107TH CONGRESS
2D 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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002''.

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

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

SEC. 2. FINDINGS.

Congress makes the following findings:

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

(2) The threat of biological and chemical weapons is real.

(A) Members of the cult Aum Shinrikyo were responsible for chemical weapons attacks in Japan that killed 12 people and injured over 5,000 on March 20, 1995. In this attack, terrorists placed plastic bags of diluted sarin, a lethal nerve agent, on crowded subway trains during the morning rush-hour. It was found that sect members had legally stockpiled sodium cyanide and hundreds of tons of chemicals used to make sarin, including sodium fluoride, phosphorous trichloride, isopropyl alcohol, and acetonitrile. Aum Shinrikyo concealed its sarin manufacturing plant in a shrine to a sect goddess. Investigators also found a biological weapons research lab on the cult's compound. The facility contained an incubator, an electron microscope, a growth medium for fermenting or

growing cultures, and cultures of the deadly botulinum toxin. Aum Shinrikyo members were apparently planning a more devastating offensive. The cult also released anthrax spores and botulinum in Tokyo nine times before it carried out its nerve gas attack. Aum's attempted germ attacks failed because the group's biologists cultured the strain of anthrax used to make vaccine, which is harmless. Had they used a potent culture, the outcome might have been very different. No one knows why the botulism attack failed. The horror is only magnified by the thought that individuals and nations would consider attacking others with such viruses. In October 1993, Shoko Asahara, head of the Aum Shinrikyo cult, and 40 followers traveled to Zaire, ostensibly to help treat Ebola victims. But the group's real intention, according to an October 31, 1995, report by the Permanent Subcommittee on Investigations of the Senate, was probably to obtain virus samples, culture them and use them in biological attacks.

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

such at the time, was with salmonella. Followers of Bhagwan Shree Rajneesh put the bacteria in salad bars in restaurants in Dalles, Oregon, in 1984, sickening 750 people.

(C) There is a long and sordid history of chemical and biological weapons, including use during the First and Second World Wars, an accidental release of anthrax spores in 1979 from a Soviet military microbiological facility, use of mustard gas, tabun, and hydrogen cyanide by Iraq in the Iran-Iraq War and against the Kurds, and development by Iraq of an offensive biological weapons capability including anthrax and botulinum toxin.

(D) The United States bioterror weapons program focused on anthrax, botulinum toxin, brucellosis, tularemia, psittacosis, plagua, Venezuelan equine encephalitis, Q fever, cholera, dengue, shigellosis dysentery, glanders, and Rocky Mountain spotted fever. The United States Army concocted a botulinum toxin that was so toxic that a pound, if expertly dispersed, could kill 1,000,000,000 people. Botulinum toxin is 15,000 times more toxic than VX and 10,000 times more toxic than Sarin. The Soviet

bioterror program involved 47 laboratories and 65,000 people. It focused on 52 different pathogens, including smallpox, anthrax, plague, Ebola and Marburg hemorrhagic fevers, yellow fever, tularemia, brucellosis, Q fever, botulinum toxin, and Venezuelan equine encephalitis. It created 2,000 strains of anthrax with 7,000 employees working on nothing but anthrax. It produced 20 tons of smallpox virus each year, created antibiotic resistant strains, strains with odd systems to confuse diagnosis, plague bacteria that secreted diphtheria toxin and resisted antibiotics, and some Venezuelan equine encephalitis. The Iraqi bioterror program focused on anthrax, botulinum toxin, cholera, plague, gas gangrene, Salmonella, ricin, staphylococcal enterotoxin, camelpox, cancer-causing molds called aflatoxins, rotavirus, and hemorrhagic conjunctivitis.

(E) A Central Intelligence Agency report concluded that ''clandestine production of chemical and biological weapons for multiple casualty attacks raises no greater technical obstacles than does the clandestine production of chemical narcotics or heroin''. One of the aspects

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

(F) The Office of Technology Assessment estimated than 100 kilograms of anthrax released upwind in an American city could cause between 130,000 and 3,000,000 deaths, depending on the weather and other variables. This degree of carnage is in the same range as that forecast for a hydrogen bomb.

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

(A) In April 2000, customs officers from Uzbekistan discovered 10 lead-lined containers at a remote border crossing with Kazakhstan. These containers were filled with enough radioactive material to make dozens of crude weapons, each capable of contaminating a large area for many years. The consignment was addressed to a company in Quetta, Pakistan, called Ahmadjan Haji Mohammed. Quetta, where border controls are virtually non-existent, is the main Pakistani crossing into southern Afghanistan and only a 6 hour drive from Kandahar.

(B) In 1994 Czech police seized 3 kilograms of highly enriched uranium During the same year German police seized 360 grams of plutonium. In 2001 Turkish police seized two men with 1.16 kilograms of weapons grade uranium. Russian general Alexander Ledbed claimed that 40 suitcase nuclear weapons were unaccounted for.

(C) In 1995 Islamic Chechen rebels announced, and Russians confirmed, that they had planted a 30 pound shielded container holding the Cesium-137 core of a cancer treatment device in a Moscow park.

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

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

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

(F) A crude but deadly radiation dispersal device (RDD) fashioned from stolen nuclear material (from a nuclear waster processor, a nuclear power plant, a university research facility, a medical radiotherapy clinic, or an industrial complex) and a few sticks of dynamite could spread radioactive material across an area without a nuclear detonation. Such a weapon could kill many, contaminate a square mile for 10 years or more, and cause widespread panic. The Chernobyl nuclear reactor meltdown in

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

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

(H) The panic at dispersal or detonation of such a device might well be much more damaging than the morbidity and mortality. Radiation is invisible and there is widespread fear of it. Few would understand the difference between a dirty and a nuclear bomb.

(I) Such a device or bomb can cause exposure to a variety of radioactive materials, including Plutonium, enriched or depleted Uranium, Radium, Cesium, Strontium, Cobalt, Iodine, Americium, etc.

(J) Such exposure can a cause immediate death, as well as adverse effects on radiosensitive tissues, including suppression of white and red blood stem and platelet cells production. Acute Radiation Syndrome (ARS), Central Nervous System syndrome (CNS), gastrointestinal syndrome, and bone marrow radiation syndrome are early effects of substantial acute exposure to ionizing radiation. Leukemia and other forms of cancer can arise many years after exposure even to lower doses. Other symptoms include nausea, vomiting, hair loss, diarrhea, hemorrhages, and internal bleeding. The United States has only one hospital emergency room dedicated to treating patients exposed to radiation hazards, at Oak Ridge, Tennessee.

(K) Medical responses currently available with respect to exposure to radioactive materials are rather limited and can include use of chelation agents to speed secretion of radioactive metals from the body if radioactive material was swallowed or inhaled, preventive blocking of thyroid uptake of radioactive iodine by use of potassium iodine tablets, and use of Investigational New Drugs like Prussian Blue.

(L) The United States needs to develop additional medical responses, including antiemetics, hematological colony-stimulating factors, and chelating agents. The United States also needs to develop better means of assessing radiation exposure using new molecular, biological, physical and other technologies.

(M) The ill-defined and uncontrolled nature of radiation exposure and nuclear accidents usually causes a non-uniform exposure with the variable dose distribution complicating dosimetry, which is important for medical management of exposed patient with a need to determine the degree to which bone marrow or gastrointestinal stem cells have survived.

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

(5) The United States faces a public health crisis with the spread of antibiotic resistant bacteria. This alone should lead us to take urgent action to develop new vaccines and medicines. The antibiotic vancomycin, our last line of defense against the often deadly bacterium, Staphylococcus aureus, is losing its effectiveness. Worldwide, many strains of S. aureus are already resistant to all antibiotics except vancomycin. Emergence of strains lacking sensitivity to vancomycin signifies that variants untreatable by every known antibiotic are on their way. S. aureus, a major cause of hospital-acquired infections, has thus moved one step closer to becoming an unstoppable killer. What is more, strains of at least three bacterial species capable of causing life-threatening illnesses (Enterococcus faecalis, Mycobacleriumn tuberculosis and Pseudomonas aeruginosa) already evade every antibiotic in the clinician's armamentarium, a stockpile of more than 100 drugs. In part because of the rise in resistance to antibiotics, the death rates for some communicable diseases (such as tuberculosis) have started to rise again, after having declined in the industrial nations.

(6) The possibility exists that terrorists or others will use biotechnology techniques to enhance the lethality of a biological agent. According to the Defense Science Board, ''Motivated researchers using advanced genetics techniques can engineer pathogens with unnatural characteristics that enhance their offensive properties by altering such characteristics as stability, dissemination properties, host range, contagiousness, resistance to drugs and vaccines, and persistence in the environment, among others''.

(7) Vaccines exist for some of the biological agents that might be used by terrorists and others, but these vaccines need substantial additional development. The current United States vaccine against anthrax was formulated in the 1960s and licensed in 1970. Before and subsequent to the licensing of this vaccine in the United States, additional preclinical and clinical studies have been conducted to confirm its safety and efficacy. The current Food and Drug Administration-licensed immunization schedule for the anthrax vaccine involves 6 doses over 18 months followed by yearly boosters. Since this is a cumbersome schedule for immunizing both military personnel and civilian laboratory workers and first responders at occupational risk of exposure to the bio-

threat from an anthrax attack, the Centers for Disease Control and Prevention has initiated multi-center studies to develop the next generation of the anthrax vaccine by reducing the number of doses and changing its route of administration. Additional early development phase studies of experimental recombinant and live attenuated anthrax vaccines are underway to determine their suitability, safety and efficacy.

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

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

fects and is one that cannot be well tolerated by many, and for those who are infected, the United States has no effective treatment. The United States has a treatment for early stage inhalation anthrax, but those treatments are ineffective when there are delays in diagnosis. The United States has very few products that are effective against viruses. The United States is not well protected with broad-spectrum antibiotics that are needed to deal with pathogens that have been modified or selected for antibiotic resistance. It takes more than 24 hours to diagnose many of the most dangerous pathogens.

(10) A ring vaccination strategy may well be impossible to implement given the mobility of Americans. Twenty-three million international airline passengers embarked or disembarked at United States airports in the fourth quarter of 2001. Nearly 500,000,000 people crossed the United States-Canada and United States-Mexico boarders by land in 2000. Tens of millions of people each day cross from one metropolitan area to another. For the same reasons, it may not be possible to enforce a quarantine. If, however, the United States has safe and effective treatments to deploy, there will be less need to at-

tempt to implement a ring vaccination strategy or quarantine.

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

(12) The United States Government is directly funding biomedical research on vaccines and treatments for biological and chemical agents and radiological materials. These funding efforts could be matched many-fold if the 1,500 biotechnology companies, 100 pharmaceutical companies, medical device and research tool companies, and research institutions were able to secure the funding from private investors, or justify the investment of retained earnings, to conduct this research.

