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Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law

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(name redacted)
(name redacted)
Domestic Social Policy Division

Mary E. Tiemann
Resources, Science, & Industry Division

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Summary

Last fall's anthrax attacks, though small in scale compared to the scenarios envisioned by bioterrorism experts, strained the public health system and raised concern that the nation is insufficiently prepared to respond to bioterrorist attacks. Improving public health preparedness and response capacity offers protection not only from bioterrorist attacks, but also from naturally occurring public health emergencies.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, H.R. 3448), which is intended to bolster the nation's ability to respond effectively to bioterrorist threats and other public health emergencies. The act builds on the programs and authorities established in Title III of the Public Health Service (PHS) Act by the Public Health Threats and Emergencies Act of 2000 (P.L. 106-505, Title I).

P.L. 107-188 is a 5-year authorization bill, which calls for a total of $2.4 billion in funding in FY2002, $2.0 billion in FY2003, and such sums as may be necessary for the remaining years. The act authorizes the Secretary of Health and Human Services (HHS) to upgrade and renovate facilities at the Centers for Disease Control and Prevention (CDC), purchase smallpox vaccine, expand the national stockpile of drugs, vaccines, and other emergency medical supplies, and provide grants to state and local governments and hospitals to improve preparedness and planning. The Secretaries of HHS and Agriculture are required to register and regulate facilities that handle potentially dangerous biological agents.

The anti-bioterrorism legislation also includes provisions to protect the nation's food and drug supply and enhance agricultural security, including new regulatory powers for the Food and Drug Administration (FDA) to block the importation of unsafe foods. To protect the drinking water supply, the act requires community water systems to conduct vulnerability assessments and develop emergency response plans. P.L. 107-188 also reauthorizes the Prescription Drug Use Fee Act through FY2007.

The following analysts may be contacted for additional information:

(name redacted) (7-....) HHS/C DC programs and policies
& Pamela Smith (7-....)
Donna Vogt (7-....) Food safety (FDA)
Jean Rawson (7-....) Agriculture safety and security (USDA)
(name redacted) (7-....) Drinking wa ter safety and security (EPA)

Contents

List of Tables

Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188): Provisions and Changes to Preexisting Law

Introduction

The September 11, 2001 terrorist attacks and the subsequent deliberate release of anthrax spores in the mail have focused policymakers' attention on the preparedness and response capability of the U.S. public health system. Though small in scale compared to the scenarios envisioned by bioterrorism experts and played out in recent government exercises, the recent anthrax attacks strained the public health system and exposed weaknesses at the federal, state, and local levels. Many bioterrorism experts believe that had those responsible for the anthrax attacks employed a more sophisticated delivery mechanism or released a deadly communicable biological agent such as smallpox, the health care system may have been overwhelmed.

Bioterrorism poses a unique challenge to the medical care and public health systems. Unlike an explosion or chemical attack, which results in immediate and visible casualties, the public health impact of a biological attack can unfold gradually over time. Until a sufficient number of people arrive at emergency rooms and doctors' offices complaining of similar illnesses, there may be no sign that an attack has taken place. The speed and accuracy with which doctors and laboratories reach the correct diagnoses and report their findings to public health authorities has a direct impact on the number of people who become ill and the number that die. The nation's ability to respond to a bioterrorist attack, therefore, depends crucially on the state of preparedness of its medical care systems and public health infrastructure.

Public health experts have for years complained about the deterioration of the public health system through neglect and lack of funding. They warn that the nation is ill-equipped and insufficiently prepared to respond to a bioterrorist attack. For example, they point out that there are too few medical personnel trained to spot biological attacks, a shortage of sophisticated laboratories to identify the agents, and inadequate supplies of drugs and vaccines to counteract the threat. They also contend that inadequate plans exist for setting up quarantines and emergency facilities to handle the sick and infectious victims. Improving public health preparedness and response capacity offers protection not only from bioterrorist attacks, but also from naturally occurring public health emergencies. Public health officials are increasingly concerned about our exposure and susceptibility to infectious disease and food-borne illness because of global travel, ubiquitous food imports, and the evolution of antibiotic-resistant pathogens.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, H.R. 3448), which is intended to bolster the nation's ability to respond effectively to bioterrorist threats and other public health emergencies. This report provides a brief overview and legislative history of P.L. 107-188, followed by a detailed side-by-side comparison of the act's provisions with preexisting law. Appendix A lists, by committee, all the bioterrorism-related hearings held in the 107th Congress prior to enactment of P.L. 107-188. In most cases, hearing testimony is available on the committee Web sites. Appendix B provides a list of bioterrorism-related Web sites. For a discussion of bioterrorism preparedness issues, see CRS Report RL31225, *Bioterrorism: Summary of a CRS/National Health Policy Forum Seminar on Federal, State, and Local Public Health Preparedness.*

Public Health Security and Bioterrorism Preparedness and Response Act

Legislative History

Representatives Tauzin (R-LA) and Dingell (D-MI) introduced the Public Health Security and Bioterrorism Response Act (H.R. 3448) on December 11, 2001. The bill was immediately considered under suspension of the rules and passed by the House the following day on a vote of 418-2. H.R. 3448 built on the provisions of a bipartisan Senate bill, the Bioterrorism Preparedness Act (S. 1765), which had been introduced by Senators Frist and Kennedy on November 15, 2001. S. 1765 incorporated ideas and objectives from several other Senate bioterrorism bills introduced in the wake of the anthrax attacks.[1] The Senate took up H.R. 3448 on December 20, 2001, following its passage in the House, substituted the text of S. 1765 and passed H.R. 3448, as amended, by unanimous consent. A conference report (H.Rept. 107-481) was filed on May 21, 2002. The next day the House agreed to the conference report by a vote of 425-1. The Senate approved the conference report 98-0 on May 23, 2002. The President signed H.R. 3448 into law (P.L. 107-188) on June 12, 2002.

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[1] Senate bioterrorism preparedness bills introduced in response to the September 11 attacks and the anthrax incidents include: the Biological and Chemical Weapons Preparedness Act of 2001 (S. 1486) introduced by Senator Edwards on October 3, 2001; the Biological and Chemical Attack Preparedness Act (S. 1508) introduced by Senator Corzine on October. 4, 2001; the State Bioterrorism Preparedness Act (S. 1520) introduced by Senator Bayh on October 9, 2001; the Protecting America's Children Against Terrorism Act (S. 1539) introduced by Senator Clinton on October 11, 2001; the Bioterrorism Awareness Act (S. 1548) introduced by Senator Carnahan on October 15, 2001; the Protecting the Food Supply from Bioterrorism Act (S. 1551) introduced by Senator Clinton on October 15, 2001; the Agricultural Bioterrorism Countermeasures Act of 2001 (S. 1563) introduced by Senator Hutchison on October 17, 2001; the Public Health Emergency Planning and Information Act of 2001 (S. 1574) introduced by Senator Rockefeller on October 25, 2001; the Pathogen Research, Emergency Preparedness and Response Efforts (PREPARE) Act of 2001 (S. 1635) introduced by Senator Hutchinson on November 6, 2001; and the Deadly Biological Agent Control Act of 2001 (S. 1661) introduced by Senator Feinstein on November 8, 2001.

Overview of P.L. 107-188

As enacted, P.L. 107-188 incorporates many of the provisions in the original House and Senate-passed bills. It adds to the programs and authorities established in Title III of the Public Health Service (PHS) Act by the Public Health Threats and Emergencies Act of 2000 (P.L. 106-505, Title I) and creates a new PHS Act Title XXVIII: National Preparedness for Bioterrorism and Other Public Health Emergencies. P.L. 107-188 is a 5-year authorization act, which calls for a total of $2.4 billion in funding for FY2002, $2.0 billion for FY2003, and such sums as may be necessary for the remaining years. The act authorizes grants to state and local health departments and hospitals to improve planning and preparedness activities, enhance laboratory capacity, and educate and train health care personnel. It also directs the Secretary to upgrade and renovate CDC's facilities. In addition, the act authorizes the HHS Secretary to purchase smallpox vaccine and expand the national stockpile of medicine and medical supplies to meet the nation's health security needs.

