

Bio Terror Bible

EXPOSING THE COMING BIO-TERROR PANDEMIC

BIOTERRORBIBLE.COM: The following news and events are in respect to bio-terror and pandemic related legislation which occurred within the calendar year of 2002. The American government, more than any other nation, has been systematically preparing its population for an upcoming bio-terror related pandemic by passing draconian bio-terror legislation in the wake of the 9/11 attacks.

LEGISLATION: [Bio-Terror Legislation \(2001\)](#), [Bio-Terror Legislation \(2002\)](#), [Bio-Terror Legislation \(2003\)](#), [Bio-Terror Legislation \(2004\)](#), [Bio-Terror Legislation \(2005\)](#), [Bio-Terror Legislation \(2010\)](#), [Bio-Terror Legislation \(2011\)](#), and [Bio-Terror Legislation \(2012\)](#).

Title: U.S. Tightening Rules On Keeping Scientific Secrets

Date: February 17, 2002

Source: [UCLA](#)

Abstract: The Bush administration is taking wide measures to tighten scientific secrecy in the hope of keeping weapons of mass destruction out of unfriendly hands.

Last month, it began quietly withdrawing from public release more than 6,600 technical documents that deal mainly with the production of germ and chemical weapons. It is also drafting a new information security policy, to be released in the next few weeks, that officials say will result in more documents' being withdrawn. It is asking scientific societies to limit what they publish in research reports.

"We're working hard for a set of guidelines so terrorists can't use information that this country produces against us," Tom Ridge, the director of homeland security, said in an interview. "This will have to be a dynamic process." He added that scientists were being closely consulted on any new guidelines.

But critics say the most extreme steps proposed could make it impossible for scientists to assess and replicate the work of their colleagues, eroding the foundations of American science. They fear that government officials eager for the protections of secrecy will overlook how open research on dangerous substances can produce a wealth of cures, disease antidotes and surprise discoveries.

"It comes down to a risk-benefit ratio," said Robert R. Rich, president of the Federation of American Societies for Experimental Biology. "I think the risk of forgone advances is much greater than the information getting into the wrong hands."

The federal reports already withdrawn, once sold freely to the public, include not only declassified ones from the 1940's, 50's and 60's but also modern ones that were previously judged to contain nothing that had to be kept secret. Experts say the sweeping withdrawal has few if any precedents.

R. Paul Ryan, deputy administrator of the federal Defense Technical Information Center, the Pentagon agency that has custody of the reports, said panels of scientific experts would be assembled to see whether the documents should once again be made available to the public or perhaps reclassified as state secrets.

The expert panels, he said, will determine "if we need major, minor or no revisions" to security guidelines.

Mr. Ryan added that he did not know when such deliberations might be completed or decisions made over the fate of the 6,600 withdrawn documents.

Since Sept. 11, the administration has sought to clamp down on the flow of information on several fronts. In October, for example, Attorney General John Ashcroft told federal officials that the Justice Department would support them if they resisted freedom-of-information requests. But science has now become the leading edge of the crackdown.

For instance, the White House has asked the American Society of Microbiology, the world's largest group of germ professionals, based in Washington, to limit potentially dangerous information in the 11 journals it publishes, including *Infection and Immunity*, *The Journal of Bacteriology* and *The Journal of Virology*.

One White House proposal is to eliminate the sections of articles that give experimental details researchers from other laboratories would need to replicate the claimed results, helping to prove their validity.

"That takes apart the whole foundation of science," Ronald M. Atlas, president-elect of the society, said of omitting methods. "I've made it reasonably clear that we would object to anything that smacked of censorship. They're discussing it, and I wouldn't rule out them doing something."

He added that he was surprised by the number of his colleagues in academia who seemed willing to discuss publishing limits. "I think it undermines science," he said.

Abigail Salyers, the society's president, offered a more pointed rebuff. "Terrorism feeds on fear, and fear feeds on ignorance," she said in a statement to appear in the March issue of the group's magazine. The best defense against anthrax or any infectious disease, Dr. Salyers added, is information that can bolster public safety.

Experts say such issues are being debated at the National Academy of Sciences, which advises the federal government.

Mr. Ridge said the critics were overreacting. "I can understand their concern, but I'm not sure the alarm bells should be rung just yet," he said.

"Let's first do the work" of producing the new guidelines, Mr. Ridge said. He added that the scientists "have to remember what we're up against": terrorism with exotic weapons that could maim or kill millions of people.

Scientists and the White House have clashed before over the flow of scientific information. In 1982, the Reagan administration, eager to thwart Soviet spies, blocked the presentation of about 100 unclassified scientific papers at an international symposium on optical engineering in San Diego. The move was loudly protested, and the administration soon dropped such restraints.

Last fall, after five people died from anthrax spores contained in letters, a new debate arose over the need for curbs on information and materials that terrorists could use to make weapons that are especially deadly. The main worries centered on lethal germs, chemicals and radioactivity.

The Bush administration, already a strong advocate of federal secrecy, quickly pulled much information on arms and national vulnerabilities from government Web sites. But to the astonishment of many experts, it continued to permit the sale of old federal documents that detailed the government's research on and production of biological weapons. The work was done between 1943 and 1969 and was later renounced as Washington pressed for a global ban on such weapons.

This year, critics called with new urgency for such reports to be locked up. "It's just plain stupid to be making this kind of sensitive information so readily available," *The Sun-Sentinel* of Fort Lauderdale, Fla., editorialized last month.

Late last month the administration began withdrawing the documents from sale, officials said. Researchers stumbled upon the gaps while trying to obtain reports from the National Technical

Information Service, an arm of the Commerce Department in Springfield, Va., that sells military and other kinds of federal documents.

"It's amazing," said Matthew Lesko, the author of more than 100 books based on federal information. "Everything that's being asked for is classified." He added that the government might be overreacting. "If it's been out there for 40 and 50 years," he asked, "how are they going to stop it?"

Cheryl Mendonsa, a spokeswoman for the Commerce Department, said that 6,619 documents had been pulled from circulation as of Thursday and that the figure would rise as new candidates were identified for security review. "The process is ongoing," she said.

After requesting a withdrawn document, visitors to the service's Web site see the message: "Selected product is not available for online ordering."

Current federal policy generally bars the reclassification of formerly secret documents, but the Bush administration is considering an executive order that would permit it.

Steven Garfinkel, who recently stepped down as director of the government's Information Security Oversight Office, said the scale of the withdrawal was large by historical standards and unusual because all the documents were already in the public domain.

