
4 able under section 41 for such taxable year.

5 “(2) EXPENSES INCLUDED IN DETERMINING  
6 BASE PERIOD RESEARCH EXPENSES.—Any qualified  
7 countermeasures research expenses for any taxable  
8 year which are qualified research expenses (within  
9 the meaning of section 41(b)) shall be taken into ac-  
10 count in determining base period research expenses  
11 for purposes of applying section 41 to subsequent  
12 taxable years.

13 “(d) SPECIAL RULES.—

14 “(1) LIMITATIONS ON FOREIGN TESTING.—No  
15 credit shall be allowed under this section with re-  
16 spect to any countermeasures research (other than  
17 human clinical testing) conducted outside the United  
18 States.

19 “(2) PRE-CLINICAL RESEARCH.—No credit shall  
20 be allowed under this section for pre-clinical re-  
21 search unless such research is pursuant to a re-  
22 search plan an abstract of which has been filed with  
23 the Director of the Office of Homeland Security be-  
24 fore the beginning of such year. The Director of the  
25 Office of Homeland Security, in consultation with

1 the Secretary of Health and Human Services, shall  
2 prescribe regulations specifying the requirements for  
3 such plans and procedures for filing under this para-  
4 graph.

5 “(3) CERTAIN RULES MADE APPLICABLE.—  
6 Rules similar to the rules of paragraphs (1) and (2)  
7 of section 41(f) shall apply for purposes of this sec-  
8 tion.

9 “(4) COORDINATION WITH CREDIT FOR CLIN-  
10 ICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR  
11 RARE DISEASES.—Any qualified countermeasures re-  
12 search expense for a taxable year shall not be taken  
13 into account for purposes of determining the credit  
14 allowable under section 45C for such taxable year.”.

15 (B) INCLUSION IN GENERAL BUSINESS  
16 CREDIT.—

17 (i) IN GENERAL.—Section 38(b) of  
18 such Code is amended by striking “plus”  
19 at the end of paragraph (14), by striking  
20 the period at the end of paragraph (15)  
21 and inserting “, plus”, and by adding at  
22 the end the following new paragraph:

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

1                   (ii) TRANSITION RULE.—Section  
2                   39(d) of such Code is amended by adding  
3                   at the end the following new paragraph:

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

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

13                  “(d) CREDIT FOR QUALIFIED COUNTERMEASURES  
14 RESEARCH EXPENSES.—

15                  “(1) IN GENERAL.—No deduction shall be al-  
16                  lowed for that portion of the qualified counter-  
17                  measures research expenses (as defined in section  
18                  45G(b)) otherwise allowable as a deduction for the  
19                  taxable year which is equal to the amount of the  
20                  credit determined for such taxable year under sec-  
21                  tion 45G(a).

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

1 (D) DEDUCTION FOR UNUSED PORTION OF  
 2 CREDIT.—Section 196(c) of such Code (defining  
 3 qualified business credits) is amended by strik-  
 4 ing “and” at the end of paragraph (9), by  
 5 striking the period at the end of paragraph (10)  
 6 and inserting “, and”, and by adding at the end  
 7 the following new paragraph:

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

12 (E) TECHNICAL AMENDMENT.—The table  
 13 of sections for subpart D of part IV of sub-  
 14 chapter A of chapter 1 of such Code is amended  
 15 by adding at the end the following new item:

“Sec. 45G. Credit for medical research related to developing coun-  
 termeasures.”.

16 (4) TAX CREDIT TO FUND COUNTERMEASURE  
 17 RESEARCH AT CERTAIN QUALIFIED NON-PROFIT AND  
 18 ACADEMIC INSTITUTIONS INCLUDING TEACHING  
 19 HOSPITALS.—

20 (A) IN GENERAL.—Subpart D of part IV  
 21 of subchapter A of chapter 1 of the Internal  
 22 Revenue Code of 1986 (relating to business re-  
 23 lated credits) is amended by inserting after sec-  
 24 tion 41 the following:

1 **“SEC. 41A. CREDIT FOR COUNTERMEASURES RESEARCH**  
2 **EXPENSES.**

3 “(a) GENERAL RULE.—For purposes of section 38,  
4 in the case of any certified entity under section 102(e)  
5 of the Biological, Chemical, and Radiological Weapons  
6 Countermeasures Research Act of 2002 which makes an  
7 election under section 201(b) of such Act to apply this  
8 section, the countermeasures research credit determined  
9 under this section for the taxable year shall be an amount  
10 equal to 35 percent of the excess (if any) of—

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

13 “(2) the countermeasures base period amount.

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

16 “(1) IN GENERAL.—The term ‘qualified coun-  
17 termeasures research expenses’ means the amounts  
18 which are paid or incurred by the taxpayer during  
19 the taxable year directly or indirectly to any quali-  
20 fied non-profit or academic institution for counter-  
21 measures research activities certified under section  
22 102(e) of such Act.

23 “(2) COUNTERMEASURES RESEARCH ACTIVI-  
24 TIES.—

25 “(A) IN GENERAL.—The term ‘counter-  
26 measures research activities’ means research to

1           develop countermeasures or research tools con-  
2           ducted at any qualified non-profit or academic  
3           institution in the development of any product,  
4           which occurs before—

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

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

12                  “(iii) the date classification or ap-  
13                  proval of such product which is a device in-  
14                  tended for human use is given under sec-  
15                  tion 513, 514, or 515 of the Federal Food,  
16                  Drug, and Cosmetic Act.

17           “(B) DEFINITIONS.—

18                   “(i) COUNTERMEASURES; RESEARCH  
19                   TOOLS.—The terms ‘countermeasures’ and  
20                   ‘research tools’ have the meanings given  
21                   such terms by section 3 of the Biological,  
22                   Chemical, and Radiological Weapons Coun-  
23                   termeasures Research Act of 2002.

1                   “(ii) PRODUCT.—The term ‘product’  
2                   means any drug, biologic, medical device,  
3                   or research tool.

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

8                   “(A) EDUCATIONAL INSTITUTION.—A  
9                   qualified organization described in section  
10                  170(b)(1)(A)(iii) which is owned or affiliated  
11                  with an institution of higher education as de-  
12                  scribed in section 3304(f).

13                  “(B) TEACHING HOSPITAL.—A teaching  
14                  hospital which—

15                         “(i) is publicly supported or owned by  
16                         an organization described in section  
17                         501(c)(3), and

18                         “(ii) is affiliated with an organization  
19                         meeting the requirements of subparagraph  
20                         (A).

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

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

3                   “(ii) a teaching hospital meeting the  
4                   requirements of subparagraph (B).

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

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

10                  “(4) EXCLUSION FOR AMOUNTS FUNDED BY  
11                  GRANTS, ETC.—The term ‘qualified countermeasures  
12                  research expenses’ shall not include any amount to  
13                  the extent such amount is funded by any grant, con-  
14                  tract, or otherwise by another person (or any gov-  
15                  ernmental entity).

16                  “(c) COUNTERMEASURES RESEARCH BASE PERIOD  
17                  AMOUNT.—For purposes of this section, the term ‘coun-  
18                  termeasures research base period amount’ means the aver-  
19                  age annual qualified countermeasures research expenses  
20                  paid by the taxpayer during the 3-taxable year period end-  
21                  ing with the taxable year immediately preceding the first  
22                  taxable year of the taxpayer beginning after December 31,  
23                  2002.

24                  “(d) SPECIAL RULES.—

1           “(1) LIMITATION ON FOREIGN TESTING.—No  
2 credit shall be allowed under this section with re-  
3 spect to any clinical testing research activities con-  
4 ducted outside the United States.

5           “(2) CERTAIN RULES MADE APPLICABLE.—  
6 Rules similar to the rules of subsections (f) and (g)  
7 of section 41 shall apply for purposes of this section.

8           “(3) COORDINATION WITH CREDIT FOR IN-  
9 CREASING RESEARCH EXPENDITURES AND WITH  
10 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER-  
11 TAIN DRUGS FOR RARE DISEASES.—Any qualified  
12 countermeasures research expense for a taxable year  
13 shall not be taken into account for purposes of de-  
14 termining the credit allowable under section 41 or  
15 45C for such taxable year.

16           “(4) QUALIFIED COUNTERMEASURES RE-  
17 SEARCH EXPENSES NOT TREATED AS UNRELATED  
18 BUSINESS TAXABLE INCOME.—For purposes of sec-  
19 tion 511, qualified countermeasures research ex-  
20 penses paid or incurred by the taxpayer directly or  
21 indirectly to any qualified non-profit or academic in-  
22 stitution shall not be considered unrelated business  
23 taxable income of such institution.”.

24                   (B) CREDIT TO BE PART OF GENERAL  
25 BUSINESS CREDIT.—

1 (i) IN GENERAL.—Section 38(b) of  
2 such Code (relating to current year busi-  
3 ness credits), as amended by this section,  
4 is amended by striking “plus” at the end  
5 of paragraph (15), by striking the period  
6 at the end of paragraph (16) and inserting  
7 “, plus”, and by adding at the end the fol-  
8 lowing:

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

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

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

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

1       “(e) CREDIT FOR COUNTERMEASURES RESEARCH  
2 EXPENSES.—

3           “(1) IN GENERAL.—No deduction shall be al-  
4 lowed for that portion of the qualified counter-  
5 measures research expenses (as defined in section  
6 41A(b)) otherwise allowable as a deduction for the  
7 taxable year which is equal to the amount of the  
8 credit determined for such taxable year under sec-  
9 tion 41A(a).

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

14           (D) DEDUCTION FOR UNUSED PORTION OF  
15 CREDIT.—Section 196(e) of such Code (defining  
16 qualified business credits), as amended by this  
17 section, is amended by striking “and” at the  
18 end of paragraph (10), by striking the period at  
19 the end of paragraph (11) and inserting “,  
20 and”, and by adding at the end the following  
21 new paragraph:

22           “(5) the countermeasures research expenses  
23 credit determined under section 41A(a) (other than  
24 such credit determined under the rules of section  
25 280C(e)(2)),”.