To help prevent bioterrorism and to establish a national database of potentially dangerous pathogens, P.L. 107-188 requires the HHS Secretary to register facilities and individuals in possession of biological agents and toxins that pose a severe threat to public health and safety, and to promulgate new safety and security requirements for such facilities and individuals. The act grants authority to the Secretary of Agriculture to establish a parallel set of requirements for facilities that handle agents and toxins that threaten crops and livestock. The bioterrorism legislation also incorporates language taken from S. 1275 that authorizes grants to states and localities to increase public access to defibrillators (i.e., devices that restore normal heart rhythm to patients in cardiac arrest by administering a controlled electric shock).

P.L. 107-188 contains several provisions to protect the nation's food and drug supply and enhance agricultural security. The act authorizes $545 million for FDA and USDA to hire new border inspectors, develop new methods of detecting contaminated foods, work with state food safety regulators, and protect crops and livestock. It also provides FDA with new regulatory powers to require prior notice of all imported foods and detain suspicious foods for inspection. All foreign and domestic food facilities are required to register with the FDA. Finally, P.L. 107-188 includes a set of provisions aimed at protecting the nation's drinking water supply, including authorizing $160 million to provide financial assistance to community water systems to conduct vulnerability assessments and prepare response plans.

The bioterrorism legislation also includes language reauthorizing the Prescription Drug User Fee Act (PDUFA), which was set to expire on September 30, 2002. Congress first enacted PDUFA in 1992.[2] The original law authorized the FDA to collect fees from pharmaceutical companies and use the funds to hire additional reviewers to expedite the drug review and approval process, in accordance with performance goals developed by the agency in consultation with the industry prior to PDUFA enactment. The 1992 law directed the FDA to provide Congress with an annual report on the agency's progress in achieving those goals. Encouraged

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[2] P.L. 102-571, 21 U.S.C. Section 379(g).

by the success of the user fee program, Congress in 1997 reauthorized PDUFA through FY2002.[3] Under PDUFA II, the FDA tried to meet tighter performance goals, as well as achieve more transparency in the drug review process and better communication with drug makers and patient advocacy groups. For more information on PDUFA, see CRS Report RL31453, *The Prescription Drug User Fee Act: Structure and Reauthorization Issues.*

Table 1 below summarizes the bioterrorism legislation's authorizations of appropriations for FY2002 and FY2003. Only those authorizations that specify a dollar amount are included.

Table 1. P.L. 107-188: Authorizations of Appropriations for FY2002 and FY2003

($ millions)

	FY2002	FY2003
Title I: National Preparedness for Bioterrorism and Other Public Health Emergencies		
Grants to state and local governments	No provision	$1,080
Grants for hospital preparedness	No provision	$520
Upgrading CDC	$300	$300
Strategic National Stockpile	$640	Such sums as may be necessary
Smallpox vaccine	$509	Such sums as may be necessary
Antimicrobial resistance	$25	$25
Emergency health professional verification system	$2	Such sums as may be necessary
Public access defibrillation programs	$5	$30
Dept. of Veterans Affairs emergency preparedness	$133	Such sums as may be necessary
Title IIIA: Food Supply Safety and Security	$130	Such sums as may be necessary
Title IIIC: Agricultural Security	$415	Such sums as may be necessary
Title IV: Drinking water Safety and Security	$210	Such sums as may be necessary
Title V: FDA Drug-Related Authorizations	No provision	$10
TOTAL	**$2,369**	**$1,965**

[3] PDUFA reauthorization was included in Title I of the Food and Drug Administration Modernization Act of 1997, P.L. 105-115.

Table 2, beginning on page 6, provides a detailed side-by-side comparison of the provisions of P.L. 107-188 with preexisting law, where applicable. All the PHS Act Title III provisions relating to public health emergencies that were established by P.L. 106-505 (i.e., Sections 319, 319A–319G) are included in the table, regardless of whether they are amended by the bioterrorism bill. Unless specifically noted otherwise, the term Secretary refers to the Secretary of HHS.

Table 2. Comparison of P.L. 107-188 with Preexisting Law

Topic	Preexisting Law	P.L. 107-188
National Preparedness for Bioterrorism and Other Public Health Emergencies		
National Preparedness Plan, reports to Congress	No statutory provisions.	Adds a new Title XXVIII (Section 2801) to the Public Health Service (PHS) Act that requires the Secretary, building on existing authority in PHS Act Section 319A, to develop and implement a national plan to prepare for and respond to bioterrorism and other public health emergencies. Establishes five national preparedness goals: (i) assist state and local governments in the event of bioterrorism or other public health emergencies; (ii) ensure that state and local governments have the capacity to detect and respond to such emergencies; (iii) develop and maintain countermeasures; (iv) ensure coordination and minimize duplication of federal, state, and local planning, preparedness, and response activities; and (v) enhance hospital and other health care facility readiness. Requires the Secretary to coordinate with the activities of state and local governments and develop outcome measures to evaluate progress in implementing the national plan and achieving its five goals. Requires the Secretary to report to Congress within 1 year, and biennially thereafter, on progress made towards meeting the national preparedness goals, including recommendations for new legislative authority to protect public health. Clarifies that the Act does not expand or limit any of the Secretary's preexisting authorities. Requires the Secretary to report to Congress within 1 year on: (i) the findings and recommendations of the National Advisory Committee on Children and Terrorism and the EPIC Advisory Committee; (ii) the vulnerability of rural and medically underserved communities to bioterrorism; (iii) recommendations for new legislative authority to strengthen rural and medically underserved communities; and (iv) the need for and benefits of a private-sector, community-based rapid response corps of medical volunteers. Requires the Secretary to conduct a study of best practices in local emergency response and report to Congress within 180 days. [Section 101]
Establishing public health capacities	Public Health Service (PHS) Act Section 319A requires the Secretary, together with state and local health officials, to establish what capacities are needed for national, state, and local public health systems to be able to detect, diagnose, and contain outbreaks of infectious disease, drug-resistant pathogens, or acts of bioterrorism. Authorizes $4 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	No provisions.

Topic	Preexisting Law	P.L. 107-188
Assessing public health needs	PHS Act Section 319B authorizes grants to states and local public health departments to evaluate the extent to which they can achieve the capacities identified pursuant to Section 319A. Requires the Secretary to develop a national framework for the evaluations. Authorizes $45 million for FY2001, and such sums as may be necessary for FY2002–FY2003.	No provisions.
Assistant Secretary for Public Health Emergency Preparedness	No statutory provisions.	Adds a new Section 2811(a) to the PHS Act authorizing the appointment of an Assistant Secretary for Public Health Emergency Preparedness to oversee the National Disaster Medical System (see below) and coordinate all HHS response activities related to bioterrorism and other public health emergencies and interface with other federal agencies and state and local entities. [Section 102(a)]
Public health emergencies	PHS Act Section 319 authorizes the Secretary to respond to public health emergencies, including diseases, disorders, or bioterrorist attacks, by supporting grants, contracts, and investigations. Establishes the Public Health Emergency Fund and authorizes such sums as may be necessary. Requires an annual report to Congress on expenditures from the Fund.	Requires the Secretary to notify Congress within 48 hours of declaring a public health emergency. Provides that public health emergencies expire by announcement of the Secretary or after 90 days, whichever comes first, and permits the Secretary to renew emergency declarations, subject to the same 90-day limitation. [Section 144] Allows the Secretary during a public health emergency to waive deadlines for the submission of data and reports by individuals or public or private entities pursuant to any law administered by the Secretary. Requires the Secretary to notify Congress of such an action and publish a notice in the *Federal Register*. [Section 141]
National Disaster Medical System (NDMS)	No statutory provisions. The NDMS was established in 1984 as a partnership of four federal agencies (HHS, FEMA, DOD, VA), state and local governments, and the private sector to provide medical assistance and hospitalization for mass casualties in the event of a natural or man-made disaster. It consists of more than 7,000 volunteer health professionals and support personnel organized into medical response teams. For more information, go to [http://ndms.dhhs.gov/NDMS/ndms.html].	Adds a new Section 2811(b) to the PHS Act providing statutory authorization for the NDMS, to be coordinated by HHS, FEMA, DOD, and the VA, in collaboration with states and other appropriate public or private entities. Requires the Secretary within 1 year, and periodically thereafter, to conduct exercises to test the capability and timeliness of the NDMS to mobilize and respond effectively to a bioterrorist attack or other public health emergency. Appoints activated NDMS volunteers as temporary federal employees. Establishes liability protections, compensation for work injuries, and employment and reemployment rights for NDMS volunteers. Authorizes such sums as may be necessary for FY2002–FY2006 for NDMS operations and for the Assistant Secretary for Public Health Emergency Preparedness. [Section 102(b)] Requires the VA Secretary, in consultation with the Secretaries of HHS and DOD and the FEMA Director, to establish a training program to facilitate the participation of VA medical center staff in the NDMS. [Section 154(e)]