He added that attempts to obtain the reports would still be possible under the Freedom of Information Act, but that "purposeful delays" would be likely until federal officials decided on the new classification levels.

Dr. Atlas of the American Society of Microbiology, who is a dean at the University of Louisville, said he was skeptical of the recall's merit. "Either the reports crossed a line they shouldn't have," he said, "or they've just removed information that would help the advancement of science."

Dr. Rich of the Federation of American Societies for Experimental Biology, who is a dean at the medical school of Emory University, was more supportive. Papers about making weapons of mass destruction, he said, should be promptly removed from public circulation.

But Dr. Rich cautioned that the benefits of basic research far outweighed any risks. He cited an example. Publishing an article on the bioengineering of viruses related to smallpox might look dangerous, he said. But such open research could greatly advance work on vaccines meant to battle a variety of ills, including the human immunodeficiency virus.

"There is very little that comes out of university labs that could conceivably be considered sensitive," he said. "So to set up any kind of blanket policy that would require general pre-review of scientific publications would be extraordinarily cost-ineffective and would stifle the communication of important research findings" ([UCLA, 2002](#)).

Title: Public Health Security And Bioterrorism Preparedness And Response Act Of 2002

Date: May 21, 2002

Source: [Library of Congress](#)

Abstract: Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - Title I: National Preparedness for Bioterrorism and Other Public Health Emergencies - Subtitle A: National Preparedness and Response Planning, Coordinating, and Reporting - Amends the Public Health Service Act to add the following title, Title XXVIII: National Preparedness for Bioterrorism and Other Public Health Emergencies. Directs the Secretary of Health and Human Services to further develop and implement a coordinated strategy, building upon core public health capabilities (established under provisions of the Act providing for national needs to combat threats to public health), for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies, including the preparation of a plan which has as a goal ensuring that the activities of the Secretary regarding bioterrorism and other public health emergencies are coordinated with activities of the States, including local governments.

Requires the provision of effective assistance to State and local governments in the event of bioterrorism or other public health emergency and ensuring that State and local governments have appropriate capacity to detect and respond effectively to such emergencies, including capacities for the following: (1) effective public health surveillance and reporting mechanisms at the State and local levels; (2) appropriate laboratory readiness; (3) properly trained and equipped emergency response, public health, and medical personnel; (4) health and safety protection of workers responding to such an emergency; (5) public health agencies that are prepared to coordinate health services (including mental health services) during and after such emergencies; and (6) participation in communications networks that can effectively disseminate relevant information in a timely and secure manner to appropriate public and private entities and to the public.

Requires: (1) developing and maintaining medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies; (2) ensuring coordination and minimizing duplication of Federal, State, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency; and (3) enhancing the readiness of hospitals and other health care facilities to respond effectively to such emergencies.

(Sec. 102) Establishes in the Department of Health and Human Services an Assistant Secretary for Public Health Emergency Preparedness to coordinate efforts on behalf of the Secretary.

Provides for the operation of a National Disaster Medical System which shall be a coordinated effort to: (1) provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency; or (2) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency. Requires the System to carry out ongoing activities and test the mobilization of the System. Requires the establishment of criteria for the System.

(Sec. 103) Revises provisions of the Act which provide for revitalizing the Centers for Disease Control and Prevention to authorize the Director of the Centers to design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities to provide for national needs to combat threats to public health, and for supporting public health activities.

Directs the Secretary to provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among: (1) Federal, State, and local public health officials; (2) public and private health-related laboratories, hospitals, and other health care facilities; and (3) any other entities determined appropriate by the Secretary. Authorizes appropriations.

(Sec. 104) Replaces provisions providing for a joint interdepartmental working group to address the public health and medical consequences of a bioterrorist attack on the civilian population with provisions providing for advisory committees to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under provisions providing for a joint interdepartmental working group on preparedness and readiness for the medical and public health effects of a bioterrorist attack on the civilian population and a joint interdepartmental working group to address the public health and medical consequences of a bioterrorist attack on the civilian population.

Requires the establishment of the National Advisory Committee on Children and Terrorism and its termination (one year after enactment of this Act) following the submission of its recommendations.

Requires the establishment of the Emergency Public Information and Communications Advisory Committee and its termination (one year after enactment of this Act) following the submission of its recommendations.

Directs the Secretary to develop a strategy for effectively communicating information regarding bioterrorism and other public health emergencies, and to develop means by which to communicate such information.

States that Congress recommends the establishment of an official Federal Internet site on bioterrorism.

(Sec. 105) Directs the Secretary to: (1) develop materials for teaching the elements of a core curriculum for the recognition and identification of potential bioweapons and other agents that may create a public health emergency, and for the care of victims of such emergencies; (2) develop a core curriculum and materials for community-wide planning by State and local governments, hospitals and other health care facilities, emergency response units, and appropriate public and private sector entities to respond to a bioterrorist attack or other public health emergency; (3) develop materials for proficiency testing of laboratory and other public health personnel for the recognition and identification of potential bioweapons and other agents that may create a public health emergency; and (4) provide for dissemination and teaching of the materials, which may include telemedicine, long-distance learning, or other such means.

(Sec. 106) Authorizes grants and cooperative agreements for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies. Authorizes appropriations.

(Sec. 107) Requires the establishment of an advance registration system of health professions volunteers for the purpose of verifying credentials during public health emergencies. Authorizes appropriations.

(Sec. 108) Directs the Secretary, in coordination with the Secretary of Agriculture, the Attorney General, the Director of Central Intelligence, the Secretary of Defense, the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Director of the Federal Emergency Management Agency, the Secretary of Labor, the Secretary of Veterans Affairs, and with other similar Federal officials as determined appropriate, to establish a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies.

(Sec. 109) Revises provisions concerning combating antimicrobial resistance and extends the authorizations of appropriations for such provisions.

(Sec. 110) Permits the provision of supplies and services in lieu of award funds to grant recipients, upon the recipient's request.

Subtitle B: Strategic National Stockpile; Development of Priority Countermeasures - Directs the Secretary of Health and Human Services, in coordination with the Secretary of Veterans Affairs, to maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies to be appropriate and practicable, to provide for the emergency health security of the United States in the event of a bioterrorist attack or other public health emergency.

Directs the Secretary to carry out such activities as required to ensure that a sufficient amount of vaccine against smallpox is available to meet the health security needs of the United States. Authorizes appropriations.