(13) The enactment of tax, procurement, patent, liability, and other incentives will enable the biotechnology, pharmaceutical, device, and research tool industries to raise equity and other capital from investors to fund research on countermeasures for biological, chemical, and radiological attacks. This will supplement direct Federal funding for this research and speed development of life saving technologies. The existence of these technologies will reassure the

public that if attacks occur, effective medical treatments are available and there is no reason for panic.

(14) Past efforts by agencies of the Federal Government to contract for the development and manufacture of countermeasures have been, and likely will continue to be, ineffective. These efforts have been under-funded, too complex, financially restrictive, and unreliable and therefore have failed to attract the commitment of capital and research-intensive biotechnology, pharmaceutical, medical device, and research tool companies. These shortcomings are likely to be even more apparent and severe with respect to proposals to use Federal taxpayer dollars for Federal Government construction, ownership, and operation of research and development and manufacturing facilities for the production of vaccines for military and civilian use (GOGOs and GOCOs) or for the establishment of a National Vaccine Authority for the research and development and production of vaccines for the protection of civilians against bioterrorist attacks. These federalized proposals will result in significantly higher costs for taxpayers, add significant additional layers of Federal bureaucracy, and delay the availability of needed countermeasures.

(15) Efforts by the Department of Defense to acquire drugs and vaccines for bioterror agents have been ineffective. The Defense Science Board has found that ''DOD has failed to implement a proactive strategy for engagement of the private sector in gaining access to new technologies relevant to biodefense . . . (There are) significant obstacles to engagement of the private sector. Neither the DOD nor the nation can achieve a robust biodefense without engagement of private sector R&D and leading scientists in academia and closer ties to industry . . . A program of longer-term investment in new R&D initiatives to address major gaps in drug and vaccine coverage is crucial but it will take 10 to 15 years to bring such investments to fruition.''

(16) The Defense Science Board has noted the ''private sector's declared lack of interest in seeking Government R&DE contracts.'' It has found that the ''medical-related industry differs from traditional defense industries. The financial disincentives inherent in producing products for limited markets (i.e. DOD only) with no commitment to longterm supply in the face of massive capitalization needs and the long, multi-year lead times to build new manufacturing facilities for drugs and vaccines are considerable.

Nonetheless, it is difficult to see how DOD or the nation can pursue a successful biodefense strategy if they do not engage leading companies and top scientists from outside the physics/engineering circles of traditional defense contractors.''

(17) This Act is premised on the belief that the most effective strategy is to capitalize on the experience and entrepreneurship of America's world preeminent biotechnology, pharmaceutical, medical device, research tool companies, and research institutions engaged in this research, development, and manufacturing at their own risk, their own expense, for their own good business reasons.

SEC. 3. DEFINITIONS.

In this Act:

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

(A) ''biological agent'', ''biological toxin'', ''chemical agent'', or ''chemical toxin'', or any variation of any such term, means any microorganism, virus, infectious substance, biological product, toxic or poisonous chemical, or precursor of a toxic or poisonous chemical, that may be used in a manner that is intended to

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

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

(C) ''terror weapon'' and ''weapon of mass destruction'' mean any matter described in subparagraph (A) or (B) that may be used in a manner that is intended to cause widespread death or serious bodily injury.

(2) COUNTERMEASURES.—The term ''countermeasures'' means—

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

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

(B) a therapy or diagnostic that may be used to detect, treat, or prevent bodily harm that may be caused by the use of nuclear or radiological material as a terror weapon.

(3) DEPARTMENT.—The term ''Department'' means the Department of Homeland Security.

(4) DEVELOPMENT.—The term ''development'' or ''to develop'' includes the identification of suitable compounds or biological materials, the conduct of preclinical and clinical studies, the preparation of an application for marketing approval, and other actions related to preparation of a countermeasure.

(5) DIAGNOSTICS.—The term ''diagnostics'' includes products, devices, and technologies to detect, identify, or analyze, the potential presence or absence of 1 or more biological agents or toxins in patient samples, environmental samples, or field samples.

(6) RESEARCH TOOL.—The term ''research tool'' includes the full range of tools that scientists may use in the laboratory, including cell lines, monoclonal antibodies, reagants, animal models, growth factors, combinatorial chemistry and DNA li-

braries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases, and other technologies that enable the rapid and effective development of countermeasures, including diagnostics, vaccines, and drugs.

(7) SECRETARY.—The term ''Secretary'' means the Secretary of the Department of Homeland Security.

TITLE I—STRATEGY FOR THE DEVELOPMENT OF COUNTERMEASURES

SEC. 101. BIOLOGICAL, CHEMICAL AND RADIOLOGICAL AGENT, TOXIN, AND MATERIAL COUNTERMEASURE RESEARCH PRIORITY LIST.

(a) DEVELOPMENT.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Defense and the Secretary of Health and Human Services, shall develop and make available to potential manufacturers of terror weapons countermeasures and, except as provided in paragraph (5) publish, a list of biological and chemical agents and toxins and nuclear and radiological materials that may be used as weapons of mass destruction with respect to which

the Secretary finds that research to develop countermeasures is in the national security interest of the United States.

(2) REQUIREMENTS.—

(A) IN GENERAL.—The Secretary shall only include on the list developed under paragraph (1) agents, toxins, and materials—

(i) that pose a significant security or medical threat to the United States military and intelligence personnel, government officials, or civilians;

(ii) that are more likely to be subject to a countermeasure that is developed as a result of the availability of the tax, procurement, intellectual property, liability, and other provisions of this Act (and the amendment made by this Act); and

(iii) with respect to which safe and effective countermeasures are not available or with respect to which the development of safer and more effective countermeasures, or countermeasures that may be deployed more safely or effectively, is in the public interest.

(B) CERTAIN DETERMINATIONS.—For purposes of subparagraph (A)(ii), in determining whether the agents, toxins, and materials are more likely to be subject to a countermeasure, the Secretary shall consider—

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

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

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

(iv) the extent to which such countermeasures may be utilized for purposes other than as a countermeasure for a biological agent or toxin or radiological material on the list developed under this section;

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

(vi) the most effective strategy for expediting development of such countermeasure, including reliance on Government contracts, grants and cooperative research agreements and utilization of the incentives provided for in this Act (and the amendments made by this Act).

(3) USE OF EXISTING LISTS AND DATA.—The list developed under paragraph (1) may, at the discretion of the Secretary, make reference to or incorporate elements of the list of biological agents and toxins established and maintained by the Secretary of Health and Human Services under section 351A of the Public Health Service Act (as added by section 201 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002) and under section 178 of title 18, United States Code.

(4) INFORMATION AND DETERMINATIONS RELATING TO POTENTIAL MANUFACTURERS.—With respect to the list developed under paragraph (1), the Secretary shall—

(A) provide such information regarding such weapons of mass destruction as the Secretary determines to be necessary to enable such potential manufacturers to structure and

manage their research and development programs for the development of terror weapons countermeasures; and

(B) determine when such a manufacturer has successfully developed a countermeasure and therefore becomes entitled to the procurement, intellectual property, and liability provisions of this Act (or an amendment made by this Act).

(5) EXEMPTION.—

(A) IN GENERAL.—The Secretary may exempt certain information concerning weapons of mass destruction from publication if the Secretary determines that such publication would (or could) be detrimental to the security of the United States. In providing an exemption under the preceding sentence, the Secretary shall develop procedures for making such list or information available on a confidential basis to potential manufacturers of countermeasures.

(B) SUFFICIENCY OF INFORMATION.—In developing the procedures described in subparagraph (A), the Secretary shall ensure that the information provided to potential manufacturers of countermeasures is sufficient to enable the

Federal Government and the manufacturer to determine when such a manufacturer has successfully developed a countermeasure and therefore becomes entitled to the procurement, intellectual property, and liability provisions of this Act (or an amendment made by this Act).

(b) INITIAL LIST.—The initial list developed under subsection (a) may, at the discretion of the Secretary, contain the following biological agents and diseases caused by biological agents, chemical toxins, and nuclear and radiological materials:

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

(2) Bacillus anthracis (anthrax).

(3) Clostridium botulinum (botulism).

(4) Francisella tularensis (tularemia).

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

(6) Ebola hemorrhagic fever.

(7) Marbug hemorrhagic fever.

(8) Lassa fever.

(9) Junin (Argentine hemmorrhagic fever).

(10) Crimean-Congo Hemmorrhagic Fever.

(11) Coxiella burnetti (Q fever).

(12) Coccidioidomycosis (San Joaquin Valley or desert fever).

(13) Clostridium perfringens.

(14) Chalydia psittaci (parrot fever).

(15) Rift Valley Fever.

(16) Rocky Mountain Spotted Fever.

(17) Brucella species (brucellosis).

(18) Burkholderia mallei (glanders).

(19) Venezuelan encephalomyelitis.

(20) Eastern and Western equine encephalomyelitis.

(21) Ricin toxin from ricinus communis (castor beans).

(22) Trichothcene Mycotoxins (Yellow Rain).

(23) Paralytic Shellfish Toxin.

(24) Aflatoxins.

(25) Epsilon toxin of clostridium perfringens.

(26) Staphylococcus enterotoxin B.

(27) Salmonella species.

(28) Salmonella Typhi (typhoid fever).

(29) Shigella dysenteriae.

(30) Escherichia coli 0157:H7.

(31) Vibrio cholerae (colera).

(32) Cryptosporidium parvum.

(33) Nipah virus.

(34) Hantaviruses.

(35) Tickborne homorrhagic fever viruses.

(36) Tickborne encephalitis virus.

(37) Yellow fever.

(38) Malaria.

(39) Typhus.

(40) Antibiotic resistant tuberculosis.

(41) Entamoeba histolytica.

(42) Bacillary dysentery.

(43) Giardiasis.

(44) Trichomoniasis.

(45) Trypanosomiasis.

(46) Visceral leishmaniasis (black fever).

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

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

(49) Blister agents (including lewisite, nitrogen and sulfur mustards).

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

(51) Colatile toxins (including benzene, chloroform, and trihalomethanes).

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

(53) Incapacitating agents (including BZ).

(54) Nuclear and radiological materials.

(c) REVISIONS.—The Secretary shall revise the list developed under subsection (a) on at least an annual basis, and make such list available, under the terms and limitations described in this section, to potential manufacturers of terror weapons countermeasures or to holders of approved certifications. Such terms and conditions shall be consistent with the security interests of the United States.

(d) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of the Secretary's determinations regarding which agents, toxins, or materials to include on the list, or revised list, developed under this section or of a determination to exempt information from public distribution under this section.