1           (E) CLERICAL AMENDMENT.—The table of  
2           sections for subpart D of part IV of subchapter  
3           A of chapter 1 of such Code is amended by  
4           adding after the item relating to section 41 the  
5           following:

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

6           (c) REPORTING; RECAPTURE.—

7           (1) REPORTING.—Each certified entity under  
8           subsection (b) shall submit to the Director and the  
9           Secretary of the Treasury such information regard-  
10          ing its election of any tax incentive under this sec-  
11          tion for the purpose certified under section 102(e) as  
12          the Director and the Secretary determine necessary  
13          to carry out the enforcement provisions prescribed  
14          under paragraph (2).

15          (2) RECAPTURE.—The Secretary of the Treas-  
16          ury, in consultation with the Director, shall provide  
17          for the recapture of any tax benefits resulting from  
18          any elected tax incentive under this section if the re-  
19          sulting research is for a purpose other than that cer-  
20          tified under section 101(e).

21          (d) EFFECTIVE DATE.—The provisions of and  
22          amendments made by this section shall apply to taxable  
23          years beginning after December 31, 2002.

1 **SEC. 202. TERROR WEAPON COUNTERMEASURE PURCHASE**

2 **FUND.**

3 (a) FINDINGS AND PURPOSE.—

4 (1) FINDINGS.—Congress finds that—

5 (A) the market for countermeasures is un-  
6 certain at best and it is not possible for private,  
7 for-profit entities to determine the prospects for  
8 a reasonable rate of return on their research  
9 and development investments relating to such  
10 countermeasures;

11 (B) such entities and their investors have  
12 reasonable concerns that they will not realize a  
13 reasonable rate of return in a market where the  
14 Federal Government has monopoly or oligopoly  
15 purchasing power;

16 (C) such entities need to know in advance,  
17 prior to undertaking the research necessary to  
18 develop a countermeasure, the nature, size, du-  
19 ration, and terms of the market that is avail-  
20 able if it is successful in such development; and

21 (D) the market and rate of return that the  
22 Federal Government guarantees for a counter-  
23 measure must be comparable to a market and  
24 rate of return that would be available to the en-  
25 tity and investors for non-countermeasure re-  
26 search.

1           (2) PURPOSE.—It is the purpose of this section  
2 to—

3           (A) establish the guaranteed market and a  
4 long-term commitment for private sector re-  
5 search that leads to the successful development  
6 of countermeasures to respond to an attack  
7 with biological and chemical agents or toxins or  
8 nuclear and radiological materials, or  
9 diagnostics or research tools with respect to  
10 such agents, toxins or materials; and

11           (B) provide advance, partial, progress or  
12 other payments to manufacturers of counter-  
13 measures, diagnostics, or research tools de-  
14 scribed in subparagraph (A).

15           (3) LIMITATION.—Private sector entities are  
16 entitled to the procurement incentives provided for  
17 in this Act (and the amendments made by this Act)  
18 only when such entities successfully develop a coun-  
19 termeasure that meets the specifications prescribed  
20 by the Secretary.

21 (b) DEFINITIONS.—In this section:

22           (1) ELIGIBLE COUNTERMEASURE, DIAGNOSTIC,  
23 OR RESEARCH TOOL.—The term “eligible counter-  
24 measure, diagnostic, or research tool” means a coun-  
25 termeasure (as defined in section 3(1)), diagnostic

1 (developed under section 103), or research tool (de-  
2 veloped under section 104)—

3 (A) that is developed by an entity that has  
4 been certified under section 102(d);

5 (B) in the case of a countermeasure, that  
6 the Secretary has determined is successful as  
7 provided for in section 101; and

8 (C) with respect to which an affirmative  
9 notice has been provided under section  
10 102(e)(3)(B), 103(e)(2), or 104(e)(2).

11 (2) FUND.—The term “Fund” means the Ter-  
12 ror Weapon Countermeasure Purchase Fund estab-  
13 lished under subsection (c).

14 (c) ESTABLISHMENT OF FUND.—There is established  
15 in the Treasury of the United States a fund to be known  
16 as the “Terror Weapon Countermeasure Purchase Fund”  
17 consisting of amounts appropriated under subsection (f).

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

23 (e) USE OF FUND.—

24 (1) IN GENERAL.—The Secretary of the Treas-  
25 ury shall expend amounts in the Fund—

1           (A) for the purchase of eligible counter-  
2           measures, diagnostics, or research tools with re-  
3           spect to which the Secretary has made an af-  
4           firmative determination as provided for in sec-  
5           tion 102(e)(3)(B), 103(e)(2), or 104(e)(2)  
6           which shall be made available to the Secretary  
7           and distributed as the Secretary, in consulta-  
8           tion with the Secretary of Health and Human  
9           Services and the Secretary of Defense, deter-  
10          mines appropriate; and

11           (B) to provide advance, partial, progress or  
12           other payments, in accordance with paragraph  
13           (4), to manufacturers of eligible counter-  
14           measures, diagnostics, or research tools with re-  
15           spect to which the Secretary has made an af-  
16           firmative determination as provided for in sec-  
17           tion 102(e)(3)(B), 103(e)(2), or 104(e)(2).

18          (2) PURCHASE.—Countermeasures, diagnostics,  
19          or research tools shall be—

20           (A) purchased by the Fund—

21           (i) in the case of a countermeasure, in  
22           the amount and at the per dosage price as  
23           described in the notice received by the enti-  
24           ty under section 102(e)(3) and in accord-

1                   ance with the contract entered into under  
2                   subparagraph (B)(i) of such section; or

3                   (ii) in the case of a diagnostic or re-  
4                   search tool, at the price and under the  
5                   terms negotiated by the Secretary and the  
6                   manufacturer; and

7                   (B) and subject to the approval of the  
8                   Food and Drug Administration if provided for  
9                   in the notice under section 102(e)(3).

10                  (3) CONDITIONS FOR PURCHASE.—Payments  
11                  made for purchases under paragraph (1)(A) shall be  
12                  made under such terms and conditions as the Sec-  
13                  retary, in consultation with the Secretary of the  
14                  Treasury, determines (in accordance with section  
15                  102) are appropriate or customary in the commer-  
16                  cial marketplace and are in the best interests of the  
17                  United States, including the provision by the manu-  
18                  facturer of adequate security for such payments. If  
19                  such security is in the form of a lien on property or  
20                  equipment in favor of the United States, such lien  
21                  shall be paramount to all other liens on such prop-  
22                  erty or equipment and shall be effective immediately  
23                  upon the first payment, without filing, notice, or  
24                  other action by the United States.

1           (4) ADVANCE, PARTIAL, PROGRESS OR OTHER  
2 PAYMENTS.—

3           (A) IN GENERAL.—The Secretary of the  
4 Treasury may make payments under paragraph  
5 (1)(B) to manufacturers of eligible counter-  
6 measures, diagnostics, or research tools prior to  
7 the final purchase of such countermeasure, di-  
8 agnostic, or research tool.

9           (B) BASIS FOR PAYMENTS.—Payments  
10 under this paragraph shall be based on—

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

19           (ii) the accomplishment of events as  
20 defined in a program management plan  
21 that is developed by the manufacturer and  
22 submitted to the Secretary of the Treas-  
23 ury; or

24           (iii) other quantifiable measures of re-  
25 sults determined appropriate by the Sec-

1           retary of the Treasury, in consultation  
2           with the Secretary.

3           (C) NUMBER, TIME, AND AMOUNT OF PAY-  
4           MENTS.—

5                   (i) IN GENERAL.—The Secretary of  
6           the Treasury, in consultation with the Sec-  
7           retary, shall, with respect to a manufac-  
8           turer of an eligible countermeasure, diag-  
9           nostic, or research tool, determine the  
10          number payments to be made, the timing  
11          of such payments, and subject to clause  
12          (ii), the amount of each such payment.

13                   (ii) LIMITATION.—The amount of any  
14          payment made to a manufacturer under  
15          this paragraph shall not exceed the amount  
16          of the final purchase price (described in  
17          paragraph (2)(A)) for the countermeasure,  
18          diagnostic, or research tool involved that  
19          remains unpaid as of the date of the pay-  
20          ment involved.

21           (D) CONDITIONS FOR PAYMENT.—The  
22          Secretary of the Treasury, in consultation with  
23          the Secretary, shall ensure that any payment to  
24          which this paragraph applies is commensurate  
25          with the actions taken by the manufacturer and

1 the progress made in achieving the performance  
2 measures under subparagraph (B)(i) through  
3 the time of such payment. The manufacturer  
4 shall provide such information and evidence as  
5 the Secretary of the Treasury and the Secretary  
6 determine is necessary to determine compliance  
7 with the preceding sentence.

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

11 (5) THIRD PARTY MANUFACTURER.—In the  
12 case of an entity that is certified under section 102  
13 and that contracts with another entity for the manu-  
14 facture of a countermeasure (as provided for in sec-  
15 tion 101(e)(2)(F)), the Secretary of the Treasury  
16 shall, after receipt of notice of such contract, ensure  
17 that payments are made to the entity at a pre-deter-  
18 mined amount to reimburse the entity for research  
19 and other administrative costs that do not include  
20 the actual manufacturing cost. Amounts for manu-  
21 facturing costs shall be passed through to the actual  
22 manufacturer.

23 (6) DISTRIBUTION.—Eligible countermeasures,  
24 diagnostics, or research tools purchased by the Fund  
25 shall be distributed as provided for by the Secretary,

1 in consultation with the Secretary of Health and  
2 Human Services, determines appropriate after—

3 (A) consideration of—

4 (i) in the case of countermeasures, the  
5 prevalence of the infection or exposure to  
6 a toxin or material to be treated by the eli-  
7 gible countermeasure; or

8 (ii) in the case of diagnostics or re-  
9 search tools, the predicted demand for the  
10 use of such diagnostics or research tools;  
11 and

12 (B) consideration of the ability of the re-  
13 cipient to effectively and safely deliver the coun-  
14 termeasures, diagnostics, or research tools.