(Sec. 122) Directs the Secretary of Health and Human Services to designate a "priority countermeasure" as a fast-track product pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

(Sec. 123) Requires the FDA to issue a final rule within 90 days allowing reliance on animal trials for priority countermeasures for public health emergencies.

(Sec. 124) Directs the Secretary, in consultation with the Attorney General and the Secretary of Defense, to provide assistance to provide security to persons or facilities that conduct the development, production, distribution, or storage of priority countermeasures.

(Sec. 125) Requires the Secretary to give priority to accelerated countermeasure research and development.

(Sec. 126) Directs the Secretary to promptly carry out a program to periodically evaluate new and emerging technologies that are designed to improve or enhance the ability of public health or safety officials to conduct public health surveillance activities relating to a bioterrorist attack or other public health emergency.

(Sec. 127) Directs the President to: (1) make available, through the national stockpile, to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant; and (2) request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale.

Subtitle C: Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies - Directs the Secretary, to enhance the security of the United States with respect to bioterrorism and other public health emergencies, to make awards of grants or cooperative agreements to eligible entities to enable such entities to conduct activities, including: (1) developing coordinated Statewide plans and community-wide plans for responding to bioterrorism and other public health emergencies; (2) addressing deficiencies in public health needs; (3) purchasing or upgrading equipment supplies, pharmaceuticals or other priority countermeasures to enhance preparedness for and response to bioterrorism or other public health emergencies; (4) conducting exercises to test the capability and timeliness of public health emergency response activities; (5) developing and implementing the trauma care and burn center care components of the State plans for the provision of emergency medical services; (6) improving training or workforce development to enhance public health laboratories; (7) training public health and health care personnel; (8) developing, enhancing, coordinating, or improving participation in systems by which disease detection and information about biological attacks and other public health emergencies can be rapidly communicated; (9) enhancing communication to the public of information on bioterrorism and other public health emergencies, including through the use of 2-1-1 call centers; (10) addressing the health security needs of children and other vulnerable populations with respect to bioterrorism and other public health emergencies; (11) providing training and developing methods to enhance the safety of workers and workplaces in the event of bioterrorism; (12) preparing and planning for contamination prevention efforts related to public health that may be implemented in the event of a bioterrorist attack; (13) preparing a plan for triage and transport management in the event of bioterrorism or other public health emergencies; (14) enhancing the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies; (15) enhancing the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon; (16) enhancing training and planning to protect the health and safety of personnel involved in responding to a biological attack; (17) improving surveillance, detection, and response activities to prepare for emergency response activities including biological threats or attacks; and (18) developing, enhancing, and coordinating or improving the ability of existing telemedicine programs to provide health care information and advice as part of the emergency public health response to bioterrorism or other public health emergencies. Authorizes appropriations.

Directs the Secretary to make awards of grants or cooperative agreements to eligible entities to enable such entities to improve community and hospital preparedness for bioterrorism and other public health emergencies. Authorizes appropriations.

Subtitle D: Emergency Authorities; Additional Provisions - Provides extensions for certain reporting deadlines during a public health emergency.

(Sec. 142) Expands the authority of the Secretary, in consultation with the Surgeon General, and under certain conditions, to specify communicable diseases that are subject to individual detention orders.

(Sec. 143) Amends title XI of the Social Security Act to add provisions with the purpose of ensuring, to the maximum extent feasible that in any emergency area during an emergency period: (1) sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP); and (2) health care providers furnishing such items and services in good faith, but that are unable to comply with one or more specified requirements may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

(Sec. 144) Sets forth provisions for determining the expiration of public health emergencies.

Subtitle E: Additional Provisions - Amends the Robert T. Stafford Disaster Relief and Emergency Assistance Act to require providing information to the public in a coordinated manner.

(Sec. 152) Directs the Secretary of Energy and the Administrator of the National Nuclear Security Administration to expand, enhance, and intensify research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency. Authorizes appropriations.

(Sec. 153) Directs the Secretary, acting through the Director of the National Institute of Occupational Safety and Health, to enhance and expand research as deemed appropriate on the health and safety of workers who are at risk for bioterrorist threats or attacks in the workplace.

(Sec. 154) Directs the Secretary of Veterans Affairs to take appropriate actions to enhance the readiness of Department of Veterans Affairs medical centers to protect the patients and staff of such centers from chemical or biological attack or otherwise to respond to such an attack and so as to enable such centers to fulfill their obligations as part of the Federal response to public health emergencies. Authorizes appropriations.

(Sec. 155) Reauthorizes a grant program through 2006 that develops programs focusing on the behavioral and biological aspects of psychological trauma response and research that will help treat psychiatric disorders of children and youth resulting from witnessing or experiencing a traumatic event.

(Sec. 156) Expresses the sense of Congress regarding the many excellent university-based programs already functioning and developing important biodefense products and solutions throughout the United States.

(Sec. 157) Requires a General Accounting Office (GAO) report to Congress on Federal bioterrorism-related activities, coordination activities, and State, local, and private sector activities.

(Sec. 158) Amends the Public Health Service Act public health emergencies provisions to authorize providing awards for expenses in addition to authorizing grants.

(Sec. 159) Community Access to Emergency Defibrillation Act of 2002 - Directs the Secretary to award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs. Authorizes appropriations.

Title II: Enhancing Controls on Dangerous Biological Agents and Toxins - Subtitle A: Department of Health and Human Services - Amends the Public Health Service Act to provide for enhanced control of certain biological agents and toxins. Directs the Secretary to: (1) establish and maintain (review at least biennially) a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety; (2) provide for the regulation of transfers of listed agents and toxins; (3) provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins; (4) require registration with the Secretary of the possession, use, and transfer of listed agents and toxins; and (5) provide appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety. Authorizes the Secretary to inspect persons subject to the above requirements to ensure their compliance with such regulations (including the risk of use in domestic or international terrorism).

Authorizes exemptions for clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that: (1) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and (2) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation. Authorizes exemptions for products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under specified, unless the Secretary by order determines that applying additional regulation to a specific product is necessary to protect public health and safety. Authorizes exemptions for an investigational product that is, bears, or contains a listed agent or toxin when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation to such product is not necessary to protect public health and safety. Authorizes exemptions, as specified, for public health and agricultural emergencies.

Sets forth: (1) rules governing disclosure of information; (2) penalties for violators; and (3) reporting requirements. Authorizes appropriations.

(Sec. 202) Requires all persons (unless exempt) in possession of biological agents or toxins listed under the Public Health Service Act to notify the Secretary of Health and Human Services of such possession.