Topic	Preexisting Law	P.L. 107-188
Upgrading CDC, national public health communications and surveillance networks	PHS Act Section 319D authorizes funds for the construction and renovation of CDC facilities, and to support the agency's activities to combat threats to public health. Authorizes $180 million for FY2001, and such sums as may be necessary for FY2002–FY2010. Since FY1999, CDC has awarded grants to all 50 states and some metropolitan health departments to enhance state and local laboratory capacity and to help develop the Health Alert Network (NAH), a national electronic communications network connecting all the components of the public health community. For more information, go to [http://www.bt.cdc.gov].	Amends PHS Act Section 319D by recognizing CDC's essential role in defending against and combating bioterrorism and other public health emergencies. Provides CDC's Director with multi-year contracting authority for facility construction, renovation, and security. Requires the Secretary to improve CDC's preparedness and response capacities. Provides for the establishment of public health communications and surveillance networks and requires the Secretary, within 1 year and in cooperation with health care providers and state and local public health officials, to establish technical and reporting standards for such networks. Authorizes $300 million for FY2002 and for FY2003, and such sums as may be necessary for FY2004–FY2006, to upgrade CDC's facilities. Authorizes such sums as may be necessary for FY2002–FY2006 for improving CDC's capacities and establishing national communications and surveillance networks. [Section 103]
Federal working groups and advisory committees	PHS Act Section 319F requires the Secretary to: (i) establish, with the Secretary of Defense, an interagency working group on bioterrorism preparedness, and (ii) establish, in collaboration with the Director of FEMA, the Attorney General, and the Secretary of Agriculture, an interagency working group to address the public health and medical consequences of a bioterrorist attack.	Amends PHS Act Section 319F by replacing the two existing working groups with a single interagency working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies, to be established by the Secretary in coordination with the Attorney General, the Directors of FEMA and Central Intelligence, the Secretaries of Agriculture, Defense, Energy, Labor, and Veterans Affairs, the EPA Administrator, and with other federal officials, as appropriate. Requires the working group, or its subcommittees, to meet periodically for the purpose of consultation on, assisting in, and making recommendations on a range of specified topics related to preparedness for and response to bioterrorism and other public health emergencies (including research and development of countermeasures to treat, prevent, and identify exposure to biological agents). [Section 108] Amends PHS Act Section 319F as follows: (i) establishes the National Advisory Committee on Children and Terrorism, and the Emergency Public Information and Communications (EPIC) Advisory Committee (both of which sunset after 1 year); (ii) requires the Secretary to develop a strategy for effectively communicating information on bioterrorism and other public health emergencies; and (iii) recommends establishing a federal web site on bioterrorism with links to state and local government sites. Requires the Secretary, in consultation with other federal agencies, to conduct a study of the ability of local public health entities to maintain communications during a bioterrorist attack or other public health emergency. [Sections 104]

Topic	Preexisting Law	P.L. 107-188
Education and training of health care personnel	PHS Act Section 319F requires the Secretary to develop programs to educate health professionals in recognizing and caring for victims of bioterrorist attacks, and programs to train laboratory personnel in identifying bioweapons.	Amends PHS Act Section 319F by requiring the Secretary, in collaboration with the interagency working group and professional organizations, to award grants: (i) to develop education materials to teach health officials and other emergency personnel to identify potential bioweapons and other dangerous agents and to care for victims of public health emergencies, recognizing the special needs of children and other vulnerable populations; (ii) to develop education materials for community-wide planning to respond to bioterrorism or other public health emergencies; (iii) to develop materials for proficiency testing of lab and other public health personnel for the recognition and identification of potential bioweapons and other dangerous agents; and (iv) to provide for the dissemination and teaching of these materials. Authorizes the Secretary, in consultation with the Attorney General and the FEMA Director, to provide technical assistance for emergency response personnel training carried out by the Justice Department and FEMA. [Section 105]
National Pharmaceutical Stockpile (NPS)	No statutory provisions. The NPS, which was established and is managed by the CDC, includes pharmaceuticals, vaccines, and medical supplies that can be deployed anywhere in the country in response to a public health emergency. For more information, go to [http://www.cdc.gov/nceh/nps/default.htm].	Provides statutory authorization for a Strategic National Stockpile of drugs, vaccines, medical devices, and other supplies to meet the nation's health security needs in the event of a bioterrorist attack or other public health emergency. Requires the Secretary to manage the stockpile, in coordination with the VA Secretary, and ensure its physical security. Protects information on stockpile locations from disclosure under the Freedom of Information Act. Authorizes $640 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 121]
Grants to address national shortages of specific types of health professionals	No applicable provisions, although PHS Act Titles VII (Health Professionals Education) and VIII (Nursing Workforce Development) authorize federal support for training of health professionals for specific purposes.	Adds a new Section 319H to the PHS Act establishing a grant program to provide financial assistance for the education and training of individuals in any category of the health professions where there is a shortage that the Secretary determines should be alleviated to improve public health emergency readiness. Authorizes sums as may be necessary for FY2002–FY2006. [Section 106]
Health professional volunteers	No applicable provisions.	Adds a new Section 319I to the PHS Act requiring the Secretary to establish a electronic database for the advance registration of health professionals to verify their credentials, licenses, accreditations, and hospital privileges when they volunteer to respond during public health emergencies. Authorizes the Secretary to encourage states to permit out-of-state health professionals to provide health services during public health emergencies. Authorizes $2 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 107]

Topic	Preexisting Law	P.L. 107-188
State public emergency announcements	The Stafford Act (42 U.S.C. 5121 et seq.) authorizes federal assistance when the President determines that a natural or man-made disaster has overwhelmed state and local resources. Stafford assistance is administered by the Federal Emergency Management Agency (FEMA).	Amends Section 613(b) of the Stafford Act by requiring states to include a plan for providing a coordinated public communications response in their submission for federal funds to help pay for state emergency preparedness personnel and administrative expenses. [Section 151]
Quarantine and inspection	PHS Act Section 361 authorizes the Surgeon General, in consultation with the Secretary, to develop quarantine, inspection, fumigation, sanitation, and pest extermination regulations to prevent the introduction, transmission, or spread of communicable diseases. Section 363 authorizes the development of regulations for the apprehension and examination of infected individuals in times of war.	Amends PHS Act Sections 361 and 363 by expanding the authority of the Secretary, in consultation with the Surgeon General, to issue a quarantine rule or a rule providing for the apprehension of individuals during wartime. Permits federal regulations under Sections 361 and 363, as amended, to preempt state laws that conflict with the exercise of such federal authority. [Section 142]
GAO Report	PHS Act Section 319F requires a GAO report to Congress, within 6 months, on federal bioterrorism-related activities, including research, preparedness, and response. [This report, GAO-01-915, was issued by GAO on September 28, 2001.]	Requires a new GAO report to Congress on federal bioterrorism-related activities, including research, preparedness, and response. [Section 157]
Occupational safety and health	Section 22 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 671) created the National Institute for Occupational Safety and Health (NIOSH) as the federal agency responsible for conducting research and making recommendations for the prevention of work-related disease and injury. NIOSH is part of the CDC.	Requires the Secretary, acting through the Director of NIOSH, to expand research on bioterrorism threats and attacks in the workplace. [Section 153]
Department of Veterans Affairs	No statutory provisions.	Directs the VA Secretary to enhance the readiness of VA medical centers and research facilities to respond to a chemical or biological attack, based on the results of an evaluation of the security needs at these facilities. Requires the VA Secretary to develop a centralized tracking system for pharmaceuticals and medical supplies and equipment throughout the VA health care system, and train VA health care personnel in emergency medical response. Authorizes $100 million for FY2002, and such sums as may be necessary for FY2003–FY2006. Requires the VA Secretary, in consultation with the HHS Secretary, the American Red Cross, and the interagency working group, to provide mental health counseling to individuals seeking care at a VA medical center following a bioterrorist attack or other public health emergency. Authorizes $33 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 154]