(e) PROCUREMENT.—

(1) PURPOSE.—It is the purpose of this subsection to provide potential manufacturers of countermeasures that are registered with the Department under section 102 with sufficient information to enable that manufacturer to structure and manage its research and development of a terror weapons countermeasure and to determine when the manufacturer has successfully developed such a countermeasure

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

(2) FEDERAL GOVERNMENT SUCCESS AND MARKET DETERMINATION.—Not later than 180 days after the development of the list, or revised list, under subsection (a), the Secretary shall, with respect to each agent, toxin, or material on the list, determine—

(A) the type of countermeasure to be developed, including whether such countermeasure is a diagnostic, vaccine, biological, drug, or other countermeasure;

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

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

(D) the projected utilization of such countermeasure in combination;

(E) the Federal procurement market that will be available to the manufacturer of such countermeasure, including the minimum number of dosages or units that will be purchased, the minimum price per dose or unit, and the timing and minimum number of years projected for such purchases;

(F) with respect to a developer of a countermeasure that contracts with another entity for the manufacturer of such countermeasure, or with respect to a developer that is one of several manufacturers of such countermeasure, the Federal Government market that will be available to the developer of such countermeasure;

(G) the advance, partial, progress, milestone or other payments that may be available to the manufacturer under section 202, and the terms and conditions for the adjustment of any such payments for uncontrollable factors; and

(H) such other information as the manufacturer may reasonably request to enable the manufacturer to structure and manage research and development activities and determine when

a countermeasure has been successfully developed therefore entitling the manufacturer to the procurement, intellectual property, and liability provisions of this Act (or an amendment made by this Act).

(3) DETERMINATIONS.—

(A) IN GENERAL.—The Secretary shall make determinations under this subsection with respect to the successful development of countermeasures in accordance with section 102(e)(3).

(B) TESTING AND CLINICAL TRIALS.—The determination by the Secretary under paragraph (2)(B) with respect to the testing and clinical trial standards that will be required shall apply only to the entitlement of the manufacturer to the procurement, intellectual property, and liability provisions of this Act (or an amendment made by this Act). Nothing in this Act shall be construed to alter or affect the authority of the Food and Drug Administration with respect to the testing, clinical trial, or other regulatory standards applicable to the countermeasure involved.

(C) NO JUDICIAL REVIEW.—Notwithstanding any other provision of law, there shall be no judicial review of determinations made by the Secretary under this subsection.

(4) REVISIONS.—The Secretary is authorized to revise upward determinations under subparagraphs (E) and (G) of paragraph (2) with respect to minimum number of dosages that will be purchased and minimum price per dose and the advance, partial, progress, milestone or other payments that may be available to the manufacturer upon a determination that such revision is necessary to protect the national security interests of the United States and provide an effective incentive to entities developing countermeasures.

SEC. 102. RESEARCH REGISTRATION REQUIREMENTS.

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

ister with the Department. Such registration shall contain—

(1) the name and address of the entity;

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

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

(4) a description of the research that is being, or that will be, conducted to develop countermeasures to, or diagnostic or research tools with respect to, such agent, toxin, or material;

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

(6) the name of each individual who is conducting the research involved;

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

(8) any other information required under regulations promulgated by the Secretary, including additions and corrections to the information required

under this subsection as may be required by the Secretary through regulation.

(b) AVAILABILITY OF INFORMATION.—

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

(2) INSPECTIONS.—Subject to regulations promulgated under paragraph (1), the Department shall make available for inspection, to any person so requesting, any registration filed pursuant to subsection (a), except as provided in paragraph (3).

(3) CERTAIN INFORMATION NOT AVAILABLE.—The Secretary shall promulgate regulations to exempt certain information from disclosure under paragraph (2). Such regulations shall exempt from publication and disclosure trade secret and commercial or financial information which is exempt from disclosure to the public under section 552(b)(4) of title 5, United States Code, national security information, and information affecting the security of research and other facilities.

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

exempt information under paragraph (3), except that this paragraph shall not apply to judicial review of the failure to exempt from publication and disclosure trade secret and commercial or financial information, national security information, and information affecting the security of research and other facilities.

(c) INSPECTIONS.—Every establishment in any State registered with the Department pursuant to this section shall be subject to inspection, limited to such information as may be necessary relating to the development of countermeasures, diagnostics, or research tools and facility security, pursuant to regulations promulgated by the Secretary.

(d) REPORTS.—The Secretary shall promulgate regulations that prescribe the reports that each establishment that is registered with the Department under this section shall be required to file with the Secretary. Such regulations shall limit such reports to those necessary to enable the Secretary to—

(1) ensure that the capital derived by the utilization of the tax incentives provided for in title II (and the amendments made by such title) is used to fund the research that is the subject of the registration and certification under this section;

(2) determine the status of the research involved; and

(3) determine the outlook for United States preparedness for a biological, chemical, or radiological attack.

(e) CERTIFICATION.—

(1) IN GENERAL.—With respect to each entity that registers with the Department under this section, the Secretary, in consultation with the Secretary of Health and Human Services, shall determine—

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

(i) countermeasure with respect to a biological or chemical agency or radiological material on the list under section 101;

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

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

(B) whether the entity is qualified to conduct research to develop the countermeasure with respect to which the entity seeks certifi-

cation, and, with respect to such determination, the Secretary shall not presume that the entity is unqualified because the entity has not previously secured approval of the Food and Drug Administration of a device, drug, or biologic; and

(C) whether the procedures of the entity will ensure compliance with section 351A of the Public Health Service Act (as added by section 201 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(2) DETERMINATION.—If the Secretary makes an affirmative determination under paragraph (1) with respect to an entity, the Secretary shall certify the entity as being entitled to utilize the tax incentive provisions described in section 201 (and the amendments made by such section).

(3) SUCCESSFUL DEVELOPMENT.—Not later than 90 days after the date on which a certified entity submits to the Secretary an application for a determination that the entity has successfully developed a terror weapons countermeasure in accordance with section 101(e)(2), diagnostic in accordance with section 103, or research tool in accordance with section 104, the Secretary shall notify the entity—

(A) of such determination; and

(B) in the case of an affirmative determination by the Secretary with respect to the countermeasure, diagnostic, or research tool involved, that the entity shall be entitled to—

(i) procurement of the countermeasure, diagnostic, or research tool under the terms and conditions described under such section 101(e)(2) (including the minimum number of doses to be purchased, the timing and minimum number of years projected for such purchases, and the minimum per dose price), in accordance with section 202, and upon the execution of a contract with the Secretary with respect to such procurement; and

(ii) the patent restoration and extension protection under section 156a or 158 of title 35, United States Code, as added by section 203; and

(iii) upon a determination by the Secretary that it is the national security interest of the United States, the liability protections provided for under the amendment made by section 204.

(4) REQUIRED AFFIRMATIVE DETERMINATION.—The Secretary shall make an affirmative determination that an entity has successfully developed a terror weapons countermeasure, diagnostic, or research tool under this subsection if such countermeasure, diagnostic, or research tool—

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

(B) has not been authorized for such introduction or distribution into commerce under subparagraph (A) but has been authorized for investigation or compassionate use as a terror weapons countermeasure, diagnostic, or research tool under such Acts and the Secretary determines that significant quantities of the countermeasure, diagnostic, or research tool have been manufactured by the entity and are available for such investigational or compassionate use; or

(C) is not required to be authorized for introduction or distribution in commerce or investigational use under such Acts under subpara-

graphs (A) or (B) but the Secretary determines that significant quantities of it have been manufactured by an entity for use as a terror weapons countermeasure, diagnostic, or research tool and are available for such use.

(5) JUDICIAL REVIEW.—An adverse determination by the Secretary with respect to the development by a manufacturer of a terror weapons countermeasure in accordance with section 101(e)(2), diagnostic in accordance with section 103, or research tool in accordance with section 104, shall be subject to appropriate judicial review.

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

(1) AUTHORITY OF SECRETARY TO WAIVE AGGREGATE GROSS ASSETS LIMITATION.—Within 60 days of the request of an entity for a certification under subsection (e)(1) or a determination under subsection (e)(3), and upon a finding by the Secretary that it is in the public interest, the Secretary may extend the entitlement to utilize the tax incentives described in the amendments made by section 201 and the patent restoration and extension protection described in the amendments made by section 203, to such an entity with aggregate gross assets

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

(2) WAIVER WITH REGARD TO ENTITIES WITH NET OPERATING LOSSES.—Any entity obtaining a certification or determination described in paragraph (1) shall be entitled to utilize the tax incentives described in paragraphs (1), (2), and (3) of section 201 and the patent restoration and extension protection described in section 158 of title 35, United States Code, as added by section 203(b), if such entity's tax status in no fewer than 3 of the 5 taxable years preceding such certification or determination is that of an entity with net operating losses (as defined in section 172(c) of the Internal Revenue Code of 1986).

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

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

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit—

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

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

(3) a private sector establishment from receiving Federal grants, contracts, or cooperative agreements for research, investigations, experiments, demonstrations, and studies in addition to the incentives provided for under this Act (and the amendments made by this Act).

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

by section 125 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(i) ACCELERATED APPROVAL.—An entity that is certified under this section shall be eligible for accelerated approval of a countermeasure as described in section 211 and as provided for in section 122 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

(j) PRIORITY FOR TECHNICAL AND OTHER ASSISTANCE.—An entity that is certified under this section shall be given priority for receiving technical and other assistance to provide security for their personnel and facilities that conduct development, production, distribution, or storage of countermeasures under section 319K of the Public Health Service Act (as added by section 124 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

SEC. 103. DIAGNOSTICS INCENTIVES.

(a) FINDINGS.—Congress finds that—

(1) in the case of a bioterrorist attack, the United States public health authorities need the capacity to quickly and accurately diagnose the agent, toxin, or material involved so that appropriate medical intervention can be implemented;

(2) public health authorities need information on which vaccines and drugs will be effective in preventing infection, or in treating those who are infected, as a result of a terrorist attack, and whether there are any existing vaccines or drugs that are effective;

(3) there is a lack of information on the complications involved in administering vaccines and drugs via the use of diagnostic devices to portions of society that are known or unknown to carry contraindication diseases or conditions;

(4) few diagnostics for agents, toxins, or materials that could be used in a terror attack are currently available;

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

(6) financial inducements to conduct screening tests for infectious diseases are nonexistent or require substantial justification before a health care provider will order a specific test to diagnose an infectious disease;

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

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

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

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

(11) screening particularly needs to be part of the routine way physicians practice medicine, and this means the ready availability of tests in emergency room settings, the ability to rapidly provide a definitive diagnosis, and the ability to report out electronically to local public health agencies and hospital infection control monitors results of these tests.

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

velop and make available to potential manufacturers, a list of the diagnostics and diagnostics for contraindicators to vaccines or drugs that need to be developed to prepare the United States for a terrorist attack with a biological or chemical agent or toxin or nuclear or radiological materials. The Secretary shall provide such information as the Secretary determines to be necessary to enable such potential manufacturers to structure and focus their research and development programs for the development of such diagnostics.