Subtitle B: Department of Agriculture - Agricultural Bioterrorism Protection Act of 2002 - Directs the Secretary of Agriculture to establish and maintain a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Sets forth criteria for list inclusion and list review. Sets forth provisions for the regulation of: (1) transfers of listed agents and toxins; (2) possession and use of listed agents and toxins; (3) registration, identification, and maintenance of database of listed toxins; and (4) security and safeguard of persons possessing, using, or transferring a listed agent. Requires the identifying information of registered persons to be submitted to the Attorney General and requires the Attorney General to promptly determine if any of the persons are within any specified criminal, immigration, national security, or other categories. Sets forth procedures concerning: (1) process regarding persons seeking to register; and (2) administrative review. Requires prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

Sets forth exemptions concerning clinical and diagnostic laboratories, products, investigational use, agricultural emergencies, and public health emergencies.

Sets forth: (1) rules governing disclosure of information; (2) penalties for violators; and (3) reporting requirements. Authorizes appropriations.

Subtitle C: Interagency Coordination Regarding Overlap Agents and Toxins - Directs the Secretary of Agriculture and the Secretary of Health and Human Services to coordinate activities regarding overlap agents and toxins.

Subtitle D: Criminal Penalties Regarding Certain Biological Agents and Toxins - Amends Federal criminal code provisions concerning the possession of listed biological agents and toxins to provide that whoever: (1) transfers a select agent to a person who the transferor knows or has reasonable cause to believe is not registered as required shall be fined, or imprisoned for not more than five years, or both; and (2) knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a required registration shall be fined, or imprisoned for not more than five years, or both.

Title III: Protecting Safety and Security of Food and Drug Supply Subtitle A: Protection of Food Supply - Directs the President's Council on Food Safety (as established by Executive Order) to, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply.

(Sec. 302) Amends the FFDCA to direct the Secretary of Health and Human Services to: (1) give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food; (2) give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act; (3) improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes; and (4) provide for research on the development of tests and sampling methodologies whose purpose is to test food in order to rapidly detect the adulteration of the food.

Sets forth reporting requirements and authorizes appropriations.

(Sec. 303) Permits an officer or qualified employee of the Food and Drug Administration to order the temporary detention (in a secured facility) of any article of food that is found during an inspection, examination, or investigation if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals, but only if the Secretary or an official designated by the Secretary approves the order. Sets forth appeal procedures.

(Sec. 304) Provides for the debarment of importers for repeated or serious food import violations.

(Sec. 305) Directs the Secretary by regulation to require that any facility (domestic and foreign) engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary.

(Sec. 306) Permits the Secretary, if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, to have access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(Sec. 307) Requires food importers to give the Secretary specified prior notice (including specified information about the source of the food) of the importation of any food for the purpose of enabling the food to be inspected.

(Sec. 308) Permits the Secretary to require the owner or consignee of food refused admission into the United States, but not ordered destroyed, to affix to the container of the food a label that clearly and conspicuously bears the statement: UNITED STATES: REFUSED ENTRY.

(Sec. 309) Prohibits an importer from port shopping with respect to food that has previously been denied entry.

(Sec. 310) Requires the Secretary, if the Secretary has credible evidence or information indicating that a shipment of imported food presents a threat of serious adverse health consequences or death to humans or animals, to provide notice regarding such threat to the appropriate States.

(Sec. 311) Authorizes the Secretary to make grants to States, territories, and Indian tribes that undertake specified examinations, inspections, and investigations, and related activities.

(Sec. 312) Authorizes grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation. Authorizes appropriations.

(Sec. 313) Directs the Secretary, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture to coordinate the surveillance of zoonotic diseases.

(Sec. 314) Authorizes the Secretary to commission officers and qualified employees of other Federal Departments or Federal agencies, pursuant to a memorandum of understanding between the Secretary and the head of the Department or agency of such other Federal employees to conduct examinations and inspections for the Secretary under the FFDCa.

Subtitle B: Protection of Drug Supply - Amends the FFDCa to mandate annual registration, through electronic means, of foreign manufacturers (as well as the importers) engaged in the import of drug and device products into United States.

(Sec. 322) Mandates a chain of possession identification (manufacturer, processor, packer, distributor, and other possessors) for those firms that seek to import components of drugs, devices, food additives, color additives, or dietary supplements for further processing and export. Requires certificates of analysis for components containing any chemical substance or biological substance intended for export.

Subtitle C: General Provisions Relating to Upgrade of Agricultural Security - Authorizes the Secretary of Agriculture to utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct specified inspection activities. Authorizes automated recordkeeping for the Service. Authorizes appropriations.

(Sec. 332) Authorizes the Secretary to utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct food safety inspection activities. Authorizes appropriations.

(Sec. 333) Authorizes appropriations for the purpose of enabling the Agricultural Research Service to conduct building upgrades to modernize specified existing facilities.

(Sec. 334) Authorizes grants to colleges and universities with programs in food and agricultural sciences to review security standards and practices at their facilities in order to protect against bioterrorist attacks. Authorizes appropriations.

(Sec. 335) Authorizes the Secretary to utilize existing research authorities and research programs to protect the food supply of the United States by conducting and supporting research specified bioterrorism agricultural research and development activities. Authorizes appropriations.

(Sec. 336) Revises federal criminal code provisions concerning animal enterprise terrorism penalties.

Title IV: Drinking Water Security and Safety - Amends the Safe Drinking Water Act to require each community water system serving a population of greater than 3,300 persons to: (1) conduct an assessment of the vulnerability of its system to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water; (2) certify that the system has conducted the assessment and submit a written copy of the assessment; and (3) prepare or revise, where necessary, an emergency response plan that incorporates the results of the vulnerability assessments. Provides for guidance and support. Authorizes appropriations.

(Sec. 401) Requires the review of current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, as specified.

Requires the review of methods and means by which terrorists or other individuals or groups could disrupt the supply of safe drinking water or take other actions against water collection, pretreatment, treatment, storage and distribution facilities which could render such water significantly less safe for human consumption, as specified.

(Sec. 403) Increases penalties under the Safe Drinking Water Act for tampering with drinking water systems and authorizes appropriations.

Title V: Additional Provisions - Subtitle A: Prescription Drug User Fees - Prescription Drug User Fee Amendments of 2002 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning definitions and the authority to assess and use drug fees. Extends authorizations of appropriations.

(Sec. 505) Provides for public accountability with respect to goals for the process for the review of human drug applications.