15 (7) PUSH PACKS.—The Secretary of the  
16 Treasury may use amounts in the Fund for the pur-  
17 chase of countermeasures to be included in Federal  
18 or State government maintained PUSH Packs to be  
19 used in the case of a terror attack using chemical,  
20 biological, or radiologic toxins, agents or materials.

21 (8) RULE OF CONSTRUCTION.—Nothing in this  
22 subsection shall be construed to require that the  
23 Fund purchase more than one eligible counter-  
24 measure, diagnostic, or research tool for each agent,  
25 toxin, or material contained on the Biological and

1 Chemical Agent Priority List developed under sec-  
2 tion 101 unless the Secretary certifies entities to  
3 produce more than one such countermeasure or ad-  
4 ditional diagnostics or research tools under section  
5 102(e).

6 (9) REGULATIONS.—The Secretary shall pro-  
7 mulgate such regulations as are necessary to carry  
8 out the provisions of this subsection.

9 (f) APPROPRIATIONS.—

10 (1) IN GENERAL.—Subject to paragraph (2),  
11 there are appropriated out of any funds in the  
12 Treasury not otherwise appropriated such sums as  
13 may be necessary to carry out the purposes of the  
14 Fund for each of 10 fiscal years beginning with the  
15 first fiscal year after the date that the Secretary of  
16 the Treasury determines that any eligible counter-  
17 measure, diagnostic, or research tool is available for  
18 purchase by the Fund.

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

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

1 (g) TERMS OF CONTRACTS.—Notwithstanding any  
2 other provision of law, a multi-year contract may be en-  
3 tered into by the Secretary under this section, except that  
4 any such contract shall be for a period of not to exceed  
5 10 years.

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

11 **SEC. 203. PATENT TERM PROTECTION AND EXCLUSIVE**  
12 **MARKETING.**

13 (a) FINDINGS AND PURPOSE.—

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

16 (A) Patents are necessary to protect the  
17 inventions of entrepreneurial firms. Without  
18 patents, the inventions of these companies can  
19 be expropriated by competitors and investors'  
20 expectations of a reasonable rate of return on  
21 their investment are frustrated. In return for a  
22 limited term of protection from competitors, in-  
23 ventors are required to publish a detailed de-  
24 scription of the invention for which the patent  
25 has been granted.

1           (B) The 20 year term of a patent is meas-  
2           ured from the date of the patent application.  
3           The effective term of a patent, however, is the  
4           term remaining after an invention has been ap-  
5           proved for sale by Government regulators. Ero-  
6           sion of the term of patents for biotechnology  
7           and pharmaceutical firms, which cannot market  
8           a product until it has been approved, is com-  
9           mon and increasing. Protection against such  
10          erosion, due to delays caused by Government  
11          regulatory review, will ensure that the full term  
12          of the patent granted by the Patent and Trade-  
13          mark Office is available to the inventor to re-  
14          coup their investment. Such protections main-  
15          tain the full term of the patent.

16          (C) As an incentive for capital formation  
17          to fund research to develop countermeasures,  
18          companies and investors will respond to the  
19          prospect of being able to extend other patents  
20          in their portfolio.

21          (D) Biotechnology and pharmaceutical  
22          companies and their investors are sensitive to  
23          any possibility that successful completion of  
24          breakthrough research leading to the approval  
25          for the sale of a product, including a counter-

1           measure, will lead to challenges to their pat-  
2           ents.

3           (2) PURPOSE.—The purpose of this section is  
4           to provide patent incentives to protect inventions  
5           from expropriation by competitors and to provide an  
6           incentive for capital formation to fund counter-  
7           measures research.

8           (3) LIMITATION.—Private sector entities are  
9           entitled to the intellectual property and marketing  
10          exclusivity incentives provided for in this Act (and  
11          the amendments made by this Act) only when such  
12          entities successfully develop a countermeasure that  
13          meets the specifications of the Director and upon  
14          execution of a contract with the Secretary with re-  
15          spect to procurement of the countermeasure in ac-  
16          cordance with section 202.

17          (b) RESTORATION OF PATENT TERMS RELATING TO  
18          COUNTERMEASURES FOR CERTAIN BIOLOGICAL OR  
19          CHEMICAL AGENTS OR TOXINS OR RADIOLOGICAL MATE-  
20          RIALS.—

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

1 **“§ 156a. Restoration of patent terms relating to coun-**  
2 **termeasures for certain biological or**  
3 **chemical agents or toxins**

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

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

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

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

22 “(B) the period beginning on the date an  
23 exemption under section 505(i) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C.  
25 355(i)) became effective for the approved prod-  
26 uct and ending on the date an application was

1 initially submitted for such product under sec-  
2 tion 351 of the Public Health Service Act (42  
3 U.S.C. 262) or section 505 of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C.  
5 355); and

6 “(C) the period beginning on the date the  
7 application was initially submitted for the ap-  
8 proved product under section 351 of the Public  
9 Health Service Act (42 U.S.C. 262) or section  
10 505 of the Federal Food, Drug, and Cosmetic  
11 Act (21 U.S.C. 355) and ending on the date  
12 such application was approved under the appli-  
13 cable section; and

14 “(3) ‘Research Act’ means the Biological,  
15 Chemical, and Radiological Weapons Counter-  
16 measures Research Act of 2002.

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

19 “(1) encompasses within its scope a composition  
20 of matter, a method of using such composition, a  
21 method of manufacturing such composition, or a  
22 process for using such composition relating to a  
23 product;

1           “(2) is for an eligible countermeasure as de-  
2           fined under section 202(b)(1) of the Research Act;  
3           and

4           “(3) is held by an entity (or is exclusively li-  
5           censed to an entity by a not-for-profit organization  
6           or is exclusively licensed to an entity under section  
7           209(e) of this title or section 12(b)(7) of the Steven-  
8           son-Wydler Technology Innovation Act of 1980 (15  
9           U.S.C. 3710a(b)(1)(7)) that has entered into a con-  
10          tract for sale of that countermeasure under section  
11          102(e)(3)(B)(i) of the Research Act.

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

17          “(d) PATENT EXTENSION.—Notwithstanding any  
18          specific limitations on the terms of patent extensions  
19          under section 156, the term of a patent described under  
20          subsection (b) shall be extended under this section from  
21          the original expiration date of the patent by the period  
22          of time that is equal to the full regulatory review period  
23          for the product, and which shall include any patent term  
24          adjustment under section 154(b).

25          “(e) ADMINISTRATIVE PROVISIONS.—

1           “(1) IN GENERAL.—To obtain an extension of  
2 the term of a patent under this section, the owner  
3 of record of the patent or the agent of the owner  
4 shall submit an application to the Patent and Trade-  
5 mark Office.

6           “(2) CONTENT.—The application shall con-  
7 tain—

8                   “(A) the identity of the approved product  
9 and the Federal statute under which regulatory  
10 review occurred;

11                   “(B) the identity of the patent for which  
12 an extension applies;

13                   “(C) documentation that the product is an  
14 eligible countermeasure as defined under section  
15 202(b)(1) of the Research Act; and

16                   “(D) such patent or other information as  
17 the Office may require.

18           “(3) SUBMISSION OF APPLICATION.—An appli-  
19 cation may only be submitted within the 60-day pe-  
20 riod beginning on the date the product became eligi-  
21 ble for purchase under section 202 of the Research  
22 Act. The submission of an application under this  
23 section is an irrevocable election of the application of  
24 this section to a patent consistent with paragraph  
25 (4).



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

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

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

9 “(2) ‘Research Act’ means the Biological,  
10 Chemical, and Radiological Weapons Counter-  
11 measures Research Act of 2002.

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

16 “(c) PATENT.—

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

19 “(A) is held by an entity (or is exclusively  
20 licensed to an entity by a not-for-profit organi-  
21 zation or is exclusively licensed to an entity  
22 under section 209(e) of this title or section  
23 12(b)(7) of the Stevenson-Wydler Technology  
24 Innovation Act of 1980 (15 U.S.C.  
25 3710a(b)(1)(7)) that—

1           “(i) holds a certification under section  
2           102(e) of the Research Act with respect to  
3           a product, a method of manufacturing  
4           such product, or a method of using such  
5           product;

6           “(ii) has entered into a contract for  
7           the sale of that product or method under  
8           section 102(e)(3)(B)(i) of the Research  
9           Act; and

10           “(iii) is a qualified small business as  
11           determined under section 1202(d) of the  
12           Internal Revenue Code of 1986, by sub-  
13           stituting ‘\$750,000,000’ for ‘\$50,000,000’  
14           each place it appears;

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

18           “(2) WAIVER.—The Assistant to the President  
19           for Homeland Security may waive the requirement  
20           of paragraph (1)(A)(iii).

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

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

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

5               “(2) no redesignation of another patent may be  
6   made; and

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

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

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

13                      “(C) may not have been acquired by that  
14   entity from another entity for the purpose of  
15   the treatment of that patent under subsection  
16   (b); and

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

19       “(f) APPLICATION.—

20               “(1) IN GENERAL.—An entity that holds a cer-  
21   tification under section 102(e) of the Research Act,  
22   may file an application with the Patent and Trade-  
23   mark Office under this section.

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

1           “(A) a copy of the certification under sec-  
2           tion 102(e) of the Research Act;

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

5           “(C) a designation of the patent to which  
6           this section applies.

7           “(3) SUBMISSION OF APPLICATION.—An appli-  
8           cation may only be submitted within the 60-day pe-  
9           riod beginning on the date that the applicable prod-  
10          uct is eligible for purchase under section 202 of the  
11          Research Act.

12          “(4) IRREVOCABLE AND EXCLUSIVE.—

13           “(A) IRREVOCABLE ELECTION.—A filing of  
14           an application under this section is an irrev-  
15           ocable election of the application of this section  
16           to a patent consistent with subparagraph (B).