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

(d) DEVELOPMENT OF CERTAIN DIAGNOSTICS.—

(1) IN GENERAL.—The Secretary shall develop and implement a strategy for the creation of infectious disease multiplexed molecular level technologies and the building of a system linking the local, State, and Federal public health systems through automated laboratory results reporting for all infectious diseases.

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

(A) include the development of confirmatory laboratory tests to back up presumptive results available from initial screening;

(B) recognize the need for advancement in the field of bioinformatics to accelerate the discovery of countermeasures using advanced mathematical techniques for pattern recognition, lossless digital data compression for storage and transmission of biomedical images, and the ability to analyze massive amounts of data; and

(C) promote the advancement of bioinformatics through the use of incentives, the procurement and rapid development of new devices, and the linkage of information systems into a medical surveillance infrastructure.

(3) TECHNOLOGY.—The specific screening and diagnostics technology used to implement the strategy described in paragraph (1) may consist of multiplexed devices that screen for routinely encountered common infectious diseases and have biothreat agent detection embedded in the devices capable of autoreporting results electronically, so results can be put into the public health system quickly.

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

(1) IN GENERAL.—The Secretary shall develop and implement a strategy that recognizes the need to provide the right incentives to the health care industry to allow them to utilize the new diagnostic tools that will be made available through research and allow for routine screening for infectious diseases.

(2) REIMBURSEMENT.—The strategy shall include appropriate incentives to allow for reimbursement to hospitals, clinics, and other providers who perform routine laboratory screening utilizing newer molecular level tests that rapidly detect infectious diseases.

(3) GUIDELINES.—The Secretary shall establish similar guidelines for States to utilize to promote infectious disease screening, including testing for the rapid identification of potential biothreat agents.

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

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

an application for a determination that the entity has successfully developed a terror weapons diagnostic in accordance with this section and section 102, the Secretary shall notify the entity—

(1) of such determination; and

(2) in the case of an affirmative determination by the Secretary with respect to the diagnostic involved, that the entity shall be entitled to—

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

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

(i) procurement of the diagnostic;

(ii) the patent restoration and extension protection under section 156a or 158 of title 35, United States Code, as added by section 203; and

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

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

SEC. 104. RESEARCH TOOLS INCENTIVES.

(a) FINDINGS.—Congress finds that—

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

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

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

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

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

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

(7) the Defense Science Board has found ''Effective biodefense measures for treatment or proactive vaccination against engineered agents introduces an additional element of technical complexity that would demand just-in-time R&D initiatives on a case-by-case basis to address the specific technical manipulation used in producing the engineered agent''.

(b) IDENTIFICATION.—Not later than 180 days after the date of enactment of this Act, the Secretary shall develop and make available to potential manufacturers, a list of the research tools that need to be developed to prepare the United States for a terrorist attack with a biological or chemical agent or toxin or nuclear or radiological materials. The list developed by the Secretary shall include research tools for which there is a need for development in order to understand why certain countermeasures may cause adverse events, how to minimize such adverse events, and how to treat such adverse events. The Secretary shall provide such information as the Secretary determines to be necessary to enable such potential manufacturers to structure and focus their research and development programs for the development of such diagnostics.

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

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

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

(e) INCENTIVES.—Not later than 90 days after the date on which a certified entity submits to the Secretary an application for a determination that the entity has successfully developed a terror weapons research tool in accordance with this section and section 102, the Secretary shall notify the entity—

(1) of such determination; and

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

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

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

(i) procurement of the research tool;

(ii) the patent restoration and extension protection under section 156a or 158

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

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

(f) JUDICIAL REVIEW.—An adverse determination by the Secretary with respect to the development by a manufacturer of a terror weapons research tool in accordance with this section, shall be subject to appropriate judicial review.

(g) UTILIZATION AND AVAILABILITY.—

(1) IN GENERAL.—Entities with respect to which an affirmative determination is made under subsection (e) shall maximize the utilization of the research tools involved for the development of countermeasures, including making such tools available on commercially reasonable terms to other entities certified under section 102 to develop countermeasures.

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

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

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

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

TITLE II—INCENTIVES FOR THE DEVELOPMENT OF COUNTER-MEASURES

Subtitle A—Primary Incentives

SEC. 201. FEDERAL TAX INCENTIVES.

(a) FINDINGS AND PURPOSE.—

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

(A) Most biotechnology companies, and many device and research tool companies, are early stage research ventures with no revenue from product sales to finance their medical research. Most biotechnology companies must rely on repeated and large infusions of investor capital to fund this research. To conduct research on countermeasures to biological agents and other toxins or any other type of research, these companies must persuade venture capitalists and other investors that funding this research

may lead to a rate of return commensurate with the risk and comparable to the rate of return available to other, comparable investment opportunities.

(B) Biotechnology companies are justifiably reluctant to modify their ongoing research priorities and devote scare management and scientific talent to new and risky projects. Their first priority and obligation is and must be to secure approval to market a product that will generate revenue sufficient to reduce the dependence of the company on continued infusions of investor capital and to provide a long-awaited return to patient investors.

(C) Biotechnology companies tend to focus on breakthrough research to develop medical treatments for diseases where no effective treatments are currently available. They often specialize in research and development on rare diseases and they are parties in the vast majority of the collaborations in the United States between private industry and academic medical centers and the National Institutes of Health. Many biotechnology companies do not have approval to market products with respect to which

they might develop minor improvements to maintain a market advantage.

(D) No type of industrial research is as costly as biotechnology research. Successful research and development of countermeasures will necessitate breakthroughs in virology, immunology, antibiotics, genetic analysis, and many other disciplines in biology.

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

(F) The provision of tax incentives will help in enabling biotechnology companies to form the capital needed to conduct research to develop countermeasures. Such incentives lower the cost of capital, induce investors to fund research, and enable biotechnology companies to justify the investment of retained earnings. Without such capital, research on countermeasures is not likely to go forward. Tax incentives are less costly than direct Federal Govern-

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

(2) PURPOSE.—It is the purpose of this section to provide tax incentives to enable biotechnology, pharmaceutical, diagnostics, and research tool companies to form capital to conduct research to develop countermeasures.

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

(1) RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIPS TO FUND COUNTERMEASURE RESEARCH.—The entity may establish a limited partnership for the certified countermeasures, diagnostics, or research tools research, but only if such entity is a qualified small business as determined under section 1202(d) of the Internal Revenue Code of 1986, by substituting ''$750,000,000'' for ''$50,000,000'' each place it appears. For purposes of the Internal Revenue Code of 1986, section 469 of such Code shall not apply with respect to a

limited partnership established under this paragraph.

(2) CAPITAL GAINS EXCLUSION FOR INVESTORS TO FUND COUNTERMEASURE RESEARCH.—The entity may issue a class of stock for the certified countermeasures, diagnostics, or research tools research under section 1202 of the Internal Revenue Code of 1986 with the following modifications:

(A) INCREASED EXCLUSION FOR NONCORPORATE TAXPAYERS.—Subsection (a) of section 1202 of such Code shall be applied by substituting ''100 percent'' for ''50 percent''.

(B) APPLICATION TO CORPORATE TAXPAYERS.—Subsection (a) of section 1202 of such Code shall be applied without regard to the phrase ''other than a corporation''.

(C) STOCK OF LARGER BUSINESSES ELIGIBLE FOR EXCLUSION.—Paragraph (1) of section 1202(d) of such Code (defining qualified small business) shall be applied by substituting ''$750,000,000'' for ''$50,000,000'' each place it appears.

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

shall be applied by substituting ''3 years'' for ''5 years''.

(E) NONAPPLICATION OF PER-ISSUER LIMITATION.—Section 1202 of such Code shall be applied without regard to subsection (b) (relating to per-issuer limitations on taxpayer's eligible gain).

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

(i) in subparagraph (B), by substituting ''5 years'' for ''2 years'', and

(ii) without regard to the last sentence.

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

(3) TAX CREDIT TO FUND COUNTERMEASURE RESEARCH.—

(A) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by adding at the end the following new section:

"SEC. 45G. CREDIT FOR MEDICAL RESEARCH RELATED TO DEVELOPING COUNTERMEASURES.

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

"(b) QUALIFIED COUNTERMEASURES RESEARCH EXPENSES.—For purposes of this section—

"(1) QUALIFIED COUNTERMEASURES RESEARCH EXPENSES.—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified countermeasures research expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

"(B) MODIFICATIONS; INCREASED INCENTIVE FOR CONTRACT RESEARCH PAYMENTS.—

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

"(i) by substituting 'qualified countermeasures research' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

"(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

"(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified countermeasures research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

"(2) COUNTERMEASURES RESEARCH.—The term 'countermeasures research' means certified countermeasures research for any biological agent or toxin on the list described in section 101 of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

"(c) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any qualified countermeasures research

expenses for a taxable year to which an election under this section applies shall not be taken into account for purposes of determining the credit allowable under section 41 for such taxable year.

''(2) EXPENSES INCLUDED IN DETERMINING BASE PERIOD RESEARCH EXPENSES.—Any qualified countermeasures research expenses for any taxable year which are qualified research expenses (within the meaning of section 41(b)) shall be taken into account in determining base period research expenses for purposes of applying section 41 to subsequent taxable years.

''(d) SPECIAL RULES.—

''(1) LIMITATIONS ON FOREIGN TESTING.—No credit shall be allowed under this section with respect to any countermeasures research (other than human clinical testing) conducted outside the United States.

''(2) PRE-CLINICAL RESEARCH.—No credit shall be allowed under this section for pre-clinical research unless such research is pursuant to a research plan an abstract of which has been filed with the Director of the Office of Homeland Security before the beginning of such year. The Director of the Office of Homeland Security, in consultation with

the Secretary of Health and Human Services, shall prescribe regulations specifying the requirements for such plans and procedures for filing under this paragraph.

''(3) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(4) COORDINATION WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any qualified countermeasures research expense for a taxable year shall not be taken into account for purposes of determining the credit allowable under section 45C for such taxable year.''.

(B) INCLUSION IN GENERAL BUSINESS CREDIT.—

(i) IN GENERAL.—Section 38(b) of such Code is amended by striking ''plus'' at the end of paragraph (14), by striking the period at the end of paragraph (15) and inserting '', plus'', and by adding at the end the following new paragraph:

''(16) the countermeasures research credit determined under section 45G.''.

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

''(11) NO CARRYBACK OF SECTION 45G CREDIT BEFORE ENACTMENT.—No portion of the unused business credit for any taxable year which is attributable to the countermeasures research credit determined under section 45G may be carried back to a taxable year beginning before January 1, 2003.''.

(C) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code is amended by adding at the end the following new subsection:

''(d) CREDIT FOR QUALIFIED COUNTERMEASURES RESEARCH EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified countermeasures research expenses (as defined in section 45G(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45G(a).