(Sec. 506) Revises provisions concerning reports of postmarketing studies.

(Sec. 507) Sets forth the effective date, savings and sunset clauses.

Subtitle B: Funding Provisions Regarding Food and Drug Administration - Reserves, from amounts appropriated to the Food and Drug Administration, specified amounts for the Office of Drug Safety.

(Sec. 522) Authorizes appropriations for the Division of Drug Marketing, Advertising, and Communications.

(Sec. 523) Authorizes appropriations for the Office of Generic Drugs.

Subtitle C: Additional Provisions - Directs the Federal Communications Commission, at the request of an eligible licensee or permittee, in order to further promote the orderly transition to digital television, and to promote the equitable allocation and use of digital channels by television broadcast permittees and

licensees, within 90 days of enactment, to allot, if necessary, and assign a paired digital television channel to that licensee or permittee, subject to stated conditions.

Sets forth licensee and permittee requirements.

(Sec. 532) Provides for specified delays in: (1) the lock-in procedures for Medicare+Choice plans; (2) the deadline for Medicare+Choice plans to submit information on Medicare benefits, premiums, cost sharing, supplemental benefits, and actuarial values of such coverage; and (3) the annual election period for Medicare enrollees to select a Medicare+Choice plan ([Library of Congress, 2002](#)).

Title: Conferees Agree On Bioterror Bill

Date: May 22, 2002

Source: [UCLA](#)

Abstract: House and Senate negotiators agreed yesterday on the final version of legislation meant to ensure a sustained, comprehensive effort to shore up the nation's defenses against a bioterror attack.

The bill, likely to win swift approval from Congress and prompt signature by President Bush, includes provisions calling for the stockpiling of drugs and vaccines and other initiatives to help prevent, detect and treat terrorism-related health threats.

It also would expand the program through which pharmaceutical companies pay large fees to the Food and Drug Administration to review their new drug applications. Drugmakers support the higher fees because they enable the agency to speed up the process of moving new products to the marketplace. Some critics, however, say the higher fees will make the FDA more dependent on an industry it regulates.

The House could take up the legislation as early as today. The Senate may act on it before this Friday's start of Congress's week-long Memorial Day recess or shortly after Congress returns June 3.

While funds to finance first-year operations were approved late last year, lawmakers said the bioterrorism authorization bill was needed for regulatory and other legal mandates and to establish a framework for allocating the money.

The legislation resulted from separate but largely similar bills passed last year by both chambers after the Sept. 11 terrorist attacks on New York and Washington and subsequent anthrax spore-tainted letters that were received on Capitol Hill and elsewhere in the country.

"Because of this bipartisan legislation, Americans will be able to sleep better at night in the knowledge that our nation is taking the steps necessary to protect them and their families against the deadly threat of bioterrorism," said Sen. Edward M. Kennedy (D-Mass.). Kennedy co-sponsored the Senate version of the legislation with Sen. Bill Frist (R-Tenn.). The House bill was sponsored by Reps. W.J. "Billy" Tauzin (R-La.) and John D. Dingell (D-Mich.).

The Senate and House bills anticipated spending about \$3 billion annually on anti-bioterrorism efforts, roughly the sum that has been appropriated for the current fiscal year. But the final version refers simply to "such sums as necessary" to pay for programs prescribed by the legislation, according to a Senate aide.

In addition to providing for stockpiling of vaccines and antibiotics to protect against biological and chemical weapons, including the possibility of a smallpox epidemic, the legislation authorizes substantial new spending to help state and local health officials prepare for bioterrorism attacks. Grants would be made available to help hospitals prepare for treatment of victims. Funding for research on prevention and treatment also would be increased.

The bill calls for tighter regulation of laboratories and people who work with materials that could be used in bioweapons to target individuals or the food supply.

Additional steps would be taken to protect the food supply, including new authority for the FDA to bar unsafe food from entering the country and grants to states to strengthen food inspections and deal with outbreaks of food-borne illnesses. New registration and record-keeping requirements would be imposed, and safety improvements would be ordered at animal research labs.

The bill would require community water systems serving more than 3,300 people to conduct vulnerability assessments and prepare emergency response plans, and calls for a review of current and future precautions. In case of an attack on a nuclear power plant, expanded supplies of potassium iodide would be made available to communities near the plants as a step to handle contamination ([UCLA, 2002](#)).

Title: Bioterrorism Legislation Puts New Scrutiny On Researchers, Allows Current Projects To Continue

Date: May 24, 2002

Source: [UCLA](#)

Abstract: Congress approved bioterrorism legislation this week that would give universities more responsibility for guarding biological agents they use in research, but would not greatly disrupt such studies, college lobbyists say.

The legislation, HR 3448, would provide \$4.6-billion to state programs and improve federal laboratories. It represents a compromise of competing bills that had previously passed the House of Representatives and the Senate. The Senate approved the compromise measure on Thursday, a day after the House overwhelmingly passed it by a vote of 425 to 1. President Bush is expected to sign the bill.

Under the legislation, every university and laboratory that works with "select agents" -- defined as biological material that could be used to pose a public health threat -- would have to be registered with the U.S. Department of Health and Human Services or the U.S. Department of Agriculture. Current law requires only laboratories that ship such materials to be listed with the government. Lawmakers have complained that they do not have a clear idea of how many people are working with potentially dangerous biological materials.

The legislation would impose new steps designed to limit access to 42 biological agents, including anthrax, the Ebola virus, and smallpox. The bill would bar from working with those materials any scientists from countries that are listed as sponsoring terrorism, including Iraq and Iran, and any researchers with criminal records. However, all scientists handling such agents -- including U.S. citizens -- would have to be screened by the government.

College lobbyists say it is unlikely that a university researcher currently working with biological materials or toxins would be restricted from such work in the future. Lobbyists said they were especially pleased that the legislation spells out that scientists who are in the midst of a research project will be allowed to continue their work while the government performs its background checks.

"We were very concerned that there would be a period of time when research would come to a halt," said Janet Shoemaker, director of public affairs for the American Society for Microbiology.

Under the terms of the bill, colleges would have to submit the names of researchers studying biological agents to the Department of Health and Human Services. Universities would also have to get clearance for scientists doing research on plant and animal pathogens for the U.S. Department of Agriculture. The U.S. attorney general's office would conduct the background checks, a step sought by college lobbyists, who had feared that research institutions would have to perform screening themselves.