17           “(B) EXCLUSIVE.—Sections 156 and 156a  
18           shall not apply to any patent for which there is  
19           a filing under this section. This section shall  
20           not apply to any patent the term of which has  
21           been extended under section 156.”.

22          (2) TECHNICAL AND CONFORMING AMEND-  
23          MENT.—The table of sections for chapter 14 of title  
24          35, United States Code, is amended by adding at  
25          the end the following:

“158. Patent term for patents held by entities with certain research certifications.”.

1 (d) EXCLUSIVE LICENSING.—

2 (1) IN GENERAL.—Notwithstanding sections  
3 200, 203, and 209 of title 35, United States Code,  
4 an entity that holds a certification under section  
5 102(e) with respect to a product that is an eligible  
6 countermeasure as defined under section 202(b)(1)  
7 may exclusively license such patented product.

8 (2) FEDERALLY OWNED INVENTIONS.—Section  
9 209 of title 35, United States Code, is amended—

10 (A) by redesignating subsections (e) and  
11 (f) as subsections (f) and (g), respectively; and

12 (B) by inserting after subsection (d) the  
13 following:

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

21 (3) COOPERATIVE RESEARCH AND DEVELOP-  
22 MENT AGREEMENTS.—Section 12(b) of the Steven-  
23 son-Wydler Technology Innovation Act of 1980 (15

1 U.S.C. 3710a(b)) is amended by adding at the end  
2 the following:

3 “(7) Each exclusive license for a patent granted  
4 under an agreement entered into under subsection  
5 (a)(1) shall include a provision that, at the discre-  
6 tion of the licensee, the licensee may act as the  
7 agent for the licensor with respect to that patent for  
8 purposes of extending a patent under section 156a  
9 or 158 of title 35, United States Code.”.

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

14 (e) EXCLUSIVE MARKETING.—Subchapter A of chap-  
15 ter V of the Federal Food, Drug, and Cosmetic Act (21  
16 U.S.C. 351 et seq.) is amended by inserting after section  
17 505A, the following:

18 **“SEC. 505B. MARKET EXCLUSIVITY FOR TERROR WEAPONS**  
19 **COUNTERMEASURES.**

20 “(a) IN GENERAL.—If, prior to approval of an appli-  
21 cation that is submitted under section 505(b)(1), the Sec-  
22 retary determines that the new drug involved is a counter-  
23 measure (as defined in section 3(1) of the Biological,  
24 Chemical, and Radiological Weapons Countermeasures  
25 Research Act of 2002) that meets the requirements of

1 subparagraphs (A) through (C) of section 202(b)(1) of  
2 such Act, the provisions of subsection (b) shall apply.

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

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

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

18 “(B) if the drug is designated under section  
19 526 for a rare disease or condition, the period re-  
20 ferred to in section 527(a) is deemed to be 10 years  
21 rather than seven years; and

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

23 “(i) a listed patent for which a certification  
24 has been submitted under subsection

1 (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505;

2 or

3 “(ii) a listed patent for which a certifi-  
4 cation has been submitted under subsections  
5 (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section  
6 505,

7 the period during which an application may not be  
8 approved under section 505(c)(3) or section  
9 505(j)(4)(B) shall be extended by a period of 5  
10 years after the date the patent expires (including  
11 any patent extensions); or

12 “(B) if the drug is the subject of a listed patent  
13 for which a certification has been submitted under  
14 subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of sec-  
15 tion 505, and in the patent infringement litigation  
16 resulting from the certification the court determines  
17 that the patent is valid and would be infringed, the  
18 period during which an application may not be ap-  
19 proved under section 505(c)(3) or section  
20 505(j)(4)(B) shall be extended by a period of 5  
21 years after the date the patent expires (including  
22 any patent extensions).”.

23 **SEC. 204. LIABILITY AND INDEMNIFICATION.**

24 (a) FINDINGS AND PURPOSE.—

1           (1) FINDINGS.—Congress makes the following  
2 findings:

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

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

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

1           lies with biotechnology and pharmaceutical com-  
2           panies.

3           (2) PURPOSE.—It is the purpose of this section  
4           to provide liability protections to encourage compa-  
5           nies to conduct research to develop and produce  
6           countermeasures.

7           (3) LIMITATION.—Upon a determination by the  
8           Secretary that it is in the national security interest  
9           of the United States under section 101(e) of this  
10          act, private sector entities are entitled to the liability  
11          protections provided for in this section (and the  
12          amendments made by this section) only when such  
13          entities successfully develop a countermeasure that  
14          meets the specifications of the Secretary and upon  
15          the execution of a contract with the Secretary with  
16          respect to procurement of the countermeasure in ac-  
17          cordance with section 202.

18          (b) INDEMNIFICATION AND DEFENSE AGREE-  
19          MENTS.—Notwithstanding sections 1341, 1342, 1349,  
20          1350, and 1351 and subchapter II of chapter 15, of title  
21          31, United States Code, or any other provision of law, the  
22          Secretary—

23                 (1) shall enter into agreements to indemnify  
24                 and defend persons or entities engaged in the re-  
25                 search, development, and production of counter-

1 measures, diagnostics, or research tools purchased  
2 under section 202;

3 (2) shall enter into agreements to indemnify  
4 and defend persons or entities from claims or civil  
5 actions arising from human clinical trials and re-  
6 search, development, and production of counter-  
7 measures developed under a certification under sec-  
8 tion 102; and

9 (3) may enter into such agreements with other  
10 persons and entities relating to such counter-  
11 measures, diagnostics, or research tools (including  
12 individuals and entities engaged in the administra-  
13 tion or use of such countermeasures, diagnostics, or  
14 research tools), whether or not listed as a counter-  
15 measure by the Secretary under section 101, if the  
16 Secretary determines that the national interest in  
17 combating terrorism, or the protection of the public  
18 health, or both, reasonably requires such an agree-  
19 ment.

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

1 research, development, production, or use of a counter-  
2 measure, diagnostic, or research tool purchased under sec-  
3 tion 202 or for claims or civil actions or research relating  
4 to countermeasures developed under a certification under  
5 section 102. Such contracts and protection against claims  
6 or civil actions shall apply only when the manufacturer  
7 of the countermeasure has entered into a contract with  
8 the Secretary, for procurement of the countermeasure in  
9 accordance with section 202. Such contracts and protec-  
10 tion against claims or civil actions shall apply only to the  
11 administration or use of a countermeasure, diagnostic, or  
12 research tool by the Federal Government or another entity  
13 with respect to a biological agent or toxin or a nuclear  
14 or radiological material used as a terror weapon.

15 (d) EXCLUSIVE REMEDY.—This section shall con-  
16 stitute the exclusive remedy with respect to a civil action  
17 filed against persons or entities within the scope of an in-  
18 demnification and defense agreement entered into under  
19 subsection (b), for damages (including bodily injury,  
20 death, economic losses, non-economic losses or damage to  
21 property or punitive damages), to the extent that the civil  
22 action arises from the research, development, production,  
23 or use of a countermeasure, diagnostic, or research tool  
24 described in such subsection.

1 (e) REQUIREMENTS.—An indemnification and de-  
2 fense agreement under this section shall—

3 (1) require notice to be provided to the United  
4 States of any claim or civil action (including an ex-  
5 clusive civil action) that is filed against persons or  
6 entities who are parties to such agreement for any  
7 alleged damages (including bodily injury, death, eco-  
8 nomic losses, non-economic losses, and loss of or  
9 damage to property or punitive damages) allegedly  
10 caused by the research, development, production,  
11 distribution, administration or use of a counter-  
12 measure, diagnostic, or research tool described in  
13 subsection (b); and

14 (2) require control of, or assistance in, the de-  
15 fense by the United States of such claim or civil ac-  
16 tion.

17 (f) VENUE; APPLICATION OF LAW; AND DAMAGES.—

18 (1) VENUE.—An exclusive civil action under  
19 this section shall be filed in any United States dis-  
20 trict court of otherwise appropriate jurisdiction. Ap-  
21 peals from appealable actions of such courts in such  
22 actions shall be taken to the Court of Appeals for  
23 the Federal Circuit and, as appropriate, to the  
24 United States Supreme Court.

1           (2) APPLICATION OF LAW.—An exclusive civil  
2           action filed under this section shall be governed by  
3           Federal law. No State or political subdivision of a  
4           State shall have any authority to enforce any other  
5           law or common law standard governing a civil action  
6           for damages (including damages for bodily injury,  
7           death, economic damages, noneconomic damages, or  
8           loss or damage to property or punitive damages)  
9           arising out of the conduct or actions covered by an  
10          indemnification and defense agreement. Any civil ac-  
11          tion in State or Federal Court that is barred from  
12          consideration by this section shall be removed or  
13          transferred to the appropriate Federal district court  
14          or dismissed, as appropriate.

15          (3) LIMITATIONS ON DAMAGES.—In an exclu-  
16          sive civil action filed under this section an award for  
17          non-economic damages shall not exceed 3 times the  
18          award for economic damages or \$250,000 per plain-  
19          tiff, whichever is greater. In no such cases shall pu-  
20          nitive or exemplary damages be awarded.

21          (4) REDUCTION IN AMOUNTS.—In an exclusive  
22          civil action under this section, an award to a plain-  
23          tiff shall be reduced, by the presiding judge, to the  
24          extent that the plaintiff has otherwise received reim-  
25          bursement for the damages at issue from the Fed-

1 eral Government or health care insurance provider  
2 for medical expenses.

3 (g) LIMITATIONS.—The protections provided for in  
4 this section shall not apply in the case of an entity de-  
5 scribed in subsection (b)(1) if—

6 (1) such entity fails to enter into a contract  
7 with the Secretary for the purchase of a counter-  
8 measure, diagnostic, or research tool developed or  
9 produced under title I; or

10 (2) such entity fails to comply with the terms  
11 of a contract described in paragraph (1).