Topic	Preexisting Law	P.L. 107-188
Supplies and services in lieu of federal grant funds	No applicable provisions.	Adds a new Section 319J to the PHS Act allowing the Secretary to provide supplies, equipment, or services instead of, or in conjunction with, grants awarded under Sections 319 through 319I, or Section 319K. [Section 110]
Psychological impact of trauma	PHS Act Section 582 authorizes the Secretary to award grants to study the psychological impact of trauma, in order to improve the treatment children and youth that suffer from psychiatric disorders as a result of witnessing or experiencing traumatic events. Authorizes $50 million for FY2001, and such sums as may be necessary for FY2002–FY2003.	Extends grant authority and authorizes such sums as may be necessary for FY2003–FY2006. [Section 155]
Public access to automated external defibrillators	PHS Act Section 247 requires the Secretary, in consultation with other federal agencies and appropriate public and private entities, to establish guidelines for placing automated external defibrillators (AEDs) in federal buildings, and to publish in the *Federal Register* recommendations for AED placement. PHS Act Section 248 establishes the conditions under which a person who uses or attempts to use an AED in a medical emergency is immune from civil liability for any resulting harm to the victim.	Community Access to Emergency Defibrillation Act of 2002: Adds a new Section 312 to the PHS Act authorizing grants to develop and implement public access defibrillation programs. Funds may be used to purchase AEDs, to provide training in AED usage, to provide information to community members about the public access defibrillation program, to provide information to local emergency medical services on AED placement, and to encourage private companies to purchase AEDs. Authorizes $25 million for FY2003, and such sums as may be necessary for FY2004–FY2006. Adds a new Section 313 to the PHS Act authorizing grants to develop and implement innovative, community-based public access defibrillation demonstration projects. Authorizes $5 million for each of FY2002–FY2006. [Section 159]
Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP)		
Emergency waivers	Medicare covers medically necessary acute care and follow-up services (hospital, short-term nursing home care, physician services, home health and a variety of outpatient services) for all persons age 65 and over, as well as certain disabled persons. Medicare beneficiaries may receive services through the traditional fee-for-service setting or may enroll in a Medicare managed care plan through the Medicare + Choice (M+C) program. Medicaid covers acute and long-term care services for low-income persons who are aged, blind, disabled, members of families with dependent children, and certain other pregnant women and children. The State Children's Health Insurance Program (SCHIP) covers uninsured children living in families with income above applicable Medicaid standards, typically up to or above 200% of the federal poverty level. In all three programs, providers must meet certain standards in order to participate and	Authorizes the Secretary to temporarily waive conditions of participation and other certification requirements for any entity that furnishes health care items or services to Medicare, Medicaid, or SCHIP beneficiaries in an emergency area during a declared disaster or public health emergency. In addition, during such an emergency, authorizes the Secretary to waive: (i) participation, state licensing (as long as equivalent licensure from another state is held and there is no exclusion from practicing in that state or any state in the emergency area), and pre-approval requirements for physicians and other practitioners; (ii) sanctions for failing to meet requirements for emergency transfers between hospitals; (iii) sanctions for physician self-referral; and (iv) limitations on payments for health care and services furnished to individuals enrolled in M+C plans when services are provided outside the plan. To the extent possible, the Secretary shall ensure that M+C enrollees do not pay more than would have been required had they

Topic	Preexisting Law	P.L. 107-188
	receive reimbursement for services rendered to program beneficiaries. For example, hospitals and other facilities must meet established conditions of participation, and laboratories must be certified under the Clinical Laboratories Improvement Act (CLIA). Physicians must be licensed to provide medical services in the state where medical care is rendered, and must follow established rules for obtaining prior approval to deliver certain types of services. Also, physicians must not refer patients to medical entities with which they have a financial relationship. Other statutory provisions require hospitals to fully stabilize patients receiving emergency care prior to transfer to another medical facility.	received care within their plan network. Requires the Secretary to provide Congress with certification and written notice at least 2 days prior to exercising this waiver authority. Provides for the waiver authority to continue for 60 days. Permits the Secretary to extend the waiver period. Requires the Secretary, within 1 year after the end of the emergency, to provide Congress with an evaluation of this approach and recommendations for improvements under this waiver authority. [Section 143]
Regulation of the Use, Possession, and Transfer of Potentially Dangerous Biological Agents and Toxins		
HHS regulation of biological agents and toxins that pose a threat to public health and safety	The 1996 Antiterrorism and Effective Death Penalty Act (P.L. 104-132, Section 511(d)-(g)) required the Secretary to: (i) establish a list of biological agents that may pose a severe threat to public health and safety; and (ii) establish safety procedures for transferring listed agents and toxins, including measures to protect public safety, prevent access by terrorists, and ensure the availability of bioagents for research, education, and other legitimate purposes. The regulations issued pursuant to the Act (i.e., 42 C.F.R. 72.6) include: (i) a list of 36 agents and toxins; (ii) registration requirements for facilities transferring these agents; (iii) transfer requirements; (iv) verification procedures including audit and quality control; (v) agent disposal requirements; and (vi) research and clinical exemptions.	Codifies and expands provisions of P.L. 104-132 in the PHS Act under a new Section 351A. Requires the Secretary to: (i) establish and, at least biennially, review and, if necessary, revise a list of biological agents and toxins that may pose a severe threat to public health and safety; (ii) establish safety procedures for transferring listed agents and toxins, including measures to protect public safety, prevent access by terrorists, and ensure the availability of agents and toxins for research, education, and other legitimate purposes; (iii) establish standards and procedures for the possession and use of listed agents and toxins, including the same measures listed in (ii); (iv) require registration for the possession, use, and transfer of listed agents and toxins; and (v) maintain a national database of registered facilities and the location of listed agents and toxins. Directs the Secretary, in consultation with the Attorney General, to establish appropriate safety and security requirements for registered entities and individuals, commensurate with the level of risk to public health and safety. These requirements must ensure that persons registering facilities: (i) limit access to listed agents and toxins to only those individuals (employees) with a legitimate need; (ii) identify such individuals to the Secretary and the Attorney General for background screening; (iii) deny access to individuals determined by the Attorney General to be “restricted individuals” (see Criminal Penalties below); and (iv) limit or deny access to individuals found to meet other specified criteria. Requires prompt screening and notification by the Attorney General and Secretary and provides for an expedited screening process where the registered person has demonstrated good cause. Establishes procedures for the review of denials based on the screening process.

Topic	Preexisting Law	P.L. 107-188
		Requires persons seeking to register a facility, as well as individuals seeking to register themselves, to be screened in the same manner as individuals working at a registered facility, but without the option of expedited review. Allows the Secretary to exempt federal, state, and local government facilities from screening. Requires that the Secretary be promptly notified of the theft or loss of listed agents or toxins. Authorizes the Secretary to conduct compliance inspections. Exempts from the above requirements clinical and diagnostic labs presented with a listed agent or toxin for diagnosis, verification, or proficiency testing, provided that they report the identification of the agent or toxin to the Secretary and transfer or destroy it. Exempts agents or toxins licensed or approved under specified federal laws, unless the Secretary determines that additional regulation is necessary to protect public health and safety. Permits the Secretary to exempt investigational products being used in research or clinical trials and requires the Secretary to make a prompt (within 14 days) determination on a request for such an exemption. Permits the Secretary to grant temporary exemptions during public health and agricultural emergencies. Protects information collected under the above requirements for the possession, use, and transfer of listed agents and toxins from disclosure under the Freedom of Information Act. Establishes civil penalties of up to $500,000 for violations of Section 351A. Requires prompt notification of the Secretary in the event of an unintentional release of a listed agent or toxin. Requires the Secretary to report to Congress within 1 year. Authorizes such sums as may be necessary for FY2002–FY2007. [Section 201]
Implementation time frame for HHS regulations	No statutory provisions.	Requires that all persons in possession of listed agents or toxins notify the Secretary within 90 days, based on guidance issued by the Secretary within 30 days. Requires the Secretary within 180 days to issue an interim final rule for carrying out Section 351A (including time frames for the applicability of the rule to minimize disruption of research and education). [Section 202] Repeals current law (i.e., P.L. 104-132, Section 511(d)-(g)). [Section 204]