If a university wished to hire a new scientist to work on select agents, that person would not be allowed to begin work on those materials until the screening is complete. The legislation also includes provisions for an appeals process if the government denies approval.

While college lobbyists are glad that universities themselves will not be responsible for screening employees, some wonder how long the government reviews will take, Ms. Shoemaker said.

In the event of an emergency, the measure would allow scientists to work on biological agents without being screened. Researchers had feared that in a crisis involving bioterrorism, scientists would lose valuable time waiting to gain clearance.

The Health and Human Services Department and the Agriculture Department would each have to draw up regulations regarding the study of biological agents. College lobbyists said they would work with the agencies to see that those rules do not go beyond the protections spelled out in the bioterrorism legislation.

The Centers for Disease Control and Prevention would get \$300-million to modernize its laboratories under the legislation. Lawmakers in Congress, chiefly Sen. Arlen Specter, a Pennsylvania Republican, have said that the center's facilities are in dire need of upgrades ([UCLA, 2002](#)).

Title: Bush Signs \$4.6B Bioterror Bill

Date: June 12, 2002

Source: [UCLA](#)

Abstract: President Bush signed bioterrorism legislation Wednesday that devotes \$4.6 billion to stockpiling vaccines, improving food inspections and boosting security for water systems, calling it his "urgent duty" to prevent germ warfare.

In a Rose Garden ceremony with the bill's sponsors, Bush said last fall's anthrax attacks were a wake-up call for the federal government. "We must be better prepared to prevent, identify and respond" to bioterrorism threats, he said.

The measure, passed overwhelming by Congress, became law as Bush pressed lawmakers to create a new Homeland Security Department.

Despite grumbling from Congress, Bush said his proposal is the best way "to make sure that we have an effective response to the enemy that still wants to hit America. This bill ... is part of the process of doing our duty to protect innocent Americans from an enemy who hates America."

Tom Ridge, the White House director of domestic security, was to brief the entire House membership later Wednesday on the proposal and follow up with senators Thursday. The closed-door sessions are intended to answer a growing number of questions about issues such as sharing of intelligence and the projected costs of transition.

Congress has been working on the bioterrorism bill since September's attacks on New York and Washington and accelerated the process after suffering a bioterrorism attack.

Mail service to Capitol Hill was stopped for six weeks after [anthrax-contaminated letters](#) were discovered in October. Five people, including two postal workers, [died from anthrax](#). New scares have occurred recently at the Federal Reserve and World Bank. Nobody has been arrested in the case, though investigators suspect the terrorist is from the United States.

"Terrorist groups seek biological weapons. We know some rogue states already have them. It is important that we confront these real threats to our country and prepare for future emergencies," Bush said. "Protecting our citizens again bioterrorism is an urgent duty of America."

The bioterrorism bill would spend \$640 million to produce and stockpile smallpox vaccines for vast numbers of Americans should terrorists reintroduce the eradicated disease. The measure also would expand availability of potassium iodide for communities near nuclear plants to treat radiation poisoning in case of terrorist attack.

The bill also would pump more money into the National Pharmaceutical Stockpile, secret stashes of medicine at locations throughout the United States.

It would provide \$1.6 billion in grants to states for hospital preparedness and assessments of the vulnerability of local water systems.

On his proposal for a new federal agency, most lawmakers were lining up to back Bush's call for swift action. Senate Majority Leader Tom Daschle, D-S.D., even suggested the Senate may be able to pass its version of the plan before the August congressional recess.

"We have a lot of questions to ask about how it works and whether or not the proposal from the White House, when it comes, is the right approach," Daschle said. "But we'll work with them to see if we can find the right approach and reach a consensus on it."

Yet even some prominent members of Bush's own party were raising questions about the plan. House Majority Leader Dick Armey, R-Texas, said many lawmakers are concerned that the president's plan does not envision the "full participation" of the FBI and CIA, which have been the subjects of heavy criticism for their pre-Sept. 11 intelligence performance.

Under Bush's plan, intelligence would be analyzed by the new department, which would have no authority over what the agencies produced.

"Many of us feel we can maybe, perhaps, more completely do that job than what was outlined" by the president, Armey said. "We may have to pull these agencies more fully into the structure than was recommended."

Appearing Tuesday on CNN, Ridge said he was confident lawmakers' concerns about intelligence sharing with the new department could be worked out ([UCLA, 2002](#)).

Title: Bioterror Defense Bill Signed

Date: June 13, 2002

Source: [UCLA](#)

Abstract: President Bush, saying that "biological weapons are potentially the most dangerous weapons in the world," signed legislation yesterday that provides \$4.3 billion for drugs, vaccines, training and other initiatives to deal with a bioterror attack.

The legislation, crafted in the wake of the terrorist attacks Sept. 11 and the subsequent anthrax outbreak, calls for tightening security at water plants, improving food inspections, and increasing stockpiles of vaccines against smallpox and other diseases. It also provides \$1.6 billion for states to aid with emergency preparedness.

"Last fall's [anthrax attacks](#) were an incredible tragedy to a lot of people in America, and it sent a warning that we needed and heeded," Bush said in a Rose Garden ceremony. "We must be better prepared to prevent, identify and respond."

The FBI has made no arrests in the anthrax attacks, which killed five people and made 13 others ill in the first fatal instance of biological terrorism on U.S. soil.

The legislation includes spending for the current fiscal year and fiscal 2003. It requires community water systems serving more than 3,300 people to conduct vulnerability assessments and prepare emergency response plans, and it gives the Food and Drug Administration new authority to bar unsafe foods from entering the country.

The package had overwhelming backing on Capitol Hill, and Bush is hoping to replicate that consensus with his proposal to create a Department of Homeland Security that would combine all or parts of 22 federal agencies. The new department would be the lead agency in dealing with bioterrorism, managing the National Pharmaceutical Stockpile and promoting research for new vaccines and antidotes.

Bush promoted the reorganization plan at the signing ceremony, saying it would "align authority and responsibility." Afterward, he joined Tom Ridge, his adviser on homeland security, in the first meeting of a group of 16 business, academic and government leaders recruited by the White House for a new anti-terror advisory council.

The Homeland Security Advisory Council will recommend ways to get the new department rolling. It is headed by Joseph J. Grano Jr., chairman of UBS PaineWebber.

"You all can play a very useful role in this process," Bush said in convening the panel. "You bring a lot of heft and a lot of experience and a lot of know-how."

With Ridge planning to present Bush with a national anti-terror strategy in July, the members will have little time to have input on the drafting of any proposals that emerge. But Ridge said the council will have a critical role in following up with more ideas and in helping with the mechanics of setting up a new department.