12 (h) DEFINITIONS.—In this section:

13 (1) EXCLUSIVE CIVIL ACTION.—The term “ex-  
14 clusive civil action” means a civil action described in  
15 subsection (c)(1).

16 (2) INDEMNIFICATION AND DEFENSE AGREE-  
17 MENTS.—The term “indemnification and defense  
18 agreements” means the agreements described in  
19 subsection (b).

## 20 **Subtitle B—Other Incentives**

### 21 **SEC. 211. ACCELERATED APPROVAL OF COUNTER-** 22 **MEASURES.**

23 (a) IN GENERAL.—The Secretary of Health and  
24 Human Services may designate a countermeasure as a  
25 fast-track product pursuant to section 506 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 356) or as a  
2 device granted priority review pursuant to section  
3 515(d)(5) of such Act (21 U.S.C. 366e(d)(5)). Such a des-  
4 ignation may be made prior to the submission of—

5 (1) a request for designation by the sponsor or  
6 applicant; or

7 (2) an application for the investigation of the  
8 drug under section 505(i) of such Act or section  
9 351(a)(3) of the Public Health Service Act.

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

12 (b) USE OF ANIMAL TRIALS.—A drug for which ap-  
13 proval is sought under section 505(d) of the Federal Food,  
14 Drug, and Cosmetic Act or section 351 of the Public  
15 Health Service Act on the basis of evidence of effectiveness  
16 that is derived from animal studies under section 212 may  
17 be designated as a fast track product for purposes of this  
18 section.

19 (c) PRIORITY REVIEW.—

20 (1) IN GENERAL.—A countermeasure that is a  
21 drug or biological product shall be subject to the  
22 performance goals established by the Commissioner  
23 of Food and Drugs for priority drugs or biological  
24 products.

1           (2) DEFINITION.—In this subsection the term  
2           “priority drugs or biological products” means a drug  
3           or biological product that is the subject of a drug  
4           application referred to in section 101(4) of the Food  
5           and Drug Administration Modernization Act of  
6           1997.

7   **SEC. 212. APPROVALS OF CERTAIN DRUGS BASED ON ANI-**  
8                                   **MAL TRIALS.**

9           (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—  
10          Section 505(d) of the Federal Food, Drug, and Cosmetic  
11          Act (21 U.S.C. 355(d)) is amended by adding at the end  
12          the following: “In the case of drugs and diagnostic devices  
13          for use against lethal or permanently disabling toxic chem-  
14          ical, biological, radiological, nuclear, or other substances,  
15          when adequate and well-controlled studies of effectiveness  
16          in humans cannot ethically be conducted because the stud-  
17          ies would involve administering a potentially lethal or per-  
18          manently disabling toxic substance or organism to healthy  
19          human volunteers, and when adequate field trials assess-  
20          ing use of the drug or diagnostic device (in situations such  
21          as after accidental or hostile exposure to the substance)  
22          have not been feasible or where adequate volumes of  
23          human samples for diagnosis from previous exposures is  
24          not available, the Secretary may grant approval based on  
25          evidence of effectiveness derived from appropriate studies

1 in animals. The Secretary may promulgate regulations es-  
2 tablishing standards, criteria, and procedures for use of  
3 the authority contained in the preceding sentence.”.

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

7 “(k) APPROVAL OF CERTAIN PRODUCTS AND DIAG-  
8 NOSTIC DEVICES BASED ON ANIMAL TRIALS.—In the  
9 case of biological products and diagnostic devices for use  
10 against lethal or permanently disabling toxic chemical, bio-  
11 logical, radiological, nuclear, or other substances, when de-  
12 finitive human effectiveness studies in humans cannot  
13 ethically be conducted because the studies would involve  
14 administering a potentially lethal or permanently disabling  
15 toxic substance or organism to healthy human volunteers,  
16 and when adequate field trials assessing use of the drug  
17 (in situations such as after accidental or hostile exposure  
18 to the substance) have not been feasible, the Secretary  
19 may grant approval based on evidence of effectiveness de-  
20 rived from appropriate studies in animals. The Secretary  
21 may promulgate regulations establishing standards, cri-  
22 teria, and procedures for use of the authority provided  
23 under this subsection.”.

1 **SEC. 213. LIMITED ANTITRUST EXEMPTION.**

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

4 “(g) LIMITED ANTITRUST EXEMPTION.—

5 “(1) COUNTERMEASURES DEVELOPMENT MEET-  
6 INGS.—

7 “(A) COUNTERMEASURES DEVELOPMENT  
8 MEETINGS AND CONSULTATIONS.—The Sec-  
9 retary may conduct meetings and consultations  
10 with parties involved in the development of  
11 countermeasures for the purpose of the develop-  
12 ment, manufacture, distribution, purchase, or  
13 sale of countermeasures consistent with the  
14 purposes of this title. The Secretary shall give  
15 notice of such meetings and consultations to the  
16 Attorney General and the Chairperson of the  
17 Federal Trade Commission (referred to in this  
18 subsection as the ‘Chairperson’).

19 “(B) MEETING AND CONSULTATION CON-  
20 DITIONS.—A meeting or consultation conducted  
21 under subparagraph (A) shall—

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

24 “(ii) be open to parties involved in the  
25 development, manufacture, distribution,

1 purchase, or sale of countermeasures, as  
2 determined by the Secretary;

3 “(iii) be open to the Attorney General  
4 and the Chairperson;

5 “(iv) be limited to discussions involv-  
6 ing the development, manufacture, dis-  
7 tribution, or sale of countermeasures, con-  
8 sistent with the purposes of this title; and

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

13 “(C) MINUTES.—The Secretary shall  
14 maintain minutes of meetings and consultations  
15 under this subsection, which shall not be dis-  
16 closed under section 552 of title 5, United  
17 States Code.

18 “(D) EXEMPTION.—The antitrust laws  
19 shall not apply to meetings and consultations  
20 under this paragraph, except that any agree-  
21 ment or conduct that results from a meeting or  
22 consultation and that does not receive an ex-  
23 emption pursuant to this subsection shall be  
24 subject to the antitrust laws.

1           “(2) WRITTEN AGREEMENTS.—The Secretary  
2 shall file a written agreement regarding covered ac-  
3 tivities, made pursuant to meetings or consultations  
4 conducted under paragraph (1) and that is con-  
5 sistent with this paragraph, with the Attorney Gen-  
6 eral and the Chairperson for a determination of the  
7 compliance of such agreement with antitrust laws.  
8 In addition to the proposed agreement itself, any  
9 such filing shall include—

10           “(A) an explanation of the intended pur-  
11           pose of the agreement;

12           “(B) a specific statement of the substance  
13           of the agreement;

14           “(C) a description of the methods that will  
15           be utilized to achieve the objectives of the  
16           agreement;

17           “(D) an explanation of the necessity of a  
18           cooperative effort among the particular partici-  
19           pating parties to achieve the objectives of the  
20           agreement; and

21           “(E) any other relevant information deter-  
22           mined necessary by the Secretary in consulta-  
23           tion with the Attorney General and the Chair-  
24           person.

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

5                   “(A) be in compliance with the antitrust  
6                   laws, and so inform the Secretary and the par-  
7                   ticipating parties; or

8                   “(B) violate the antitrust laws, in which  
9                   case, the filing shall be deemed to be a request  
10                  for an exemption from the antitrust laws, lim-  
11                  ited to the performance of the agreement con-  
12                  sistent with the purposes of this title.

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

14                   “(A) IN GENERAL.—The Attorney General,  
15                   in consultation with the Chairperson, shall  
16                   grant, deny, grant in part and deny in part, or  
17                   propose modifications to a request for exemp-  
18                   tion from the antitrust laws under paragraph  
19                   (3) within 15 days of the receipt of such re-  
20                   quest.

21                   “(B) EXTENSION.—The Attorney General  
22                   may extend the 15-day period referred to in  
23                   subparagraph (A) for an additional period of  
24                   not to exceed 10 days. Such additional period  
25                   may be further extended only by the United

1 States district court, upon an application by the  
2 Attorney General after notice to the Secretary  
3 and the parties involved.

4 “(C) DETERMINATION.—In granting an  
5 exemption under this paragraph, the Attorney  
6 General, in consultation with the Chairperson  
7 and the Secretary—

8 “(i) must find—

9 “(I) that the agreement involved  
10 is necessary to ensure the availability  
11 of countermeasures;

12 “(II) that the exemption from  
13 the antitrust laws would promote the  
14 public interest; and

15 “(III) that there is no substantial  
16 competitive impact to areas not di-  
17 rectly related to the purposes of the  
18 agreement; and

19 “(ii) may consider any other factors  
20 determined relevant by the Attorney Gen-  
21 eral and the Chairperson.

22 “(5) LIMITATION ON AND RENEWAL OF EXEMP-  
23 TIONS.—An exemption granted under paragraph (4)  
24 shall be limited to covered activities, and shall expire  
25 on the date that is 3 years after the date on which

1 the exemption becomes effective (and at 3 year in-  
2 tervals thereafter, if renewed) unless the Attorney  
3 General in consultation with the Chairperson deter-  
4 mines that the exemption should be renewed (with  
5 modifications, as appropriate) considering the fac-  
6 tors described in paragraph (4).

7 “(6) LIMITATION ON PARTIES.—The use of any  
8 information acquired under an exempted agreement  
9 by the parties to such an agreement for any pur-  
10 poses other than those specified in the antitrust ex-  
11 emption granted by the Attorney General shall be  
12 subject to the antitrust laws and any other applica-  
13 ble laws.

14 “(7) GUIDELINES.—The Attorney General and  
15 the Chairperson may develop and issue guidelines to  
16 implement this subsection.

17 “(8) REPORT.—Not later than 1 year after the  
18 date of enactment of the Biological, Chemical, and  
19 Radiological Weapons Countermeasures Research  
20 Act of 2002, and annually thereafter, the Attorney  
21 General and the Chairperson shall report to Con-  
22 gress on the use and continuing need for the exemp-  
23 tion from the antitrust laws provided by this sub-  
24 section.