Topic	Preexisting Law	P.L. 107-188
USDA regulation of biological agents and toxins that pose a threat to agriculture	No statutory provisions.	Gives USDA comparable regulatory authority to that provided to HHS under Section 201 of the Act for regulating the use, possession, and transfer of listed biological agents and toxins that may pose a severe threat to animal or plant health, or to animal or plant products. The USDA provisions differ from those of HHS in the criteria used to develop a list of agriculturally significant biological agents and toxins. Also, there is no mandated denial of access for "restricted individuals" because possession of USDA-listed agents by such persons is not a federal crime. Additional provisions address overlap agents and toxins that appear in both the HHS and the USDA list. [Section 212]
Implementation time frame for USDA regulations	No statutory provisions.	Requires the USDA Secretary to issue an interim final rule establishing the initial list of agents and toxins within 60 days and, no later than 60 days after that date, requires all persons in possession of listed agents or toxins to notify the Secretary. Requires the USDA Secretary within 180 days to issue an interim final rule for carrying out Section 212 of the Act (including time frames for the applicability of the rule to minimize disruption of research and education). [Section 213]
HHS-USDA coordination	No statutory provisions.	Requires the Secretaries of HHS and Agriculture to coordinate activities regarding overlap agents and toxins that appear in both lists, so as to minimize the administrative burden on those persons subject to both sets of regulations. Requires both Secretaries, within 180 days, to enter into a memorandum of understanding providing for the development of a single system of registration for persons who use, possess, or transfer overlap agents or toxins, and to coordinate inspections and enforcement. Requires the Secretaries to issue joint regulations for the use, possession, and transfer of overlap agents and toxins within 18 months. [Section 221]
Criminal penalties	Section 175 of the U.S. Criminal Code (i.e., 18 U.S.C. 175): (i) prohibits the production, stockpiling, transfer, acquisition, or possession of biological agents for use as a weapon, subject to fines and/or imprisonment for life or any term of years; and (ii) establishes fines and/or up to 10 years imprisonment for individuals who knowingly possess any biological agent, toxin, or delivery system of a type and in a quantity not reasonably justified by research or other peaceful purposes. Section 175b prohibits "restricted individuals" (i.e., indicted criminals, illegal aliens, and other specified individuals) from possessing, shipping, or receiving listed agents or toxins, subject to fines and/or up to 10 years imprisonment. Section 176 provides for the seizure, forfeiture, and destruction of biological weapons.	Amends 18 U.S.C. 175b by adding the following criminal penalties: (i) fines and/or up to 5 years imprisonment for anyone who transfers a listed agent or toxin to a person whom the transferor knows or has reasonable cause to believe has not obtained a registration; and (ii) fines and/or up to 5 years imprisonment for unregistered persons in possession of listed agents or toxins. Note: These new penalties apply to both the HHS and USDA regulations described above. [Section 231]

Topic	Preexisting Law	P.L. 107-188
State and Local Preparedness and Response Capacity		
Core capacity grants to state and local public health agencies	PHS Act Section 319C authorizes grants to states and local governments, after they have completed a Section 319B evaluation, to address core public health capacity needs. Requires the Secretary to report to Congress on activities carried out under Sections 319A, 319B, and 319C by January 1, 2005. Authorizes $50 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	Deletes PHS Act Section 319C(f) (i.e., Authorization of Appropriations). [Section 131(b)]
Bioterrorism preparedness grants to states and local public health agencies, and health care facilities	PHS Act Section 319F(c) authorizes grants to states, localities, and health care facilities to increase their capacity to detect, diagnose, and respond to bioterrorist attacks, including training of personnel. [Note: For all activities under Section 319F, authorizes $215 million for FY2001, and such sums as may be necessary for FY2002–FY2006.]	Adds a new Section 319C-1 to the PHS Act authorizing grants to states and local governments to improve preparedness and response to bioterrorism and other public health emergencies. Eligible entities must have completed a Section 319B evaluation of core public health capacity needs and must, within 60 days of receiving an award, submit an emergency preparedness and response plan (including performance measures) describing the activities to be carried out by the entity to address identified needs. Use of funds for preparedness and response to bioterrorism and outbreaks of infectious disease takes priority over other public health emergencies, subject to any modification in the assessment of risk by the Secretary. Authorizes $1.6 billion for FY2003: $1.08 billion for block grants to states and territories based on population, with each state/territory guaranteed a minimum level of funding; and $520 million for grants to states for hospital preparedness. Authorizes such sums as may be necessary for FY2004–FY2006. Note: The requirement that public health preparedness funding be awarded as block grants applies only to FY2003; greater flexibility in awarding funding is provided to the Secretary beyond FY2003. [Section 131(a)]
Grants to hospitals	No applicable provisions.	Adds a new Section 319C-2 to the PHS Act authorizing grants to improve community and hospital preparedness for bioterrorism and other public health emergencies. Eligible entities must be a partnership between one or more hospitals (or other health care facilities) and one or more states and/or local governments. Grant proposals must be coordinated and consistent with the state's emergency preparedness and response plan. Use of funds for preparedness and response to bioterrorism and outbreaks of infectious disease takes priority over other public health emergencies, subject to any modification in the assessment of risk by the Secretary. Authorizes such sums as may be necessary for FY2004–FY2006. [Section 131(a)]

Topic	Preexisting Law	P.L. 107-188
Demonstration grants	PHS Act Section 319G authorizes up to three demonstration grants for up to 5 years to states, localities, or non-profit organizations to carry out programs to improve biopathogen detection, develop plans for responding to bioterrorist attacks, and train response personnel. Requires a GAO report to Congress at the conclusion of the demonstration programs describing the capabilities of the grantees. Authorizes $6 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	No provisions.
Countermeasures (Research, Development, and Production of New Vaccines, Drugs, and Technologies)		
Smallpox vaccine	No statutory provisions. Existing supplies of smallpox vaccine consist of 15.4 million doses of freeze-dried vaccine (produced by Wyeth Laboratories) that HHS indicates could be expanded to 77 million doses by 1:5 dilution, plus another 75–90 million doses of a different vaccine (produced by Aventis Pasteur) that HHS is testing for safety and effectiveness. In addition, HHS has contracted with Acambis Inc. to produce a total of 209 million doses of a new type of smallpox vaccine by the end of 2002 (the new vaccine needs FDA approval before it can be used).	Requires the Secretary to ensure that the national stockpile contains enough smallpox vaccine to meet the nation's health security needs. Authorizes $509 million for FY2002, and such sums as may be necessary for FY2003–FY2006, to purchase smallpox vaccine. [Section 121]
FDA approval of drugs and biologics	Under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 et seq.), manufacturers of drugs and biologics (e.g., vaccines) must provide clinical trial data to demonstrate that their product is safe and effective, in order to obtain FDA marketing approval. The FFDCA provides for the designation of products as fast track to expedite the approval process.	Authorizes the Secretary to designate a priority countermeasure as a fast-track product for accelerated approval by the FDA. Permits a drug for which FDA approval is being sought on the basis of animal data to be designated a fast-track product. Requires the FDA, within 90 days, to issue as a final rule the October 5, 1999 proposed rule (64 *Fed. Reg.* 53960) permitting the use of animal data for demonstrating the effectiveness of new drugs and vaccines when ethical issues preclude conducting human clinical trials. (Note: FDA published a final rule on May 31, 2002 (67 *Fed. Reg.* 37988).) [Section 122, 123]
Security at research and production facilities	No applicable provisions.	Adds a new Section 319K to the PHS Act authorizing the Secretary, in consultation with the Secretary of Defense and the Attorney General, to provide technical or other assistance to enhance security at facilities that develop, produce, distribute, or store priority countermeasures. [Section 124]