''(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.''.

(D) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of such Code (defining qualified business credits) is amended by striking ''and'' at the end of paragraph (9), by striking the period at the end of paragraph (10) and inserting '', and'', and by adding at the end the following new paragraph:

''(11) the countermeasures research credit determined under section 45G(a) (other than such credit determined under the rules of section 280C(d)(2)).''.

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

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

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

(A) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business related credits) is amended by inserting after section 41 the following:

"SEC. 41A. CREDIT FOR COUNTERMEASURES RESEARCH EXPENSES.

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

"(1) the qualified countermeasures research expenses for the taxable year, over

"(2) the countermeasures base period amount.

"(b) QUALIFIED COUNTERMEASURES RESEARCH EXPENSES.—For purposes of this section—

"(1) IN GENERAL.—The term 'qualified countermeasures research expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year directly or indirectly to any qualified non-profit or academic institution for countermeasures research activities certified under section 102(e) of such Act.

"(2) COUNTERMEASURES RESEARCH ACTIVITIES.—

"(A) IN GENERAL.—The term 'countermeasures research activities' means research to

develop countermeasures or research tools conducted at any qualified non-profit or academic institution in the development of any product, which occurs before—

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

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

"(iii) the date classification or approval of such product which is a device intended for human use is given under section 513, 514, or 515 of the Federal Food, Drug, and Cosmetic Act.

"(B) DEFINITIONS.—

"(i) COUNTERMEASURES; RESEARCH TOOLS.—The terms 'countermeasures' and 'research tools' have the meanings given such terms by section 3 of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

"(ii) PRODUCT.—The term 'product' means any drug, biologic, medical device, or research tool.

"(3) QUALIFIED NON-PROFIT OR ACADEMIC INSTITUTION.—The term 'qualified non-profit or academic institution' means any of the following institutions:

"(A) EDUCATIONAL INSTITUTION.—A qualified organization described in section 170(b)(1)(A)(iii) which is owned or affiliated with an institution of higher education as described in section 3304(f).

"(B) TEACHING HOSPITAL.—A teaching hospital which—

"(i) is publicly supported or owned by an organization described in section 501(c)(3), and

"(ii) is affiliated with an organization meeting the requirements of subparagraph (A).

"(C) FOUNDATION.—A medical research organization described in section 501(c)(3) (other than a private foundation) which is affiliated with, or owned by—

''(i) an organization meeting the requirements of subparagraph (A), or

''(ii) a teaching hospital meeting the requirements of subparagraph (B).

''(D) CHARITABLE RESEARCH HOSPITAL.—A hospital that is designated as a cancer center by the National Cancer Institute.

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

''(4) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term 'qualified countermeasures research expenses' shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

''(c) COUNTERMEASURES RESEARCH BASE PERIOD AMOUNT.—For purposes of this section, the term 'countermeasures research base period amount' means the average annual qualified countermeasures research expenses paid by the taxpayer during the 3-taxable year period ending with the taxable year immediately preceding the first taxable year of the taxpayer beginning after December 31, 2002.

''(d) SPECIAL RULES.—

''(1) LIMITATION ON FOREIGN TESTING.—No credit shall be allowed under this section with respect to any clinical testing research activities conducted outside the United States.

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

''(3) COORDINATION WITH CREDIT FOR INCREASING RESEARCH EXPENDITURES AND WITH CREDIT FOR CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS FOR RARE DISEASES.—Any qualified countermeasures research expense for a taxable year shall not be taken into account for purposes of determining the credit allowable under section 41 or 45C for such taxable year.

''(4) QUALIFIED COUNTERMEASURES RESEARCH EXPENSES NOT TREATED AS UNRELATED BUSINESS TAXABLE INCOME.—For purposes of section 511, qualified countermeasures research expenses paid or incurred by the taxpayer directly or indirectly to any qualified non-profit or academic institution shall not be considered unrelated business taxable income of such institution.''.

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

(i) IN GENERAL.—Section 38(b) of such Code (relating to current year business credits), as amended by this section, is amended by striking ''plus'' at the end of paragraph (15), by striking the period at the end of paragraph (16) and inserting '', plus'', and by adding at the end the following:

''(17) the countermeasures research credit determined under section 41A(a).''.

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

''(12) NO CARRYBACK OF SECTION 41A CREDIT BEFORE ENACTMENT.—No portion of the unused business credit for any taxable year which is attributable to the countermeasures research credit determined under section 41A may be carried back to a taxable year beginning before January 1, 2003.''.

(C) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code, as amended by this section, is amended by adding at the end the following new subsection:

''(e) CREDIT FOR COUNTERMEASURES RESEARCH EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the qualified countermeasures research expenses (as defined in section 41A(b)) otherwise allowable as a deduction for the taxable year which is equal to the amount of the credit determined for such taxable year under section 41A(a).

''(2) CERTAIN RULES TO APPLY.—Rules similar to the rules of paragraphs (2), (3), and (4) of subsection (c) shall apply for purposes of this subsection.''.

(D) DEDUCTION FOR UNUSED PORTION OF CREDIT.—Section 196(c) of such Code (defining qualified business credits), as amended by this section, is amended by striking ''and'' at the end of paragraph (10), by striking the period at the end of paragraph (11) and inserting '', and'', and by adding at the end the following new paragraph:

''(5) the countermeasures research expenses credit determined under section 41A(a) (other than such credit determined under the rules of section 280C(e)(2)),''.

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

"Sec. 41A. Credit for countermeasures research expenses.".

(c) REPORTING; RECAPTURE.—

(1) REPORTING.—Each certified entity under subsection (b) shall submit to the Director and the Secretary of the Treasury such information regarding its election of any tax incentive under this section for the purpose certified under section 102(e) as the Director and the Secretary determine necessary to carry out the enforcement provisions prescribed under paragraph (2).

(2) RECAPTURE.—The Secretary of the Treasury, in consultation with the Director, shall provide for the recapture of any tax benefits resulting from any elected tax incentive under this section if the resulting research is for a purpose other than that certified under section 101(e).

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

SEC. 202. TERROR WEAPON COUNTERMEASURE PURCHASE FUND.

(a) FINDINGS AND PURPOSE.—

(1) FINDINGS.—Congress finds that—

(A) the market for countermeasures is uncertain at best and it is not possible for private, for-profit entities to determine the prospects for a reasonable rate of return on their research and development investments relating to such countermeasures;

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

(C) such entities need to know in advance, prior to undertaking the research necessary to develop a countermeasure, the nature, size, duration, and terms of the market that is available if it is successful in such development; and

(D) the market and rate of return that the Federal Government guarantees for a countermeasure must be comparable to a market and rate of return that would be available to the entity and investors for non-countermeasure research.

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

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

(B) provide advance, partial, progress or other payments to manufacturers of countermeasures, diagnostics, or research tools described in subparagraph (A).

(3) LIMITATION.—Private sector entities are entitled to the procurement incentives provided for in this Act (and the amendments made by this Act) only when such entities successfully develop a countermeasure that meets the specifications prescribed by the Secretary.

(b) DEFINITIONS.—In this section:

(1) ELIGIBLE COUNTERMEASURE, DIAGNOSTIC, OR RESEARCH TOOL.—The term ''eligible countermeasure, diagnostic, or research tool'' means a countermeasure (as defined in section 3(1)), diagnostic

(developed under section 103), or research tool (developed under section 104)—

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

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

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

(2) FUND.—The term ''Fund'' means the Terror Weapon Countermeasure Purchase Fund established under subsection (c).

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

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

(e) USE OF FUND.—

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

(A) for the purchase of eligible countermeasures, diagnostics, or research tools with respect to which the Secretary has made an affirmative determination as provided for in section 102(e)(3)(B), 103(e)(2), or 104(e)(2) which shall be made available to the Secretary and distributed as the Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of Defense, determines appropriate; and

(B) to provide advance, partial, progress or other payments, in accordance with paragraph (4), to manufacturers of eligible countermeasures, diagnostics, or research tools with respect to which the Secretary has made an affirmative determination as provided for in section 102(e)(3)(B), 103(e)(2), or 104(e)(2).

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

(A) purchased by the Fund—

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

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

(ii) in the case of a diagnostic or research tool, at the price and under the terms negotiated by the Secretary and the manufacturer; and

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

(3) CONDITIONS FOR PURCHASE.—Payments made for purchases under paragraph (1)(A) shall be made under such terms and conditions as the Secretary, in consultation with the Secretary of the Treasury, determines (in accordance with section 102) are appropriate or customary in the commercial marketplace and are in the best interests of the United States, including the provision by the manufacturer of adequate security for such payments. If such security is in the form of a lien on property or equipment in favor of the United States, such lien shall be paramount to all other liens on such property or equipment and shall be effective immediately upon the first payment, without filing, notice, or other action by the United States.

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

(A) IN GENERAL.—The Secretary of the Treasury may make payments under paragraph (1)(B) to manufacturers of eligible countermeasures, diagnostics, or research tools prior to the final purchase of such countermeasure, diagnostic, or research tool.

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

(i) the performance of the manufacturer involved as measured by the Secretary of the Treasury using objective, quantifiable methods (such as delivery of acceptable items, work measurement, or statistical process controls) established by the Secretary of the Treasury in consultation with the Secretary;

(ii) the accomplishment of events as defined in a program management plan that is developed by the manufacturer and submitted to the Secretary of the Treasury; or

(iii) other quantifiable measures of results determined appropriate by the Sec-

retary of the Treasury, in consultation with the Secretary.

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

(i) IN GENERAL.—The Secretary of the Treasury, in consultation with the Secretary, shall, with respect to a manufacturer of an eligible countermeasure, diagnostic, or research tool, determine the number payments to be made, the timing of such payments, and subject to clause (ii), the amount of each such payment.

(ii) LIMITATION.—The amount of any payment made to a manufacturer under this paragraph shall not exceed the amount of the final purchase price (described in paragraph (2)(A)) for the countermeasure, diagnostic, or research tool involved that remains unpaid as of the date of the payment involved.

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

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

(E) SECURITY.—The provisions of paragraph (3) relating to security shall apply to payments made under this paragraph.

(5) THIRD PARTY MANUFACTURER.—In the case of an entity that is certified under section 102 and that contracts with another entity for the manufacture of a countermeasure (as provided for in section 101(e)(2)(F)), the Secretary of the Treasury shall, after receipt of notice of such contract, ensure that payments are made to the entity at a pre-determined amount to reimburse the entity for research and other administrative costs that do not include the actual manufacturing cost. Amounts for manufacturing costs shall be passed through to the actual manufacturer.

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

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

(A) consideration of—

(i) in the case of countermeasures, the prevalence of the infection or exposure to a toxin or material to be treated by the eligible countermeasure; or

(ii) in the case of diagnostics or research tools, the predicted demand for the use of such diagnostics or research tools; and

(B) consideration of the ability of the recipient to effectively and safely deliver the countermeasures, diagnostics, or research tools.