1           “(9) SUNSET.—The authority of the Attorney  
2           General to grant or renew a limited antitrust exemp-  
3           tion under this subsection shall expire at the end of  
4           the 10-year period that begins on the date of enact-  
5           ment of the Biological, Chemical, and Radiological  
6           Weapons Countermeasures Research Act of 2002.

7           “(h) DEFINITIONS.—In this section:

8           “(1) ANTITRUST LAWS.—The term ‘antitrust  
9           laws’—

10                   “(A) has the meaning given such term in  
11                   subsection (a) of the first section of the Clayton  
12                   Act (15 U.S.C. 12(a)), except that such term  
13                   includes the Act of June 19, 1936 (15 U.S.C.  
14                   13 et seq.) commonly known as the Robinson-  
15                   Patman Act), and section 5 of the Federal  
16                   Trade Commission Act (15 U.S.C. 45) to the  
17                   extent such section 5 applies to unfair methods  
18                   of competition; and

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

21           “(2) COUNTERMEASURE.—The term ‘counter-  
22           measure’ has the meaning given such term in section  
23           3(2) of the Biological, Chemical, and Radiological  
24           Weapons Countermeasures Research Act of 2002.

25           “(3) COVERED ACTIVITIES.—

1           “(A) IN GENERAL.—Except as provided in  
2           subparagraph (B), the term ‘covered activities’  
3           means any group of activities or conduct, in-  
4           cluding attempting to make, making, or per-  
5           forming a contract or agreement or engaging in  
6           other conduct, for the purpose of—

7                   “(i) theoretical analysis, experimen-  
8                   tation, or the systematic study of phe-  
9                   nomena or observable facts necessary to  
10                  the development of countermeasures;

11                  “(ii) the development or testing of  
12                  basic engineering techniques necessary to  
13                  the development of countermeasures;

14                  “(iii) the extension of investigative  
15                  findings or theory of a scientific or tech-  
16                  nical nature into practical application for  
17                  experimental and demonstration purposes,  
18                  including the experimental production and  
19                  testing of models, prototypes, equipment,  
20                  materials, and processes necessary to the  
21                  development of countermeasures;

22                  “(iv) the production, distribution, or  
23                  marketing of a product, process, or service  
24                  that is a countermeasures;

1           “(v) the testing in connection with the  
2           production of a product, process, or serv-  
3           ices necessary to the development of coun-  
4           termeasures;

5           “(vi) the collection, exchange, and  
6           analysis of research or production informa-  
7           tion necessary to the development of coun-  
8           termeasures; or

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

11          and such term may include the establishment  
12          and operation of facilities for the conduct of  
13          covered activities described in clauses (i)  
14          through (vi), the conduct of such covered activi-  
15          ties on a protracted and proprietary basis, and  
16          the processing of applications for patents and  
17          the granting of licenses for the results of such  
18          covered activities.

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

22               “(i) Exchanging information among  
23               competitors relating to costs, sales, profit-  
24               ability, prices, marketing, or distribution of  
25               any product, process, or service if such in-

1 formation is not reasonably necessary to  
2 carry out the purposes of covered activi-  
3 ties.

4 “(ii) Entering into any agreement or  
5 engaging in any other conduct—

6 “(I) to restrict or require the  
7 sale, licensing, or sharing of inven-  
8 tions, developments, products, proc-  
9 esses, or services not developed  
10 through, produced by, or distributed  
11 or sold through such covered activi-  
12 ties; or

13 “(II) to restrict or require par-  
14 ticipation by any person who is a  
15 party to such covered activities in  
16 other research and development activi-  
17 ties, that is not reasonably necessary  
18 to prevent the misappropriation of  
19 proprietary information contributed  
20 by any person who is a party to such  
21 covered activities or of the results of  
22 such covered activities.

23 “(iii) Entering into any agreement or  
24 engaging in any other conduct allocating a  
25 market with a competitor that is not ex-

1            expressly exempted from the antitrust laws  
2            by a determination under subsection (i)(4).

3            “(iv) Exchanging information among  
4            competitors relating to production (other  
5            than production by such covered activities)  
6            of a product, process, or service if such in-  
7            formation is not reasonably necessary to  
8            carry out the purpose of such covered ac-  
9            tivities.

10           “(v) Entering into any agreement or  
11           engaging in any other conduct restricting,  
12           requiring, or otherwise involving the pro-  
13           duction of a product, process, or service  
14           that is not so expressly exempted from the  
15           antitrust laws by a determination under  
16           subsection (i)(4).

17           “(vi) Except as otherwise provided in  
18           this subsection, entering into any agree-  
19           ment or engaging in any other conduct to  
20           restrict or require participation by any per-  
21           son who is a party to such activities, in  
22           any unilateral or joint activity that is not  
23           reasonably necessary to carry out the pur-  
24           pose of such covered activities.

1           “(4) DEVELOPMENT.—The term ‘development’  
2 includes the identification of suitable compounds or  
3 biological materials, the conduct of preclinical and  
4 clinical studies, the preparation of an application for  
5 marketing approval, and any other actions related to  
6 preparation of a countermeasure.

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

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

12 **SEC. 214. BIOLOGICS MANUFACTURING CAPACITY INCEN-**  
13 **TIVES.**

14           (a) FINDINGS.—Congress makes the following find-  
15 ings:

16           (1) When the United States develops new bio-  
17 logically derived materials, including vaccines,  
18 monoclonal antibodies, and recombinant proteins, to  
19 prevent infection by bioterrorist agents or toxins or  
20 to treat those infected in bioterrorist attacks, a  
21 shortage of manufacturing facilities for biologics  
22 may delay or prevent the production and stockpiling  
23 of such materials.

24           (2) There is a serve shortage of manufacturing  
25 capacity to produce such materials. There are nearly

1 100 biologics in clinical trials, and current manufac-  
2 turing capacity is 475,000 liters, virtually all of  
3 which is utilized. An additional 1,100,000 liters of  
4 capacity will come online by the end of 2006, but  
5 civilian demand will continue to outstrip capacity.  
6 There is little or no available capacity to produce  
7 such biologically derived materials to treat those who  
8 might be infected by bioterror agents.

9 (3) The Defense Science Board has found “Any  
10 bioterrorism attack that created the need to treat  
11 more than 50,000 people with an extended course of  
12 antibiotic therapy...or to immunize more than 1 to  
13 3 million people with a vaccine would completely  
14 overwhelm the total production capacity of the in-  
15 dustry.” The Federal Government “must establish a  
16 proactive long-term plan to address these inventory  
17 and production shortfalls”.

18 (4) A typical manufacturing facility costs be-  
19 tween \$200,000,000 and \$400,000,000 to build, and  
20 there is no incentive for companies to build these fa-  
21 cilities until a product has been developed and ap-  
22 proved. On average, a plant takes 4 years to build,  
23 considering the intricacies of the process and the  
24 necessary Food and Drug Administration proce-  
25 dures.

1           (5) Biotechnology and pharmaceutical compa-  
2           nies have no reason to fund the construction of bio-  
3           logics manufacturing facilities unless and until there  
4           is a market demand for the facilities.

5           (6) The incentives provided under this Act, and  
6           the amendments made by this Act, should lead to  
7           the development of new biologically derived materials  
8           to prevent and treat bioterrorist attacks and deci-  
9           sions to purchase, stockpile and perhaps deploy such  
10          materials.

11          (7) It is in the national interest for the United  
12          States to provide incentives for the construction of  
13          sufficient biologics manufacturing facilities so that  
14          there will be no delay in the production of bio-  
15          logically active materials once such materials are de-  
16          veloped.

17          (b) SURVEY AND PLAN.—Not later than 90 days  
18          after the date of enactment of this Act, the Secretary  
19          shall—

20                (1) conduct a survey of the biologics manufac-  
21                turing facilities operating in the United States and  
22                determine whether additional manufacturing facili-  
23                ties that will be needed (and if so the number of  
24                such facilities) to manufacture and stockpile bio-  
25                logically active materials for bioterrorist attacks; and

1           (2) develop a plan to ensure that sufficient bio-  
2           logics manufacturing facilities are available in the  
3           United States when they are needed, including an  
4           analysis of the feasibility of the Federal Government  
5           contracting for the construction of such facilities or  
6           of providing tax and other incentives for the con-  
7           struction of such facilities by private sector entities.

8           (c) SUBMISSION TO CONGRESS.—The Secretary shall  
9           submit the plan developed under subsection (b)(2) to Con-  
10          gress together with recommendations concerning the man-  
11          ner in which to ensure that the needed biologics manufac-  
12          turing facilities available for the production of counter-  
13          measures under this Act are constructed and available, in-  
14          cluding the siting, design and certification costs, costs of  
15          training and recruitment of expert staff, and other costs  
16          associated with such facilities.

17          (d) INCENTIVES FOR THE CONSTRUCTION OF BIO-  
18          LOGICS MANUFACTURING FACILITIES AVAILABLE FOR  
19          THE PRODUCTION OF COUNTERMEASURES.—

20               (1) IN GENERAL.—The Secretary shall issue  
21               regulations regarding the selection of an entity that  
22               agrees to operate as a biologics manufacturing facil-  
23               ity available for the production of countermeasures  
24               under this Act in accordance with the plan developed  
25               under subsection (b)(2) for the investment tax credit

1 provided under paragraph (2). Such regulations  
2 shall state when such an entity shall be available  
3 and the terms for the use for the production of such  
4 countermeasures. If an entity is constructed to  
5 produce such countermeasures, such entity shall pro-  
6 vide notice that such entity is available to produce  
7 such countermeasures.