Topic	Preexisting Law	P.L. 107-188
Research and development	PHS Act Section 319F requires the Secretary, in consultation with the interagency working group, to conduct research on the epidemiology and pathogenesis of biopathogens, diagnostic tests for biopathogens, and vaccines and other therapeutics.	Directs the Secretary to accelerate research and development on priority pathogens (as determined by the NIH Director in consultation with the interagency working group) and priority countermeasures. Requires the Secretary to consider research collaboration with the VA. Defines priority countermeasures as any drug, vaccine, biological product, device, or diagnostic test that the Secretary determines to be a priority to treat, identify, or prevent infection by a listed biological agent or toxin, or harm from any other agent that may cause a public health emergency. [Section 125]
Detection, identification, diagnosis, and surveillance technologies	No applicable provisions.	Requires the Secretary of Energy and the Administrator of the National Nuclear Safety Administration, in coordination with the interagency working group, to expand research on the rapid detection and identification of biopathogens and other agents that may cause a public health emergency, and report to Congress within 180 days. Authorizes such sums as may be necessary for FY2002–FY2006. [Section 152] Requires the Secretary, in consultation with the interagency working group, to evaluate new and emerging technologies for improving surveillance of public health emergencies and report to Congress within 180 days, and periodically thereafter. [Section 126]
Potassium iodide	Under general authority provided by the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.) and the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.), the Nuclear Regulatory Commission (NRC) requires that the use of potassium iodide (KI) by the public be considered during development of nuclear power plant emergency plans (see 10 C.F.R. 50.47). Under a policy adopted December 22, 2000, NRC will pay for state KI stockpiles. Note: Taking KI in the event of a nuclear attack or accident slows a person's uptake of radioactive iodine by flooding the thyroid gland with nonradioactive iodine.	Directs the President to provide KI from the national stockpile to state and local governments that submit a plan for the local stockpiling and distribution to everyone within 20 miles of a nuclear power plant. Additional eligibility requirements apply to local government plans. Requires the President within 1 year, in consultation with appropriate federal, state, and local agencies, to establish guidelines on stockpiling, distributing, and using KI in the event of a nuclear incident. Requires the President within 6 months to report to Congress on state and local KI stockpiles. Directs the President to request a study by the National Academy of Sciences on the safest and most effective way to distribute and administer KI on a large scale, to be submitted to Congress within 6 months. Permits the program to be terminated if the President determines that there are more effective measures to protect against thyroid disease. [Section 127]

Topic	Preexisting Law	P.L. 107-188
Antimicrobial Resistance		
Combating antimicrobial resistance	PHS Act 319E requires the Secretary to establish an Antimicrobial Resistance Task Force to coordinate federal programs on antimicrobial resistance and to work on surveillance plans and information systems for detection and control of drug-resistant pathogens. Authorizes research and development initiatives for new antimicrobial drugs and diagnostics. Directs the Secretary to conduct a nationwide campaign to educate the public and health care professionals about the appropriate use of antibiotics. Authorizes grants for public health agencies to combat antimicrobial resistance. Authorizes demonstration grants for hospitals, clinics, and other entities to promote the judicious use of antibiotics and to control the spread of resistant infections. Authorizes $40 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	Amends PHS Act Section 319E to authorize additional research on priority pathogens. Authorizes $25 million for FY2002 and for FY2003, and such sums as may be necessary for FY2004–FY2006. [Section 109]
Drug and Device Supply Safety and Security		
Drug and device importation	FFDCA Section 510(i) requires foreign drug and device manufacturers that import into the United States to register with the Secretary their name, place of business, and the name of their U.S. agent. Section 801 governs the import and export of food, drugs, devices, and other items, and specifies the circumstances under which imported articles are inspected, detained, or refused entry into the United States.	Amends Section 510(i) of the FFDCA by requiring annual registration, through electronic means, of foreign manufacturers importing drugs and devices into the United States. Requires the registration to include the name of each importer and agent used by the manufacturer, and the name of each person who imports or offers for import such drugs or devices. Amends Section 801 by refusing entry to drugs or devices that are offered for importation, if the import declaration does not include registration information about the manufacturer. Requires refused articles to be held at the port of entry or removed to a secure facility, as appropriate, until registration information is provided. [Section 321]
Import components intended for export	FFDCA Section 301 is the prohibited acts and penalties section of the statute. Section 801 governs the import and export of food, drugs, devices, and other items, and specifies the circumstances under which imported articles are inspected, detained, or refused entry into the United States.	Amends Section 801 of the FFDCA mandating a chain-of-possession identification and a customs bond for firms seeking to import components of drugs, devices, food additives, color additives, or dietary supplements for further processing and export. Requires certificates of analysis to identify such components, except for components of devices and blood and tissue components. Permits the Secretary to exclude from importation any article for which there is credible evidence or information indicating that the article is not intended to be imported for export. Amends Section 301 making it illegal to knowingly submit false statements, certificates, records, or reports required under Section 801, as amended. [Section 322]

Topic	Preexisting Law	P.L. 107-188
Additional Authorizations of Appropriations for FDA Drug Regulation		
Drug safety	The Office of Drug Safety in FDA's Center for Drug Evaluation and Research (CDER) conducts postmarket surveillance and monitors adverse drug reactions and medication errors.	Authorizes the following amounts for the Office of Drug Safety (ODS): FY2003=ODS FY2002 appropriation + $5 million; FY2004=ODS FY2002 appropriation + $10 million; each subsequent fiscal year=ODS FY2004 appropriation adjusted for inflation since beginning of FY2004. [Section 521]
Drug marketing, advertising, and communications	FDA/CDER's Division of Drug Marketing, Advertising, and Communications is responsible for ensuring that prescription drug information provided by manufacturers is truthful, balanced, and accurate.	Authorizes the following amounts for the Division of Drug Marketing, Advertising, and Communications, expressed as an increase over its FY2002 appropriation: FY2003=$2.5 million; FY2004=$4 million; FY2005=$5.5 million; FY2006=$7.5 million; FY2007= $7.5 million. [Section 522]
Generic drugs	FDA/CDER's Office of Generic Drugs is responsible for reviewing and approving generic product applications.	Authorizes the following amounts for the Office of Generic Drugs, expressed as an increase over its FY2002 appropriation: FY2003=$3 million; FY2004=$6 million; FY2005=$9 million; FY2006=$12 million; FY2007=$15 million. [Section 523]
Food Supply Safety and Security		
Food safety and security strategy.	Executive Order 13100 created the President's Council on Food Safety, headed by the Secretaries of Agriculture and HHS, the EPA Administrator, and the Assistant to the President for Science and Technology. On January 18, 2001, the Council published a strategic plan for food safety, which contained recommendations on making statutory changes to unify federal food safety regulations.	Requires the Council, in consultation with the Secretaries of Transportation and Treasury, other interested federal agencies, states, the food industry, scientific organizations, and consumer and producer groups to develop a crisis communications and education strategy against bioterrorist threats to the food supply. Requires the strategic plan to address threat assessments, technologies and procedures for securing food processing facilities, modes of transportation of foods, response and notification procedures, and public risk communication plans. Authorizes $750,000 for FY2002, and such sums as may be necessary in each subsequent fiscal year, to implement the strategy. [Section 301]
Protection against adulteration of food.	FFDCA Chapter IV prohibits the entry into interstate commerce of adulterated or misbranded foods. FDA monitors through inspections whether food manufacturers adhere to their legal responsibility to produce food that is not defective, unsafe, filthy, or produced under unsanitary conditions. FFDCA Section 801 gives general authority to the Secretary to sample and regulate imported products.	Amends FFDCA Section 801 to create a new subsection (h): to authorize the Secretary to increase inspections for the detection of intentional adulteration of imported food; to give high priority to improving FDA's food import information management systems; to improve linkages with other federal regulatory agencies, states and Indian tribes (under the Indian Self-Determination and Education Assistance Act) that share responsibility for food safety; to fund research on improved testing and sampling methods to rapidly detect intentionally adulterated food at ports of entry; to coordinate with the heads of CDC, NIH, EPA and USDA on the research; and to provide an annual report to Congress on the research findings. Requires the