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

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

Chemical Agent Priority List developed under section 101 unless the Secretary certifies entities to produce more than one such countermeasure or additional diagnostics or research tools under section 102(e).

(9) REGULATIONS.—The Secretary shall promulgate such regulations as are necessary to carry out the provisions of this subsection.

(f) APPROPRIATIONS.—

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

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

(3) AVAILABILITY.—Amounts appropriated under this section shall remain available until expended.

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

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

SEC. 203. PATENT TERM PROTECTION AND EXCLUSIVE MARKETING.

(a) FINDINGS AND PURPOSE.—

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

(A) Patents are necessary to protect the inventions of entrepreneurial firms. Without patents, the inventions of these companies can be expropriated by competitors and investors' expectations of a reasonable rate of return on their investment are frustrated. In return for a limited term of protection from competitors, inventors are required to publish a detailed description of the invention for which the patent has been granted.

(B) The 20 year term of a patent is measured from the date of the patent application. The effective term of a patent, however, is the term remaining after an invention has been approved for sale by Government regulators. Erosion of the term of patents for biotechnology and pharmaceutical firms, which cannot market a product until it has been approved, is common and increasing. Protection against such erosion, due to delays caused by Government regulatory review, will ensure that the full term of the patent granted by the Patent and Trademark Office is available to the inventor to recoup their investment. Such protections maintain the full term of the patent.

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

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

measure, will lead to challenges to their patents.

(2) PURPOSE.—The purpose of this section is to provide patent incentives to protect inventions from expropriation by competitors and to provide an incentive for capital formation to fund countermeasures research.

(3) LIMITATION.—Private sector entities are entitled to the intellectual property and marketing exclusivity incentives provided for in this Act (and the amendments made by this Act) only when such entities successfully develop a countermeasure that meets the specifications of the Director and upon execution of a contract with the Secretary with respect to procurement of the countermeasure in accordance with section 202.

(b) RESTORATION OF PATENT TERMS RELATING TO COUNTERMEASURES FOR CERTAIN BIOLOGICAL OR CHEMICAL AGENTS OR TOXINS OR RADIOLOGICAL MATERIALS.—

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

"§ 156a. Restoration of patent terms relating to countermeasures for certain biological or chemical agents or toxins

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

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

''(2) 'regulatory review period' means—

''(A) the period beginning on the date a patent is issued through the date of the first filing of an application relating to human clinical trials for the subject of that patent with the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.), and includes any period prior to such issuance during which the Food and Drug Administration is reviewing such application;

''(B) the period beginning on the date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective for the approved product and ending on the date an application was

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

''(C) the period beginning on the date the application was initially submitted for the approved product under section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and ending on the date such application was approved under the applicable section; and

''(3) 'Research Act' means the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

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

''(1) encompasses within its scope a composition of matter, a method of using such composition, a method of manufacturing such composition, or a process for using such composition relating to a product;

''(2) is for an eligible countermeasure as defined under section 202(b)(1) of the Research Act; and

''(3) is held by an entity (or is exclusively licensed to an entity by a not-for-profit organization or is exclusively licensed to an entity under section 209(e) of this title or section 12(b)(7) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)(1)(7)) that has entered into a contract for sale of that countermeasure under section 102(e)(3)(B)(i) of the Research Act.

''(c) CERTAIN ACTION NOT NECESSARY.—With respect to the owner of record of a patent described under subsection (b), it shall be presumed that no action under this section is necessary to effect the policies and objectives of title 18.

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

''(e) ADMINISTRATIVE PROVISIONS.—

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

''(2) CONTENT.—The application shall contain—

''(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

''(B) the identity of the patent for which an extension applies;

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

''(D) such patent or other information as the Office may require.

''(3) SUBMISSION OF APPLICATION.—An application may only be submitted within the 60-day period beginning on the date the product became eligible for purchase under section 202 of the Research Act. The submission of an application under this section is an irrevocable election of the application of this section to a patent consistent with paragraph (4).

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

''(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit an extension of the term of patent relating to a product that, before the effective date of this section—

''(A) was approved for commercial marketing for non-countermeasure uses; or

''(B) was approved for commercial marketing.''.

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

''156a. Restoration of patent terms relating to countermeasures for certain biological or chemical agents or toxins.''.

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

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

"§ 158. Patent term for patents held by entities with certain research certifications

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

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

''(2) 'Research Act' means the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

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

''(c) PATENT.—

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

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

''(i) holds a certification under section 102(e) of the Research Act with respect to a product, a method of manufacturing such product, or a method of using such product;

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

''(iii) is a qualified small business as determined under section 1202(d) of the Internal Revenue Code of 1986, by substituting '$750,000,000' for '$50,000,000' each place it appears;

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

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

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

''(e) LIMITATIONS AND CONDITIONS.—In the administration of this section—

''(1) only 1 patent may be designated with respect to each certification held by an entity;

''(2) no redesignation of another patent may be made; and

''(3) the patent designated by the entity—

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

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

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

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

''(f) APPLICATION.—

''(1) IN GENERAL.—An entity that holds a certification under section 102(e) of the Research Act, may file an application with the Patent and Trademark Office under this section.

''(2) CONTENT.—The application shall contain—

''(A) a copy of the certification under section 102(e) of the Research Act;

''(B) a copy of any waiver granted under subsection (c)(2); and

''(C) a designation of the patent to which this section applies.

''(3) SUBMISSION OF APPLICATION.—An application may only be submitted within the 60-day period beginning on the date that the applicable product is eligible for purchase under section 202 of the Research Act.

''(4) IRREVOCABLE AND EXCLUSIVE.—

''(A) IRREVOCABLE ELECTION.—A filing of an application under this section is an irrevocable election of the application of this section to a patent consistent with subparagraph (B).

''(B) EXCLUSIVE.—Sections 156 and 156a shall not apply to any patent for which there is a filing under this section. This section shall not apply to any patent the term of which has been extended under section 156.''.

(2) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 14 of title 35, United States Code, is amended by adding at the end the following:

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

(d) EXCLUSIVE LICENSING.—

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

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

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

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

"(e) TERMS AND CONDITIONS OF EXCLUSIVE LICENSE.—Each exclusive license granted under section 207(a)(2) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to any patent for the licensed invention for purposes of extending a patent under section 156a or 158.".

(3) COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.—Section 12(b) of the Stevenson-Wydler Technology Innovation Act of 1980 (15

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

''(7) Each exclusive license for a patent granted under an agreement entered into under subsection (a)(1) shall include a provision that, at the discretion of the licensee, the licensee may act as the agent for the licensor with respect to that patent for purposes of extending a patent under section 156a or 158 of title 35, United States Code.''.

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

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

''SEC. 505B. MARKET EXCLUSIVITY FOR TERROR WEAPONS COUNTERMEASURES.

''(a) IN GENERAL.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that the new drug involved is a countermeasure (as defined in section 3(1) of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002) that meets the requirements of

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

''(b) EXCLUSIVITY.—With respect to a new drug described in subsection (a)—

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

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

''(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be 10 years rather than seven years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection

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

''(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

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

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of 5 years after the date the patent expires (including any patent extensions).''.

SEC. 204. LIABILITY AND INDEMNIFICATION.

(a) FINDINGS AND PURPOSE.—

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

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

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

(C) The United States faces dire public health consequences if agents, toxins, and materials are used in an attack for which no countermeasures are available. The United States has enemies who will not hesitate to use these agents in an attack. Our national security requires that we ensure that these countermeasures are developed and the most effective available research and development expertise

lies with biotechnology and pharmaceutical companies.

(2) PURPOSE.—It is the purpose of this section to provide liability protections to encourage companies to conduct research to develop and produce countermeasures.

(3) LIMITATION.—Upon a determination by the Secretary that it is in the national security interest of the United States under section 101(e) of this act, private sector entities are entitled to the liability protections provided for in this section (and the amendments made by this section) only when such entities successfully develop a countermeasure that meets the specifications of the Secretary and upon the execution of a contract with the Secretary with respect to procurement of the countermeasure in accordance with section 202.

(b) INDEMNIFICATION AND DEFENSE AGREEMENTS.—Notwithstanding sections 1341, 1342, 1349, 1350, and 1351 and subchapter II of chapter 15, of title 31, United States Code, or any other provision of law, the Secretary—

(1) shall enter into agreements to indemnify and defend persons or entities engaged in the research, development, and production of counter-

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

(2) shall enter into agreements to indemnify and defend persons or entities from claims or civil actions arising from human clinical trials and research, development, and production of countermeasures developed under a certification under section 102; and

(3) may enter into such agreements with other persons and entities relating to such countermeasures, diagnostics, or research tools (including individuals and entities engaged in the administration or use of such countermeasures, diagnostics, or research tools), whether or not listed as a countermeasure by the Secretary under section 101, if the Secretary determines that the national interest in combating terrorism, or the protection of the public health, or both, reasonably requires such an agreement.

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

research, development, production, or use of a countermeasure, diagnostic, or research tool purchased under section 202 or for claims or civil actions or research relating to countermeasures developed under a certification under section 102. Such contracts and protection against claims or civil actions shall apply only when the manufacturer of the countermeasure has entered into a contract with the Secretary, for procurement of the countermeasure in accordance with section 202. Such contracts and protection against claims or civil actions shall apply only to the administration or use of a countermeasure, diagnostic, or research tool by the Federal Government or another entity with respect to a biological agent or toxin or a nuclear or radiological material used as a terror weapon.

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

(e) REQUIREMENTS.—An indemnification and defense agreement under this section shall—

(1) require notice to be provided to the United States of any claim or civil action (including an exclusive civil action) that is filed against persons or entities who are parties to such agreement for any alleged damages (including bodily injury, death, economic losses, non-economic losses, and loss of or damage to property or punitive damages) allegedly caused by the research, development, production, distribution, administration or use of a countermeasure, diagnostic, or research tool described in subsection (b); and

(2) require control of, or assistance in, the defense by the United States of such claim or civil action.

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

(1) VENUE.—An exclusive civil action under this section shall be filed in any United States district court of otherwise appropriate jurisdiction. Appeals from appealable actions of such courts in such actions shall be taken to the Court of Appeals for the Federal Circuit and, as appropriate, to the United States Supreme Court.

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

(3) LIMITATIONS ON DAMAGES.—In an exclusive civil action filed under this section an award for non-economic damages shall not exceed 3 times the award for economic damages or $250,000 per plaintiff, whichever is greater. In no such cases shall punitive or exemplary damages be awarded.

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

eral Government or health care insurance provider for medical expenses.