8 (2) BIOLOGICS MANUFACTURING FACILITIES IN-  
9 VESTMENT TAX CREDIT.—

10 (A) ALLOWANCE OF CREDIT.—Section  
11 46(a) of the Internal Revenue Code of 1986  
12 (relating to amount of investment credit) is  
13 amended by striking “and” at the end of para-  
14 graph (2), by striking the period at the end of  
15 paragraph (3) and inserting “, and”, and by  
16 adding at the end the following new paragraph:  
17 “(4) the biologics manufacturing facilities in-  
18 vestment credit.”.

19 (B) AMOUNT OF CREDIT.—Section 48 of  
20 such Code is amended by adding at the end the  
21 following new subsection:

22 “(c) BIOLOGICS MANUFACTURING FACILITIES IN-  
23 VESTMENT CREDIT.—

24 “(1) IN GENERAL.—For purposes of section 46,  
25 in the case of any entity selected under section

1 214(d)(1) of the Biological, Chemical, and Radio-  
2 logical Weapons Countermeasures Research Act of  
3 2002, the biologics manufacturing facilities invest-  
4 ment credit for any taxable year is an amount equal  
5 to 20 percent of the qualified investment for such  
6 taxable year.

7 “(2) QUALIFIED INVESTMENT.—For purposes  
8 of paragraph (1), the qualified investment for any  
9 taxable year is the basis of each biologics manufac-  
10 turing facilities property placed in service by the tax-  
11 payer during such taxable year.

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

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

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

20 “(B) which is depreciable under section  
21 167, and

22 “(C) which is used for the manufacture,  
23 distribution, or research and development of  
24 vaccines and other biologics.

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

7           (C) TECHNICAL AMENDMENTS.—

8           (i) Subparagraph (C) of section  
 9           49(a)(1) of such Code is amended by strik-  
 10          ing “and” at the end of clause (ii), by  
 11          striking the period at the end of clause (iii)  
 12          and inserting “, and”, and by adding at  
 13          the end the following new clause:

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

16          (ii) Subparagraph (E) of section  
 17          50(a)(2) of such Code is amended by strik-  
 18          ing “section 48(a)(5)(A)” and inserting  
 19          “section 48(a)(5) or 48(c)(4)”.

20          (iii)(I) The section heading for section  
 21          48 of such Code is amended to read as fol-  
 22          lows:

23         **“SEC. 48. OTHER CREDITS.”.**

24                 (II) The table of sections for subpart  
 25                 E of part IV of subchapter A of chapter 1

1 of such Code is amended by striking the  
2 item relating to section 48 and inserting  
3 the following:

“Sec. 48. Other Credits.”.

4 (e) PREEMPTION OF ZONING LAWS FOR SITING OF  
5 BIOLOGICS MANUFACTURING FACILITIES.—The provi-  
6 sions of this section relating to the operation and location  
7 of biologics manufacturing facilities, in accordance with  
8 the plan developed under subsection (b)(2), shall preempt  
9 State and local laws relating to zoning. State and local  
10 laws relating to the construction and maintenance of such  
11 facilities shall be preempted to the extent that such laws  
12 conflict with such plan and the purposes of this section.

13 **SEC. 215. BIOLOGICS MANUFACTURING EFFICIENCY INCEN-**  
14 **TIVES.**

15 (a) FINDINGS.—Congress finds that—

16 (1) the manufacturing of biologics, which are  
17 living organisms, is an art as well as a science;

18 (2) the efficiency of the biologics manufacturing  
19 process determines the output capacity, purity, and  
20 manufacturing cost of vaccines;

21 (3) technical advances in manufacturing  
22 sciences for biologics can increase the capacity of the  
23 Federal Government to ensure that vaccines are  
24 available as part of a bioterror plan and to reduce

1 the cost of manufacturing and stockpiling these vac-  
2 cines; and

3 (4) the subjects of research relating to the man-  
4 ufacturing of biologics may include the development  
5 of—

6 (A) additional well characterized cell lines  
7 for vaccine and monoclonal antibody produc-  
8 tion;

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

12 (C) improved preservatives for vaccines or  
13 other biologics to prolong shelf-life;

14 (D) adjuvants that enhance the immune  
15 response to a vaccine or antigen;

16 (E) tests to determine contamination with  
17 human or animal viruses or prions;

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

21 (G) improved characterization of biologics  
22 at the macro-molecular level;

23 (H) processes that enhance the yield and  
24 quality of biologics;

1 (I) improved methods that enhance dis-  
2 infection and sterilization of material and facili-  
3 ties;

4 (J) new methods to improve output, manu-  
5 facturing costs, and product quality with a par-  
6 ticular emphasis on downstream processing  
7 (separation and purification) where particular  
8 bottlenecks occur with much lost product, com-  
9 plexity and very high costs; and

10 (K) improved methods for decontamination  
11 of production of facilities to enable switching  
12 from one product to another.

13 (b) SURVEY AND PLAN.—Not later than 90 days  
14 after the date of enactment of this Act, the Secretary  
15 shall—

16 (1) conduct a survey of existing biologics manu-  
17 facturing sciences and determine whether technical  
18 advances in such sciences might increase the bio-  
19 logics output capacity and purity, and lower the  
20 manufacturing cost of vaccines; and

21 (2) develop a plan to provide incentives to en-  
22 hance scientific research to develop new technologies  
23 identified under the survey conducted under para-  
24 graph (1), including a list of the possible tech-

1 nologies that may be developed and the possible in-  
2 centives that may lead to their development.

3 (c) SUBMISSION TO CONGRESS.—The Secretary shall  
4 submit the plan developed under subsection (b)(2) to Con-  
5 gress together with recommendations concerning the pro-  
6 vision of funding or incentives for the conduct of scientific  
7 research to develop new technologies relating to biologics  
8 manufacturing sciences.

9 (d) INCENTIVES.—The Secretary shall establish a  
10 program under which entities that agree to develop new  
11 technologies in accordance with the plan developed under  
12 subsection (b)(2) are eligible for the tax incentives pro-  
13 vided for under the amendments made by section 201.

14 **SEC. 216. 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 can be handled safely;

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

22 (3) the Federal Government can facilitate re-  
23 search and development of countermeasures by fi-  
24 nancing the construction of these special facilities.

25 (b) GRANTS AUTHORIZED.—

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

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

7           (A) allow use of the facility involved by  
8 only those researchers who meet qualifications  
9 set by the Secretary;

10           (B) give priority for the use of the facility  
11 involved to those entities that have been reg-  
12 istered and certified by the Secretary to develop  
13 countermeasures; and

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

16           (3) NUMBER OF GRANTS.—The Secretary of  
17 the Department of Homeland Defense shall deter-  
18 mine the number of facilities that need to be con-  
19 structed under this section, not to exceed 10 such  
20 facilities nationwide, and the Secretary shall award  
21 grants based on such determination.

22           (c) APPLICATION.—

23           (1) IN GENERAL.—To be eligible to receive a  
24 grant under this section an entity shall submit to  
25 the Secretary an application at such time, in such

1 form and containing such information, as the Sec-  
2 retary may require.

3 (2) CONTENTS.—Each application submitted  
4 pursuant to paragraph (1) shall—

5 (A) provide detailed information on the  
6 technical specifications of proposed facilities;

7 (B) propose a design that includes offices  
8 for personnel, visiting researchers, and facilities  
9 for research and laboratory materials;

10 (C) provide assurances that the facilities  
11 shall be available on a fee-for-service or other  
12 basis to companies and academic researchers;  
13 and

14 (D) provide assurances that the facilities  
15 will be constructed as secure facilities.

16 (d) DEFINITIONS.—For the purposes of this sec-  
17 tion—

18 (1) unless otherwise specifically identified, the  
19 term “Director” means the Director of the National  
20 Institutes of Health; and

21 (2) a “biosafety level 3–4 facility” means a fa-  
22 cility for research on indigenous, exotic, or dan-  
23 gerous agents with the potential for aerosol trans-  
24 mission of disease that may have serious or lethal  
25 consequences or that pose a high risk of life-threat-

1        ening disease, aerosol-transmitted laboratory infec-  
2        tions, or related agents with unknown risk of trans-  
3        mission.

4        (e) AUTHORIZATION OF APPROPRIATIONS.—There  
5        are authorized to be appropriated such sums as may be  
6        necessary to carry out this section.

7        **SEC. 217. NATIONAL INSTITUTES OF HEALTH COUNTER-**  
8                    **MEASURES      PARTNERSHIP      CHALLENGE**  
9                    **GRANTS.**

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

18        (b) REGULATIONS.—The Director shall issue regula-  
19        tions within 90 days of the date of enactment of this sec-  
20        tion to implement the awarding of grants under subsection  
21        (a).

22        (c) RULE OF CONSTRUCTION.—Nothing in this sec-  
23        tion shall be construed to preclude an entity that receives  
24        a partnership challenge grant under this section from also

1 being certified as being eligible for incentives under this  
2 Act (and the amendments made by this Act).

3 (d) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated \$200,000,000 for each  
5 of fiscal years 2002, 2003, 2004, 2005, and 2006 for the  
6 purpose of carrying out this section.

7 **SEC. 218. HUMAN CLINICAL TRIALS AND DRUGS FOR RARE**  
8 **DISEASES AND CONDITIONS.**

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

11 (1) IN GENERAL.—Subclause (I) of section  
12 45C(b)(2)(A)(ii) of the Internal Revenue Code of  
13 1986 is amended to read as follows:

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

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

23 (3) EFFECTIVE DATE.—The amendments made  
24 by this subsection shall apply to amounts paid or in-  
25 curred after December 31, 2002.

1 (b) PUBLICATION OF FILING AND APPROVAL OF RE-  
2 QUESTS FOR DESIGNATION OF DRUGS FOR RARE DIS-  
3 EASES OR CONDITIONS.—Subsection (c) of section 526 of  
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 360bb) is amended to read as follows:

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

11 “(1) the name and address of the manufacturer  
12 and the sponsor;

13 “(2) the date of the request for designation or  
14 of the approval of such request;

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

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

21 “(5) the proposed indication for use of the  
22 product.”.