Topic	Preexisting Law	P.L. 107-188
		Secretary, acting through FDA and not later than 6 months after enactment, to complete an assessment of threats to food posed by intentional adulteration and report to Congress. Authorizes a total of $100 million for FY2002, and such sums as are necessary for FY2003–FY2006, to carry out these activities. [Section 302]
Administrative detention	FFDCA Section 304 allows for the seizure of food in interstate commerce under restricted circumstances. FFDCA Section 301 lists prohibited acts; Section 801 is the general authority for regulating imports and exports.	Amends FFDCA Section 304 to add a new subsection (h) to authorize the detention of food for 20 days, and if needed for 30 days and to institute an action if an officer or qualified employee of FDA has credible evidence (and the Secretary or Secretary's designee approves) showing the food presents a threat of serious adverse health consequences or death to humans or animals, with expedited procedures for perishable foods. A detained food may be placed in a secure facility, may be marked or labeled as detained, and cannot be transferred out of detention unless it is released by the Secretary or the detention period expires, whichever occurs first. The person responsible for the detained food can appeal the decision to the Secretary. After an appeal is filed, within 5 days the Secretary must provide for an informal hearing to confirm or end the detention order. If the Secretary fails to act, the detention is terminated. An appeal is also terminated if the district court files an injunction or restraining order on the food. Amends FFDCA Section 301 prohibiting the removal of a detained product or any mark or label identifying the product as detained. Amends FFDCA Section 801to authorize an FDA officer or qualified employee to request the Treasury Secretary to temporarily hold imported food at a port for 24 hours, if FDA has credible evidence indicating that the food presents a threat of serious adverse health consequences or death to humans or animals, and the FDA official is unable to inspect, examine, or investigate the import to determine whether to detain the food. If necessary, the Treasury Secretary may remove the food to a secure facility from where it will not be delivered pursuant to the execution of a bond. Requires that the Secretary notify the state in which the involved port is located. [Section 303]
Debarment for repeated or serious food import violations.	FFDCA Section 306 gives the Secretary authority to debar, temporarily deny approval, or suspend the rights of individuals who have been convicted of a felony to submit an application for approval of a drug.	Amends FFDCA Section 306 to debar from importing foods any person who is convicted of a felony related to the importation of food or who repeatedly imports, or knows, or should have known, that the imported food was adulterated. Requires food imported by a debarred person to be refused admission and held in a secure facility, as appropriate, unless a non-debarred person establishes that the food complies with the requirements of the FFDCA, as determined by the Secretary. Imported food that is refused admission may not be delivered pursuant to the

Topic	Preexisting Law	P.L. 107-188
		execution of a bond under Section 801(b). Amends FFDCA Section 301 prohibiting the importing of a food by a debarred person. Amends FFDCA Section 801 to include in the definition of "adulterated food" any food imported by debarred persons as a prohibited act under Section 301. The prohibited act is not intended to include an innocent purchaser who did not know of the importer's debarred status. Authorizes the Secretary to terminate the debarment of companies or persons. [Section 304]
Registration of food facilities.	Currently, only states have records of food processing, packing and holding facilities. The federal government must ask the states for this information.	Creates a new Section 415 in the FFDCA requiring all facilities, domestic and foreign, that manufacture, process, and handle food to register with the Secretary on a one-time basis and give timely updates of all the identities (trade names) under which business is conducted, names and addresses of the facilities, and general food categories (as identified in 21 C.F.R. 170.3). Foreign registrants must name a U.S. agent. Requires the Secretary to give each facility a number and the failure of a facility to register is a prohibited act under FFDCA Section 301. Protect the list of registrants from disclosure under the Freedom of Information Act. Exempts restaurants, certain retail stores, nonprofit food establishments, fishing vessels, and farms from registration requirements. Registration does not imply a license. Amends 801 to prohibit foods from being imported from unregistered foreign facilities. Adds that the Secretary may provide for and encourage the use of electronic submissions to register as long as there are authorization protocols used to identify the registrant and validate the data. Requires the Secretary within 18 months to promulgate regulations for facilities to register. If the final regulations had not become effective after 18 months, the requirements for registration will be self-executing. [Section 305]
Maintenance and inspection of records for foods	FDCA Section 701(a) authorizes FDA to promulgate regulations to enforce the Act. FFDCA Section 704 authorizes FDA to conduct factory inspections. Currently, FDA inspectors have access to company records but can only request access to copy, and verify records for restricted medical devices, prescription drugs, not for foods. Inspectors may not require that records be kept nor do officials have authority to copy records found during inspections.	Adds a new Section 414 to the FFDCA allowing the Secretary to inspect records, if a food is believed to be adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Inspectors must present credentials and written notice in a reasonable manner to access and copy all records related to the food to help the Secretary decide if the food is a threat to health. Excludes restaurants and farms. The Secretary is to consider the size of a business in promulgating regulations. Requires records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to be kept no longer than 2 years. The Secretary will use the records to identify the immediate previous sources and immediate subsequent recipients of food. including its packaging. Excludes records on USDA-regulated foods (meat, poultry, and egg products).

Topic	Preexisting Law	P.L. 107-188
		Requires procedures to protect trade secrets or confidential information. Inspection of records does not extend to recipes for food, or financial, pricing, personnel, research, or sales data (other than shipment data regarding sales). Amends FFDCA Section 704(a) to add a clause to allow the inspection of all records and other information described in the new Section 414. Requires final record keeping rules to be issued within 18 months. [Section 306]
Prior notice of imported food shipments	Under FFDCA Section 801, a food that (i) is found to be manufactured, processed, or packed under unsanitary conditions, (ii) is forbidden or restricted in the producing country or from where it was exported, or (iii) is adulterated or misbranded at the border, can have its admission deferred while the food is reconditioned, relabeled or destroyed.	Adds a new section 801(m)(1) to the FFDCA to require the Secretary, after consultation with the Secretary of the Treasury, to promulgate regulations, not later than 18 months after enactment, requiring that the importer give notice that a food will be presented for import. Requires that the notice include the following: a description of the food; the identity of the manufacturer and shipper and, if possible, the grower; the country of origin of the food; the country from which the article is shipped; and the anticipated U.S. port of entry. Requires the Secretary to establish by regulation the period of time for prior notice, that must be no less than the minimum amount of time necessary for the Secretary to receive, review, and respond to the notice, but that may not exceed 5 days. In developing these regulations, the Secretary should consider the effect on commerce, locations of U.S. ports, the transport modes, the types of food, and other such considerations. Requires that food without a notice be held at the port of entry until such notice is delivered to the Secretary and found to be in order. Food so held may not be delivered pursuant to the execution of a bond under Section 801(b) and may be taken to a secure facility, as appropriate. During this period, the Secretary will decide if there is evidence or information on whether the food presents a threat to health. All USDA-regulated foods (i.e., meat, poultry, and egg products) are exempt from this section. Amends Section 301 prohibiting imports of food without prior notice. If the final rules are not effective within 18 months, the requirement for an import notice is self executing and will take effect so that notice must be given not less than 8 hours nor more than 5 days when a food is be offered for import. [Section 307]

Topic	Preexisting Law	P.L. 107-188
Authority to mark articles refused admission into the United States.	FFDCA Section 403 defines misbranded foods as food whose labeling or advertising is false or misleading. Section 801(a) gives the Secretary the general authority to refuse imports deemed adulterated or misbranded.	Amends Sections 403 and 801(a) definitions of misbranded food to include food that has been refused admission to the United States and not destroyed, and which presents a threat of serious adverse health consequences or death, unless the packaging is clearly and conspicuously labeled *United States: Refused Entry* at the expense of the food's owner until the food is brought into compliance. If there is an adverse health threat, the Secretary must notify the owner or consignee that the food presents a threat. Nothing in this section limits the Secretaries of HHS or Treasury to require marketing the refused articles under any other provision of law. [Section 308]
Prohibition against port shopping	FFDCA Section 402 defines "adulterated" food as any food that bears or contains any poisonous or deleterious substance which may render it injurious to health.	Amends FFDCA Section 402 to require that an importer offering food that has been refused admission prove at his own expense that the food is in compliance with the applicable requirements of the Act. [Section 309]
Notices to states regarding imported food	No statutory provisions.	Amends Chapter IX of the FFDCA to add a new Section 908 to require that the Secretary notify the states that hold or will hold imported food, and the states where the manufacturer, packer, or distributor of the imported food is located, when there is credible evidence that it presents a threat of serious adverse health consequences or death to humans or animals. Requires the Secretary to request that states take appropriate action to protect the public health. [Section 310]
Grants to states for inspections	FFDCA Section 702 states that the Secretary is authorized to conduct food inspections (examinations and investigations) through officers and employees of HHS, or any health, food, or drug officer of a state that has been duly commissioned by the Secretary as an officer of the Department.	Amends Chapter IX of the FFDCA to add a new Section 909 authorizing the Secretary to make grant to states for increased food safety inspection, examinations, and investigations under Section 702, and to cover the costs of taking appropriate actions to protect the public health as required under Section 908. Authorizes $10 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 311]
Surveillance and information grants and authorities	FoodNet, established in 1995 by USDA and FDA, tracks the incidence of illnesses caused by nine pathogens in nine geographic areas across the United States. PulseNet compares genetic patterns of bacteria isolated from patients with foodborne illness and/or contaminated food.	Amends PHS Act Title III, Part B to create a new Section 317R to authorize $19.5 million for FY2002, and such sums as may be necessary for FY2003–FY2006, in grants to states, and Indian tribes to expand the number participating in FoodNet and PulseNet and other surveillance networks and to maintain technical and laboratory capacity needed for such participation. [Section 312]
Surveillance of zoonotic diseases.	CDC has more than 20 surveillance programs that monitor outbreaks of food borne illness caused by specific pathogens.	Requires the Secretary to coordinate surveillance of zoonotic diseases (i.e., animal diseases communicable to man) through FDA, CDC, and USDA. [Section 313]