(g) LIMITATIONS.—The protections provided for in this section shall not apply in the case of an entity described in subsection (b)(1) if—

(1) such entity fails to enter into a contract with the Secretary for the purchase of a countermeasure, diagnostic, or research tool developed or produced under title I; or

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

(h) DEFINITIONS.—In this section:

(1) EXCLUSIVE CIVIL ACTION.—The term ''exclusive civil action'' means a civil action described in subsection (c)(1).

(2) INDEMNIFICATION AND DEFENSE AGREEMENTS.—The term ''indemnification and defense agreements'' means the agreements described in subsection (b).

Subtitle B—Other Incentives

SEC. 211. ACCELERATED APPROVAL OF COUNTERMEASURES.

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

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

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

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

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

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

(c) PRIORITY REVIEW.—

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

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

SEC. 212. APPROVALS OF CERTAIN DRUGS BASED ON ANIMAL TRIALS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended by adding at the end the following: ''In the case of drugs and diagnostic devices for use against lethal or permanently disabling toxic chemical, biological, radiological, nuclear, or other substances, when adequate and well-controlled studies of effectiveness in humans cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers, and when adequate field trials assessing use of the drug or diagnostic device (in situations such as after accidental or hostile exposure to the substance) have not been feasible or where adequate volumes of human samples for diagnosis from previous exposures is not available, the Secretary may grant approval based on evidence of effectiveness derived from appropriate studies

in animals.The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority contained in the preceding sentence.''.

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

''(k) APPROVAL OF CERTAIN PRODUCTS AND DIAGNOSTIC DEVICES BASED ON ANIMAL TRIALS.—In the case of biological products and diagnostic devices for use against lethal or permanently disabling toxic chemical, biological, radiological, nuclear, or other substances, when definitive human effectiveness studies in humans cannot ethically be conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers, and when adequate field trials assessing use of the drug (in situations such as after accidental or hostile exposure to the substance) have not been feasible, the Secretary may grant approval based on evidence of effectiveness derived from appropriate studies in animals. The Secretary may promulgate regulations establishing standards, criteria, and procedures for use of the authority provided under this subsection.''.

SEC. 213. LIMITED ANTITRUST EXEMPTION.

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

''(g) LIMITED ANTITRUST EXEMPTION.—

''(1) COUNTERMEASURES DEVELOPMENT MEETINGS.—

''(A) COUNTERMEASURES DEVELOPMENT MEETINGS AND CONSULTATIONS.—The Secretary may conduct meetings and consultations with parties involved in the development of countermeasures for the purpose of the development, manufacture, distribution, purchase, or sale of countermeasures consistent with the purposes of this title. The Secretary shall give notice of such meetings and consultations to the Attorney General and the Chairperson of the Federal Trade Commission (referred to in this subsection as the 'Chairperson').

''(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

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

''(ii) be open to parties involved in the development, manufacture, distribution,

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

"(iii) be open to the Attorney General and the Chairperson;

"(iv) be limited to discussions involving the development, manufacture, distribution, or sale of countermeasures, consistent with the purposes of this title; and

"(v) be conducted in such manner as to ensure that national security, confidential, and proprietary information is not disclosed outside the meeting or consultation.

"(C) MINUTES.—The Secretary shall maintain minutes of meetings and consultations under this subsection, which shall not be disclosed under section 552 of title 5, United States Code.

"(D) EXEMPTION.—The antitrust laws shall not apply to meetings and consultations under this paragraph, except that any agreement or conduct that results from a meeting or consultation and that does not receive an exemption pursuant to this subsection shall be subject to the antitrust laws.

''(2) WRITTEN AGREEMENTS.—The Secretary shall file a written agreement regarding covered activities, made pursuant to meetings or consultations conducted under paragraph (1) and that is consistent with this paragraph, with the Attorney General and the Chairperson for a determination of the compliance of such agreement with antitrust laws. In addition to the proposed agreement itself, any such filing shall include—

''(A) an explanation of the intended purpose of the agreement;

''(B) a specific statement of the substance of the agreement;

''(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

''(D) an explanation of the necessity of a cooperative effort among the particular participating parties to achieve the objectives of the agreement; and

''(E) any other relevant information determined necessary by the Secretary in consultation with the Attorney General and the Chairperson.

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

''(A) be in compliance with the antitrust laws, and so inform the Secretary and the participating parties; or

''(B) violate the antitrust laws, in which case, the filing shall be deemed to be a request for an exemption from the antitrust laws, limited to the performance of the agreement consistent with the purposes of this title.

''(4) ACTION ON REQUEST FOR EXEMPTION.—

''(A) IN GENERAL.—The Attorney General, in consultation with the Chairperson, shall grant, deny, grant in part and deny in part, or propose modifications to a request for exemption from the antitrust laws under paragraph (3) within 15 days of the receipt of such request.

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

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

''(C) DETERMINATION.—In granting an exemption under this paragraph, the Attorney General, in consultation with the Chairperson and the Secretary—

''(i) must find—

''(I) that the agreement involved is necessary to ensure the availability of countermeasures;

''(II) that the exemption from the antitrust laws would promote the public interest; and

''(III) that there is no substantial competitive impact to areas not directly related to the purposes of the agreement; and

''(ii) may consider any other factors determined relevant by the Attorney General and the Chairperson.

''(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and shall expire on the date that is 3 years after the date on which

the exemption becomes effective (and at 3 year intervals thereafter, if renewed) unless the Attorney General in consultation with the Chairperson determines that the exemption should be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

''(6) LIMITATION ON PARTIES.—The use of any information acquired under an exempted agreement by the parties to such an agreement for any purposes other than those specified in the antitrust exemption granted by the Attorney General shall be subject to the antitrust laws and any other applicable laws.

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

''(8) REPORT.—Not later than 1 year after the date of enactment of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, and annually thereafter, the Attorney General and the Chairperson shall report to Congress on the use and continuing need for the exemption from the antitrust laws provided by this subsection.

''(9) SUNSET.—The authority of the Attorney General to grant or renew a limited antitrust exemption under this subsection shall expire at the end of the 10-year period that begins on the date of enactment of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

''(h) DEFINITIONS.—In this section:

''(1) ANTITRUST LAWS.—The term 'antitrust laws'—

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

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

''(2) COUNTERMEASURE.—The term 'countermeasure' has the meaning given such term in section 3(2) of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002.

''(3) COVERED ACTIVITIES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered activities' means any group of activities or conduct, including attempting to make, making, or performing a contract or agreement or engaging in other conduct, for the purpose of—

"(i) theoretical analysis, experimentation, or the systematic study of phenomena or observable facts necessary to the development of countermeasures;

"(ii) the development or testing of basic engineering techniques necessary to the development of countermeasures;

"(iii) the extension of investigative findings or theory of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, prototypes, equipment, materials, and processes necessary to the development of countermeasures;

"(iv) the production, distribution, or marketing of a product, process, or service that is a countermeasures;

''(v) the testing in connection with the production of a product, process, or services necessary to the development of countermeasures;

''(vi) the collection, exchange, and analysis of research or production information necessary to the development of countermeasures; or

''(vii) any combination of the purposes described in clauses (i) through (vi);

and such term may include the establishment and operation of facilities for the conduct of covered activities described in clauses (i) through (vi), the conduct of such covered activities on a protracted and proprietary basis, and the processing of applications for patents and the granting of licenses for the results of such covered activities.

''(B) EXCEPTION.—The term 'covered activities' shall not include the following activities involving 2 or more persons:

''(i) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service if such in-

formation is not reasonably necessary to carry out the purposes of covered activities.

''(ii) Entering into any agreement or engaging in any other conduct—

''(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

''(II) to restrict or require participation by any person who is a party to such covered activities in other research and development activities, that is not reasonably necessary to prevent the misappropriation of proprietary information contributed by any person who is a party to such covered activities or of the results of such covered activities.

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

pressly exempted from the antitrust laws by a determination under subsection (i)(4).

''(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out the purpose of such covered activities.

''(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not so expressly exempted from the antitrust laws by a determination under subsection (i)(4).

''(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person who is a party to such activities, in any unilateral or joint activity that is not reasonably necessary to carry out the purpose of such covered activities.

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

''(5) PERSON.—The term 'person' has the meaning given such term in subsection (a) of the first section of this Act.

''(6) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.''.

SEC. 214. BIOLOGICS MANUFACTURING CAPACITY INCENTIVES.

(a) FINDINGS.—Congress makes the following findings:

(1) When the United States develops new biologically derived materials, including vaccines, monoclonal antibodies, and recombinant proteins, to prevent infection by bioterrorist agents or toxins or to treat those infected in bioterrorist attacks, a shortage of manufacturing facilities for biologics may delay or prevent the production and stockpiling of such materials.

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

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

(3) The Defense Science Board has found ''Any bioterrorism attack that created the need to treat more than 50,000 people with an extended course of antibiotic therapy...or to immunize more than 1 to 3 million people with a vaccine would completely overwhelm the total production capacity of the industry.'' The Federal Government ''must establish a proactive long-term plan to address these inventory and production shortfalls''.

(4) A typical manufacturing facility costs between $200,000,000 and $400,000,000 to build, and there is no incentive for companies to build these facilities until a product has been developed and approved. On average, a plant takes 4 years to build, considering the intricacies of the process and the necessary Food and Drug Administration procedures.

(5) Biotechnology and pharmaceutical companies have no reason to fund the construction of biologics manufacturing facilities unless and until there is a market demand for the facilities.

(6) The incentives provided under this Act, and the amendments made by this Act, should lead to the development of new biologically derived materials to prevent and treat bioterrorist attacks and decisions to purchase, stockpile and perhaps deploy such materials.

(7) It is in the national interest for the United States to provide incentives for the construction of sufficient biologics manufacturing facilities so that there will be no delay in the production of biologically active materials once such materials are developed.

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

(1) conduct a survey of the biologics manufacturing facilities operating in the United States and determine whether additional manufacturing facilities that will be needed (and if so the number of such facilities) to manufacture and stockpile biologically active materials for bioterrorist attacks; and

(2) develop a plan to ensure that sufficient biologics manufacturing facilities are available in the United States when they are needed, including an analysis of the feasibility of the Federal Government contracting for the construction of such facilities or of providing tax and other incentives for the construction of such facilities by private sector entities.

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

(d) INCENTIVES FOR THE CONSTRUCTION OF BIOLOGICS MANUFACTURING FACILITIES AVAILABLE FOR THE PRODUCTION OF COUNTERMEASURES.—

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

provided under paragraph (2). Such regulations shall state when such an entity shall be available and the terms for the use for the production of such countermeasures. If an entity is constructed to produce such countermeasures, such entity shall provide notice that such entity is available to produce such countermeasures.

(2) BIOLOGICS MANUFACTURING FACILITIES INVESTMENT TAX CREDIT.—

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

''(4) the biologics manufacturing facilities investment credit.''.