23 **SEC. 219. USE OF ADJUVANTS IN VACCINE PRODUCTION.**

24 (a) PURPOSE.—The purpose of this section is to cre-  
25 ate incentives for the conduct of research by private for-

1 profit entities relating to the development and use of adju-  
2 vants to enhance the potency of, and increase the period  
3 of protection and the number of useful doses from, a lim-  
4 ited supply of antigen in response to an attack with a bio-  
5 logical agent or toxin or nuclear or radiological material.

6 (b) DEFINITION OF ADJUVANT.—In this section, the  
7 term “adjuvant” means a substance included in a vaccine  
8 formulation to enhance or prolong the immune response  
9 of the vaccine.

10 (c) ELIGIBILITY FOR CLASSIFICATION.—

11 (1) CRITERIA.—

12 (A) IN GENERAL.—For purposes of this  
13 section, in determining whether a proposed use  
14 of an adjuvant is safe, the Secretary of Health  
15 and Human Services (in this section referred to  
16 as the “Secretary”) shall—

17 (i) consider—

18 (I) the views of experts qualified  
19 by scientific training and experience  
20 to evaluate the safety of vaccines (the  
21 basis of such views being scientific  
22 procedures or experience based on  
23 common use in vaccines);

24 (II) common knowledge con-  
25 cerning the adjuvant throughout that

1 portion of the scientific community  
2 that is knowledgeable about the safety  
3 of such adjuvant substances that are  
4 directly or indirectly added to vac-  
5 cines;

6 (III) scientific procedures that  
7 are ordinarily based on published  
8 peer-reviewed studies which may be  
9 corroborated by unpublished studies  
10 and other data and information; and

11 (IV) other factors that the Sec-  
12 retary determines appropriate;

13 (ii) require—

14 (I) the conduct of human trials  
15 using at least two different antigens  
16 relating to the adjuvant;

17 (II) the consideration of the cu-  
18 mulative experience of at least 2,000  
19 human subjects of the human trials;  
20 and

21 (III) the conduct of at least one  
22 safety assessment, using the param-  
23 eters described in subparagraph (B),  
24 of the toxicity profile of the adjuvant  
25 in which the dose per injection should

1 equal to, or exceed, the intended  
2 human dose, if feasible.

3 (B) PARAMETERS.—The parameters to be  
4 evaluated in a safety assessment conducted  
5 under subparagraph (A)(ii)(III) include—

6 (i) laboratory analyses (for example  
7 serum chemistry, hematology and  
8 immunogenicity);

9 (ii) injection site observations;

10 (iii) histopathology;

11 (iv) necropsy; and

12 (v) pyrogenicity.

13 (2) DEEMING SAFE.—An adjuvant determined by the  
14 Secretary to be safe under paragraph (1) shall, with re-  
15 spect to any particular use or intended use of such adju-  
16 vant, be deemed to be safe for the purposes of the applica-  
17 tion of section 351 of the Public Health Service Act (42  
18 U.S.C. 262) or section 505 of the Federal Food, Drug,  
19 and Cosmetic Act (21 U.S.C. 355).

20 (d) ESTABLISHMENT OF A PREFERRED LIST OF AD-  
21 JUVANTS.—

22 (1) IN GENERAL.—The Secretary shall establish  
23 a list of preferred adjuvants that are generally rec-  
24 ognized as safe for use in vaccine formulation and  
25 production.

1           (2) REGULATIONS.—The Secretary shall pro-  
2 mulgate such regulations as are necessary to carry  
3 out the provisions of this subsection.

4           (3) PUBLICATION.—The Secretary shall publish  
5 the preferred list of adjuvants not less than quar-  
6 terly in the Federal Register.

7 (e) PETITION FOR ELIGIBILITY.—

8           (1) IN GENERAL.—Any person may, with re-  
9 spect to any intended use of an adjuvant, file with  
10 the Secretary a petition proposing to list the adju-  
11 vant on the list of preferred adjuvants described in  
12 subsection (d).

13           (2) CONTENTS.—The petition described in  
14 paragraph (1) shall, in addition to any explanatory  
15 or supporting data, contain—

16           (A) the name and all pertinent information  
17 concerning such adjuvant, including, where  
18 available, its chemical identity and composition;

19           (B) a statement of the conditions of the  
20 proposed use of such adjuvant, including any  
21 proposed use of such adjuvant;

22           (C) all relevant data bearing on the phys-  
23 ical or other technical effect that such adjuvant  
24 is intended to produce, and the quantity of such  
25 adjuvant required to produce such effect; and

1 (D) full reports of investigations made  
2 with respect to the safety of such adjuvant, in-  
3 cluding the full disclosure of information as to  
4 the methods and controls used in conducting  
5 such investigations.

6 (3) ADDITIONAL INFORMATION.—Upon the re-  
7 quest of the Secretary, a petitioner under this sub-  
8 section shall provide the Secretary, as part of the pe-  
9 tition process under this subsection, a full descrip-  
10 tion of the methods used in, and the facilities and  
11 controls used for, the production of the adjuvant  
12 that is the subject of the petition and samples of the  
13 adjuvant involved, or articles used as components  
14 thereof, and samples of the vaccine in or on which  
15 the adjuvant is proposed to be used.

16 (4) NOTIFICATION.—

17 (A) IN GENERAL.—Except as provided in  
18 subparagraph (B), not later than 90 days after  
19 the date on which a petition is filed under para-  
20 graph (1), the Secretary shall provide the peti-  
21 tioner with notice of the approval or disapproval  
22 of such petition.

23 (B) EXCEPTION.—If the Secretary deter-  
24 mines that study of a petition beyond the 90-  
25 day period described in subparagraph (A) is re-

1           required, the Secretary shall notify the petitioner  
2           in writing during such period of the additional  
3           period required prior to approval or dis-  
4           approval.

5           (f) CONDITIONAL APPROVAL.—

6           (1) ESTABLISHING CONDITIONS.—The Sec-  
7           retary may provide for the conditional approval of a  
8           petition submitted under subsection (e). Such condi-  
9           tional approval shall limit the use of an adjuvant un-  
10          less conditions prescribed by the Secretary are com-  
11          plied with by the petitioner with respect to the use  
12          of the adjuvant. Such conditions may include—

13                   (A) specifications as to the particular vac-  
14                   cine or classes of vaccines in which such adju-  
15                   vant may be used;

16                   (B) the manner in which such adjuvant  
17                   may be added to or used in or on such vaccine;

18                   (C) the maximum quantity of the adjuvant  
19                   which may be used; and

20                   (D) any labeling requirements for such ad-  
21                   juvant that are determined necessary to ensure  
22                   the safety of the use of the adjuvant.

23           (2) NOTIFICATION.—If an adjuvant is condi-  
24           tionally approved by the Secretary for inclusion on  
25           the list described in subsection (d), the Secretary

1 shall notify (as part of the notice provided under  
2 subsection (e)(4)) the petitioner of the conditions ap-  
3 plicable to the adjuvant under paragraph (1) with  
4 respect to such approval and the reasons for requir-  
5 ing such conditions.

6 (g) STUDY.—The Secretary, acting through the Di-  
7 rector of the National Institute of Allergy and Infectious  
8 Diseases, shall conduct a study on the effectiveness of the  
9 use of adjuvants, in response to an attack with biological  
10 or chemical agents or toxins or nuclear or radiological ma-  
11 terials, to—

12 (1) enhance the potency of a given supply of  
13 antigen;

14 (2) increase the period of protection of a given  
15 supply of antigen; and

16 (3) increase the number of useful doses from a  
17 given supply of antigen.

18 **SEC. 220. ANNUAL REPORT.**

19 (a) IN GENERAL.—Not later than January 1, 2004,  
20 and each January 1 thereafter, the Secretary shall prepare  
21 and submit to the appropriate committees of Congress and  
22 make available to the public, a report concerning the im-  
23 plementation of the Act (and the amendment made by this  
24 Act). Such reports shall include—

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

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

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

21           (4) an assessment of whether such incentives  
22 will lead to the development of research tools;

23           (5) an assessment of whether sections 211, 212,  
24 213, 214, 215, 216, 217, 218, and 219 are being

1 carried out and having the intended effect on indus-  
2 try activity;

3 (6) a description of how such incentives for pri-  
4 vate sector research relate to the provision of public  
5 funding for the development of countermeasures;  
6 and

7 (7) recommendations for the modification of  
8 such incentives to increase their effectiveness.

9 (b) **LIMITATION ON PUBLICATION.**—In making the  
10 report under subsection (a) available to the public, the  
11 Secretary may exempt certain information from disclosure  
12 if the Secretary determines that such publication would  
13 (or could) be detrimental to the security of the United  
14 States. Such determinations by the Secretary shall not be  
15 subject to judicial review.

16 **SEC. 221. INTERNATIONAL CONFERENCE ON RESEARCH TO**  
17 **DEVELOP COUNTERMEASURES.**

18 (a) **IN GENERAL.**—The Director of the Centers for  
19 Disease Control and Prevention shall annually convene an  
20 International Conference on Research to Develop Counter-  
21 measures to biological, chemical and nuclear terror at-  
22 tacks.

23 (b) **FOCUS OF CONFERENCE.**—Each conference con-  
24 vened under subsection (a) shall focus on one ore more  
25 of the following:

1           (1) An assessment of the biological, chemical,  
2 or radiological threats that may arise and the coun-  
3 termeasures that may be needed.

4           (2) The status of research to develop counter-  
5 measures, including research tools.

6           (3) The need for and effectiveness of incentives  
7 for such research by private sector entities, including  
8 tax, procurement, intellectual property, and liability  
9 incentives.

10          (4) Mechanisms that will improve coordination  
11 among public and private sector entities conducting  
12 such research and development.

13          (5) The potential benefits and applications of  
14 such research for the prevention and treatment of  
15 tropical and other diseases.

16          (c) AUTHORIZATION OF APPROPRIATIONS.—There  
17 are authorized to be appropriated, such sums as be nec-  
18 essary in each fiscal year to carry out this section.

○