The council's members include William H. Webster, former head of the FBI and CIA; James R. Schlesinger, who helped create the Energy Department in the late 1970s; Kathleen M. Bader, a vice president with Dow Chemical Co.; Jared L. Cohon, president of Carnegie Mellon University; Utah Gov. Mike Leavitt (R); Sidney Taurel, chairman of Eli Lilly and Co.; and D.C. Mayor Anthony A. Williams (D).

Schlesinger had these words of caution: "It is easier to develop a plan and a strategy than to see it is executed, particularly in the federal government."

Ridge said the council will help with putting the strategy into action because the members "are all very successful leaders. They've all delivered on ideas.... They've been involved in merger and acquisition work. They know the pitfalls."

Ridge spent an hour with the council, then dashed to Capitol Hill, where he briefed House members on the new department in a closed session. A similar meeting is scheduled for today with the Senate. Ridge said that he was encouraged by House leaders who want to take action by Sept. 11 but that the process might prove to be more time-consuming than that, with the end of the year a more achievable target ([UCLA, 2002](#)).

Title: A First Step On U.S. Biodefense

Date: July 14, 2002

Source: [UCLA](#)

Abstract: Nine months after the most serious outbreak of biological warfare in U.S. history, the United States has taken its first tentative steps toward biodefense readiness, but experts say it will take years for the nation to build a robust system after decades of neglect.

The first post-Sept. 11 trickle of federal funds devoted strictly to biological warfare defense began last month, when the Department of Health and Human Services started distributing \$1.1 billion to states and some cities to upgrade community public health preparedness.

It is a startup program, aimed at attacking the basic weakness of U.S. biodefenses by requiring communities to begin developing infrastructure, including chains of command, response patterns, and communications, a condition of receiving their share of the payout.

"This is only the first year, and in this context, it's going to take maybe five years to build the systems and capacity," said Thomas Milne, executive director of the National Association of County and City Health Officials. "What we'll get this year is an increment of improvement, not preparedness. Not yet."

Besides the HHS money, the centerpieces of national biodefense include a plan to shift \$1.9 billion in research funds from the National Institutes of Health to a new Department of Homeland Security, and a new \$420 million program to transform four urban areas -- including metropolitan Washington -- into state-of-the-art showcases for the best in biodefense.

The NIH plan in particular is controversial, and the fate of all the programs depends on both the 2003 budget that Congress eventually passes and the way bureaucratic lines of authority are redrawn in the proposed Department of Homeland Security.

President Bush in February announced a \$5.9 billion biological warfare defense budget for 2003, on top of \$2.5 billion in new money made available in an emergency spending bill passed by Congress in January.

But nine months after the mail-borne [anthrax attacks](#) killed five people, officials in most parts of the country are only beginning to grapple with a threat that until recently was regarded as little more than a highly hypothetical what-if.

"We have practice with explosions or chemical spills," said epidemiologist Donald A. Henderson, principal science adviser for public health preparedness at HHS. "The biological has been more difficult because of the misapprehension that you could deal with it the same way as a chemical incident, when, in fact, these events could not be any more dissimilar."

In ramping up the nation's biodefenses, no part of the country has gotten more attention than metropolitan Washington. Besides its share of the HHS money, the region in January received a \$292 million congressional appropriation to upgrade emergency preparedness, and is slated to get \$85 million more in 2003. In all, greater Washington could receive about \$400 million in federal emergency preparedness and biodefense funds in 2002 and 2003.

"There are lots of downsides to being the national capital," said Margaret Kellems, deputy mayor for public safety and justice, who is in charge of biodefense for the District. "The upside is that when you're in the spotlight, you get the best treatment. We think the District is a bull's eye."

By reason of its privileged status, however, the region has also become a closely watched laboratory as it tries to parlay federal largess into a seamless biodefense infrastructure that can work across 17 jurisdictions.

"The federal government is not in the habit of funneling money to local governments to accomplish a federal priority; there was no plan that could be tweaked," said Robert Malson, chairman of the Metropolitan Washington Council of Governments' Bioterrorism Task Force. "We had to do it from scratch, and that challenge can't be overstated."

Of the \$292 million the region got in January, the District's share was \$154 million destined for 14 municipal departments. Much of the money can be used to handle different types of disasters, but there was a clear recognition of the region's biodefense shortcomings.

"After September 11th, if we did nothing else, we needed to communicate better," Kellems said, so the city invested \$46 million in a new wireless radio system, with attendant technologies and improved land-line security.

Kellems today also has seven ways to stay in touch, among them a special card to get priority dial tones, two different two-way pagers and dedicated circuits and tie lines: "I like toys, but this was a good excuse," Kellems said. "We've become quite the experts."

Other city priorities included new protective gear, traffic light upgrades, video camera technology for managing traffic flow, pathogen testing equipment and a mobile laboratory. The Fire Department bought a new hazardous materials unit equipped to handle biological, chemical and radiological events. The District had not had its own hazmat capability since 1998.

Across the region, communities were funding similar priorities, and now that that job seems to be nearing completion, the goal "is, to the fullest extent possible, to have a stitching together of the individual jurisdiction plans," Malson said.

"Each has its own police force, its own fire department and public health structure, as well as privately owned hospitals, physicians and health care providers with their own way of doing things," Malson said. "We want an arrangement so all these entities can respond together. There are a lot of pieces to this."

But even as the region tries to get comfortable with this first set of innovations, it is getting ready to receive the additional \$85 million earmarked for the as-yet vaguely defined biodefense upgrade to be administered by the new Department of Homeland Security.

The program started out in the Bush 2003 budget as a \$420 million Defense Department initiative called the National Bioweapons Defense Analysis Center, with \$120 million to be used to build a facility to study bioterrorism, and the other \$300 million going to four urban areas -- beginning with greater Washington -- to create biodefense models that can be used as national templates.

Anna Johnson-Winegar, deputy assistant to the secretary of defense for chemical and biological defense, said the urban areas program seeks "to demonstrate how much we can do in one year" in selected areas.

Washington was chosen because of obvious target potential and because it has already received considerable money, she said. The second site is Albuquerque, which has a well-developed radiological accident response system. The other two sites have not yet been chosen.

The aim is to create what the Defense Department called a "system of systems," Johnson-Winegar said. "It would include biodetection, using information from medical surveillance systems and environmental sensors and integrating the data into one comprehensive system."