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

''(c) BIOLOGICS MANUFACTURING FACILITIES INVESTMENT CREDIT.—

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

214(d)(1) of the Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002, the biologics manufacturing facilities investment credit for any taxable year is an amount equal to 20 percent of the qualified investment for such taxable year.

''(2) QUALIFIED INVESTMENT.—For purposes of paragraph (1), the qualified investment for any taxable year is the basis of each biologics manufacturing facilities property placed in service by the taxpayer during such taxable year.

''(3) BIOLOGICS MANUFACTURING FACILITIES PROPERTY.—For purposes of this subsection, the term 'biologics manufacturing facilities property' means real and tangible personal property—

''(A)(i) the original use of which commences with the taxpayer, or

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

''(B) which is depreciable under section 167, and

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

''(4) CERTAIN PROGRESS EXPENDITURE RULES MADE APPLICABLE.—Rules similar to rules of subsection (c)(4) and (d) of section 46 (as in effect on the day before the date of the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this subsection.''.

(C) TECHNICAL AMENDMENTS.—

(i) Subparagraph (C) of section 49(a)(1) of such Code is amended by striking ''and'' at the end of clause (ii), by striking the period at the end of clause (iii) and inserting '', and'', and by adding at the end the following new clause:

''(iv) the basis of any biologics manufacturing facilities property.''.

(ii) Subparagraph (E) of section 50(a)(2) of such Code is amended by striking ''section 48(a)(5)(A)'' and inserting ''section 48(a)(5) or 48(c)(4)''.

(iii)(I) The section heading for section 48 of such Code is amended to read as follows:

''SEC. 48. OTHER CREDITS.''.

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

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

"Sec. 48. Other Credits.".

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

SEC. 215. BIOLOGICS MANUFACTURING EFFICIENCY INCENTIVES.

(a) FINDINGS.—Congress finds that—

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

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

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

the cost of manufacturing and stockpiling these vaccines; and

(4) the subjects of research relating to the manufacturing of biologics may include the development of—

(A) additional well characterized cell lines for vaccine and monoclonal antibody production;

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

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

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

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

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

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

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

(I) improved methods that enhance disinfection and sterilization of material and facilities;

(J) new methods to improve output, manufacturing costs, and product quality with a particular emphasis on downstream processing (separation and purification) where particular bottlenecks occur with much lost product, complexity and very high costs; and

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

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

(1) conduct a survey of existing biologics manufacturing sciences and determine whether technical advances in such sciences might increase the biologics output capacity and purity, and lower the manufacturing cost of vaccines; and

(2) develop a plan to provide incentives to enhance scientific research to develop new technologies identified under the survey conducted under paragraph (1), including a list of the possible tech-

nologies that may be developed and the possible incentives that may lead to their development.

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

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

SEC. 216. CONSTRUCTION OF BIOSAFETY LEVEL 3-4 RESEARCH FACILITIES.

(a) FINDINGS.—Congress finds that—

(1) research to develop countermeasures requires the use of special facilities where biological agents can be handled safely;

(2) very few companies can capitalize the construction of these special facilities; and

(3) the Federal Government can facilitate research and development of countermeasures by financing the construction of these special facilities.

(b) GRANTS AUTHORIZED.—

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

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

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

(B) give priority for the use of the facility involved to those entities that have been registered and certified by the Secretary to develop countermeasures; and

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

(3) NUMBER OF GRANTS.—The Secretary of the Department of Homeland Defense shall determine the number of facilities that need to be constructed under this section, not to exceed 10 such facilities nationwide, and the Secretary shall award grants based on such determination.

(c) APPLICATION.—

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

form and containing such information, as the Secretary may require.

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

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

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

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

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

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

(1) unless otherwise specifically identified, the term ''Director'' means the Director of the National Institutes of Health; and

(2) a ''biosafety level 3–4 facility'' means a facility for research on indigenous, exotic, or dangerous agents with the potential for aerosol transmission of disease that may have serious or lethal consequences or that pose a high risk of life-threat-

ening disease, aerosol-transmitted laboratory infections, or related agents with unknown risk of transmission.

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

SEC. 217. NATIONAL INSTITUTES OF HEALTH COUNTERMEASURES PARTNERSHIP CHALLENGE GRANTS.

(a) GRANTS AUTHORIZED.—The Director of the National Institutes of Health (in this section referred to as the ''Director'') is authorized to award partnership challenge grants to promote joint ventures between the National Institutes of Health, its grantees, and for-profit biotechnology, pharmaceutical, and medical device industries for the development of countermeasures and research tools.

(b) REGULATIONS.—The Director shall issue regulations within 90 days of the date of enactment of this section to implement the awarding of grants under subsection (a).

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

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

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

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

(a) EXPANDED HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.—

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

''(I) after the date that the application is filed for designation under such section 526, and''.

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

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to amounts paid or incurred after December 31, 2002.

(b) PUBLICATION OF FILING AND APPROVAL OF REQUESTS FOR DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS.—Subsection (c) of section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) is amended to read as follows:

''(c) Not less than monthly, the Secretary shall publish in the Federal Register, and otherwise make available to the public, notice of requests for designation of a drug under subsection (a) and approvals of such requests. Such notice shall include—

''(1) the name and address of the manufacturer and the sponsor;

''(2) the date of the request for designation or of the approval of such request;

''(3) the nonproprietary name of the drug and the name of the drug under which an application is filed under section 505(b) or section 351 of the Public Health Service Act;

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

''(5) the proposed indication for use of the product.''.

SEC. 219. USE OF ADJUVANTS IN VACCINE PRODUCTION.

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

profit entities relating to the development and use of adjuvants to enhance the potency of, and increase the period of protection and the number of useful doses from, a limited supply of antigen in response to an attack with a biological agent or toxin or nuclear or radiological material.

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

(c) ELIGIBILITY FOR CLASSIFICATION.—

(1) CRITERIA.—

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

(i) consider—

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

(II) common knowledge concerning the adjuvant throughout that

portion of the scientific community that is knowledgeable about the safety of such adjuvant substances that are directly or indirectly added to vaccines;

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

(IV) other factors that the Secretary determines appropriate;

(ii) require—

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

(II) the consideration of the cumulative experience of at least 2,000 human subjects of the human trials; and

(III) the conduct of at least one safety assessment, using the parameters described in subparagraph (B), of the toxicity profile of the adjuvant in which the dose per injection should

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

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

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

(ii) injection site observations;

(iii) histopathology;

(iv) necropsy; and

(v) pyrogenicity.

(2) DEEMING SAFE.—An adjuvant determined by the Secretary to be safe under paragraph (1) shall, with respect to any particular use or intended use of such adjuvant, be deemed to be safe for the purposes of the application of section 351 of the Public Health Service Act (42 U.S.C. 262) or section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(d) ESTABLISHMENT OF A PREFERRED LIST OF ADJUVANTS.—

(1) IN GENERAL.—The Secretary shall establish a list of preferred adjuvants that are generally recognized as safe for use in vaccine formulation and production.

(2) REGULATIONS.—The Secretary shall promulgate such regulations as are necessary to carry out the provisions of this subsection.

(3) PUBLICATION.—The Secretary shall publish the preferred list of adjuvants not less than quarterly in the Federal Register.

(e) PETITION FOR ELIGIBILITY.—

(1) IN GENERAL.—Any person may, with respect to any intended use of an adjuvant, file with the Secretary a petition proposing to list the adjuvant on the list of preferred adjuvants described in subsection (d).

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

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

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

(C) all relevant data bearing on the physical or other technical effect that such adjuvant is intended to produce, and the quantity of such adjuvant required to produce such effect; and

(D) full reports of investigations made with respect to the safety of such adjuvant, including the full disclosure of information as to the methods and controls used in conducting such investigations.

(3) ADDITIONAL INFORMATION.—Upon the request of the Secretary, a petitioner under this subsection shall provide the Secretary, as part of the petition process under this subsection, a full description of the methods used in, and the facilities and controls used for, the production of the adjuvant that is the subject of the petition and samples of the adjuvant involved, or articles used as components thereof, and samples of the vaccine in or on which the adjuvant is proposed to be used.

(4) NOTIFICATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), not later than 90 days after the date on which a petition is filed under paragraph (1), the Secretary shall provide the petitioner with notice of the approval or disapproval of such petition.

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

quired, the Secretary shall notify the petitioner in writing during such period of the additional period required prior to approval or disapproval.

(f) CONDITIONAL APPROVAL.—

(1) ESTABLISHING CONDITIONS.—The Secretary may provide for the conditional approval of a petition submitted under subsection (e). Such conditional approval shall limit the use of an adjuvant unless conditions prescribed by the Secretary are complied with by the petitioner with respect to the use of the adjuvant. Such conditions may include—

(A) specifications as to the particular vaccine or classes of vaccines in which such adjuvant may be used;

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

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

(D) any labeling requirements for such adjuvant that are determined necessary to ensure the safety of the use of the adjuvant.

(2) NOTIFICATION.—If an adjuvant is conditionally approved by the Secretary for inclusion on the list described in subsection (d), the Secretary

shall notify (as part of the notice provided under subsection (e)(4)) the petitioner of the conditions applicable to the adjuvant under paragraph (1) with respect to such approval and the reasons for requiring such conditions.

(g) STUDY.—The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall conduct a study on the effectiveness of the use of adjuvants, in response to an attack with biological or chemical agents or toxins or nuclear or radiological materials, to—

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

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

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

SEC. 220. ANNUAL REPORT.

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

(1) an assessment of whether the incentives provided for in this title are sufficient, as determined by the Secretary, to induce the biotechnology, pharmaceutical, device, and research tools industries to modify their ongoing research priorities and devote scarce management and scientific talent to research to develop terror weapons countermeasures;

(2) an assessment of whether such incentives are sufficient, as determined by the Secretary, to address the sensitivity of such industries to the possibility of challenges to their prices and patents and the terms of sales that may arise when the Federal Government is an oligopoly or monopoly purchaser;

(3) an assessment of whether such incentives are likely to lead to the development of countermeasures to prepare the United States in the event of the use of biological, chemical, and radiological weapons by terrorists and others against both military or intelligence, government, and civilian personnel;

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

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

carried out and having the intended effect on industry activity;

(6) a description of how such incentives for private sector research relate to the provision of public funding for the development of countermeasures; and

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

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

SEC. 221. INTERNATIONAL CONFERENCE ON RESEARCH TO DEVELOP COUNTERMEASURES.

(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall annually convene an International Conference on Research to Develop Countermeasures to biological, chemical and nuclear terror attacks.

(b) FOCUS OF CONFERENCE.—Each conference convened under subsection (a) shall focus on one ore more of the following:

(1) An assessment of the biological, chemical, or radiological threats that may arise and the countermeasures that may be needed.

(2) The status of research to develop countermeasures, including research tools.

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

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

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

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as be necessary in each fiscal year to carry out this section.

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