Johnson-Winegar said the District program will get the best available off-the-shelf equipment, while the other "test beds" will use more experimental technologies. Although the Pentagon will not control the program, Gordon Johndroe, spokesman for the White House's Office of Homeland Security, said its goals would remain the same under Homeland Security.

To help smooth all these changes, Malson said the District is using part of its \$11.9 million share of the HHS money to hire a physician to serve as medical director for bioterrorism response coordination for the D.C. Hospital Association. Malson is the association's executive director.

Hiring the physician -- who will help coordinate regional biodefense -- was part of the District's response to an HHS requirement that states and cities, before receiving their share of the \$1.1 billion, comply with 16 "Benchmarks for Bioterrorism Preparedness Planning," among them designation of a "senior health official" as a state coordinator for biodefense.

Other benchmarks included development of communications systems to link hospitals, public health offices and law enforcement, and preparation of hospital emergency plans to accommodate a "surge" of up to 500 gravely ill patients.

Besides the benchmarks, states were urged to come up with their own innovations. The District decided to make its coordinator a physician. Oregon is hiring a mental health expert to cope with "demoralization" caused by a bioterror attack. Wyoming developed a plan to counter a terrorism-related outbreak of livestock disease.

"I've been really gratified at how much has been done," said HHS's Henderson, who is coordinating the program. "People are taking this very seriously, and are spending not only the money we've given them, but state money as well."

Other federal biodefense programs will remain somewhat vague, at least until the 2003 budget is passed and the Department of Homeland Security comes into focus. Only then would the new department take charge of NIH's proposed \$1.9 billion in bioterrorism research.

"We will provide the money and inform the scientists of the threat we want to examine," Johndroe said. "They do the research, and disburse the money with their oversight."

Several experts suggested that the White House's desire to split this responsibility could fragment biodefense research rather than consolidate it, a danger that could be further enhanced because the Bush plan does not give the new department any authority over \$1.07 billion in Defense Department biodefense programs, many of which have important civilian applications.

"You really have to be careful not to disconnect some of these programs from where the expertise is," said Peggy Hamburg, a vice president at NTI, a nonprofit organization that studies weapons of mass destruction. "You can't just carve out pieces of a department, label them 'bioterrorism' and expect to get the same results" ([UCLA, 2002](#)).

Title: Many States Reject Bioterrorism Law

Date: July 23, 2002

Source: [USA Today](#)

Abstract: Nearly 10 months after anthrax attacks caused chaos among health officials from Florida to New York, fewer than a third of the states have adopted laws to give governors and state health officials powers to respond to a bioterrorism attack or other public-health emergencies.

A model law developed for the federal Centers for Disease Control and Prevention and provided to state legislatures last year would give authorities the right to enforce quarantines, vaccinate people, seize and destroy property without compensation, and ration medical supplies, food and fuel in a public-health emergency.

Such laws are needed, federal officials say, because they give authorities the guidance and legal ability to make quick decisions in an emergency involving contagious or deadly pathogens.

Most state health emergency laws haven't been updated since polio tore through the population a half-century ago.

"We have not used emergency powers in probably 50 years," says Gene Matthews, a lawyer for the Department of Health and Human Services. "This is something we need to attend to."

But a broad coalition of opponents, ranging from civil libertarians to conservative physicians, says the proposed law would violate individual rights and give government too much power. Their objections have caused lawmakers in some states to scuttle the bill.

The Model State Emergency Health Powers Act "gives governors and state health officials a blank check to impose the most draconian sorts of measures," Barry Steinhardt of the American Civil Liberties Union says. It's "designed to bring quarantine and other laws into the 21st century, but in many ways it is a throwback."

So far, 16 states and the District of Columbia have passed all or parts of the model law. It has been rejected or stalled in 22 states.

In California, efforts to pass the law were shot down in April. Republican Assemblyman Keith Richman, the bill's sponsor and the Legislature's only physician, says lawmakers are "already suffering from disaster amnesia. They have their heads stuck in the sand."

The act "goes far beyond bioterrorism," says Andrew Schlafly of the conservative Association of American Physicians and Surgeons. "Unelected state officials can force treatment or vaccination of citizens against the advice of their doctors."

But James Hodge of the Center for Law and the Public's Health at Georgetown and Johns Hopkins universities, which drafted the law, says it would be used only in extreme cases. He says he is encouraged that so many states have adopted all or parts of the law.

"There's nothing in this act that's not constitutionally possible," Hodge says ([USA Today, 2002](#)).

Title: Biological, Chemical, And Radiological Weapons Countermeasures Research Act Of 2002

Date: October 17, 2002

Source: [Library of Congress](#)

Abstract: Biological, Chemical, and Radiological Weapons Countermeasures Research Act of 2002 - Directs the Secretary of Homeland Security to make available to manufacturers of terror weapons countermeasures, and to publish, a list of materials that may be used as weapons of mass destruction (WMD). Requires the Secretary to determine countermeasures that diagnose, treat, or prevent infection from biological agents or toxins ("countermeasures") for each item on the list.

Requires private sector entities that are engaged in certain research to register with the Department of Homeland Security if they wish to benefit from various tax, patent, procurement, liability limitations, and other incentives established under this Act. Classifies such research as: (1) countermeasures; (2) diagnostics to detect, identify, or analyze biological agents or toxins ("diagnostics"); and (3) research tools used in the laboratory ("research tools") that enable the rapid and effective development of countermeasures.

Establishes in the Treasury of the United States a "Terror Weapon Countermeasure Purchase Fund (TWCPF)" to purchase, and provide adequate payment for, countermeasures, diagnostics, and research tools.

Extends market exclusivity for new drugs that are countermeasures.

Directs the Secretary to enter into agreements to indemnify and defend persons or entities: (1) involved in the research, development, and production of countermeasures, diagnostics, or research tools purchased under the TWCPF; or (2) who face civil actions arising from human trials and research, development, and production of countermeasures certified under this Act ([Library of Congress, 2002](#)).

Title: Anthrax Cleanup Assistance Act Of 2002

Date: September 20, 2002

Source: [Library of Congress](#)

Abstract: Directs the Administrator of General Services to accept title to the Florida building that was the site of the first anthrax attack. Requires the Administrator of the Environmental Protection Agency to remediate the property to ensure that it is anthrax-free.

Permits any biohazard waste from the property to be disposed of at a suitable Federal installation, whether or not title to the property is transferred to General Services.

Requires the sale of the remediated property once it has been certified as fit for habitation ([Library of Congress, 2002](#)).