Topic	Preexisting Law	P.L. 107-188
Authority to commission other federal officials to conduct inspections.	FFDCA Section 702 states that the Secretary is authorized to conduct food inspections (examinations and investigations) through officers and employees of HHS, or any health, food, or drug officer of a state that has been duly commissioned by the Secretary as an officer of the Department.	Amends FFDCA Section 702 to authorize the Secretary to commission other federal officials to conduct inspections, examinations, and investigations, pursuant to a memorandum of understanding (MOU) between the Secretary and the head of the agency to which the other officials belong. Inspections can take place only at facilities or other locations that are jointly regulated by HHS and the other agency. Requires the Secretary and the other agency head to report to Congress on the number of persons that carried out activities under the MOU, and the number of additional investigations and foods inspected or examined as a result of the MOU. [Section 314]
Rule of construction.	USDA regulates meat under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), poultry under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and processed egg products under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).	Prohibits FDA from regulating any food under USDA's jurisdiction. [Section 315]
Agricultural Security		
USDA activities	USDA's Food Safety and Inspection Service (FSIS) inspects meat, poultry, and processed egg products sold for human consumption for safety, wholesomeness, and proper labeling. The Animal and Plant Inspection Service (APHIS) inspects cargo and passengers at U.S. ports for animal and plant pests, quarantines some of these products, and responds to animal disease outbreaks. The Agricultural Research Service (ARS) conducts research on animal diseases and food safety to support other USDA regulatory responsibilities.	Authorizes $15 million for FY2002, and such sums as may be necessary for each subsequent fiscal year, for enhanced FSIS inspections domestically and internationally and collaboration with other federal agencies. Authorizes $30 million for FY2002, and such sums as may be necessary for each subsequent fiscal year, for APHIS for increased inspections, cooperative agreements with state and private veterinarians, and an automated, integrated, interagency emergency warning, response, and record-keeping system. Authorizes $180 million for FY2002, and such sums as may be necessary for FY2003–FY2006, to upgrade biosecurity at ARS labs in New York and Iowa. Authorizes the appropriation of such sums as necessary for: (i) grants not exceeding $50,000 to land grant colleges of agriculture for reviewing security standards and practices; and (ii) grants not exceeding $100,000 to agricultural producer groups to develop and implement on-farm biosecurity education programs. Authorizes $190 million for FY2002, and such sums as may be necessary in subsequent years, to support ARS and federal-state cooperative research on bioterrorism prevention, preparedness, and response; to strengthen coordination with U.S. intelligence agencies; and to develop an early warning surveillance system for agricultural bioterrorism. Establishes civil fines and criminal penalties for acts of terrorism against animal enterprises. [Sections 331–336]

Topic	Preexisting Law	P.L. 107-188
Drinking Water Security and Safety		
Vulnerability assessments and emergency response plans	PHS Act Title XIV, the Safe Drinking Water Act (SDWA), authorizes federal regulation of public water systems, particularly through a program that regulates contaminants in public water supplies. The Act defines a community water system as a public water system that serves at least 15 service connections used by year-round residents or that regularly serves at least 25 year-round residents. The SDWA is administered and enforced by the Environmental Protection Agency (EPA).	Adds a new Section 1433 to the SDWA to require each community water system serving 3,300 or more individuals to conduct a vulnerability assessment. Requires EPA, not later than August 1, 2002, to provide information to these systems concerning probable threats. Establishes deadlines for community water systems to certify to EPA that they have conducted vulnerability assessments and to submit to EPA a copy of the assessment. Certifications and submissions must be made before March 31, 2003, by systems serving 100,000+ persons; December 31, 2003, by systems serving 50,000–99,999 persons; and June 30, 2004, by systems serving 3,300–49,999 persons. Exempts assessments from disclosure under the Freedom of Information Act and requires EPA to develop protocols to protect the assessments from unauthorized disclosure. Provides that any individual designated by the Administrator who acquires assessments or information from them and who knowingly or recklessly reveals such information to unauthorized individuals shall be subject to up to 1 year imprisonment or a fine, unless the information is revealed for specified purposes. Requires each community water system serving 3,300+ individuals to prepare or revise an emergency response plan incorporating the results of the vulnerability assessment. Systems must certify to EPA, within 6 months of completing an assessment, that they have completed response plans, and each system must keep a copy of its plan for 5 years. Directs EPA to provide guidance to community water systems serving fewer than 3,300 individuals on how to conduct vulnerability assessments, prepare emergency response plans, and address threats. Authorizes $160 million for FY2002, and such sums as may be necessary for FY2003–FY2005, to provide financial assistance to community water systems to conduct assessments and prepare response plans, and to address basic security enhancements and significant threats. Security enhancements may include purchase and installation of intruder detection equipment and lighting, enhancing security of automated systems, personnel training and security screening. Authorizes EPA to use not more than $5 million of the funds to make grants to community water systems to assist in responding to and alleviating any vulnerability to an attack or intentional act, which the Administrator determines to present an immediate and urgent security need. Further authorizes EPA to use not more than $5 million of the funds made available to make grants to community water systems serving fewer than 3,300 persons for activities and projects undertaken in accordance with the guidance for small systems that EPA must provide. [Section 401]

Topic	Preexisting Law	P.L. 107-188
Contaminant prevention, detection, and response	No statutory provisions.	Adds a new Section 1434 to the SDWA directing the EPA Administrator, in consultation with CDC, and after consultation with other federal departments and state and local governments, to review (directly or through contracts or cooperative agreements) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and their source waters. The review must cover methods, means and equipment, including real time monitoring systems, for monitoring and detecting levels of contaminants; methods for providing sufficient notice to water system operators and those served by the system of the introduction of contaminants; methods, means and equipment for preventing the flow of contaminated water to people served by a system and for mitigating adverse effects on public health; methods and means for developing educational and awareness programs for water systems; and biomedical research on the public health impact of various contaminants that may be used in attacks on water systems. Funding is authorized under Section 1435. [Section 402]
Supply disruption: prevention, detection and response	No statutory provisions.	Adds a new Section 1435 to the SDWA directing the EPA Administrator, in coordination with appropriate federal departments and agencies, to review methods and means by which terrorists or others could disrupt the drinking water supply or render it unsafe. This review must include a review of methods and means by which water systems could be destroyed, impaired, or made subject to cross-contamination, or by which information systems, including process controls, supervisory control and data acquisition (SCADA) and computer systems could be disrupted. EPA must also review methods and means by which systems could be reasonably protected from attacks, and by which alternative drinking water supplies could be provided if a water system was destroyed, impaired or contaminated. Requires EPA to ensure that these reviews reflect the needs of water systems of various sizes and geographic locations; EPA may consider the vulnerability of a specific region or service area, including the National Capital area. Directs EPA to share, as appropriate, the information developed under this section and Section 1434 with community water systems through the Information Sharing and Analysis Center (ISAC). Authorizes $15 million for FY2002, and such sums as may be necessary for FY2003–FY2005 to carry out Sections 1434 and 1435. [Section 402]
Enforceable requirements	SDWA Section 1414(i)(1) identifies the sections of SDWA for which the Act's enforcement authorities apply.	Amends SDWA Section 1414(i)(1) to include a new Section 1433 requiring community water systems to conduct vulnerability assessments and to prepare emergency response plans, as an applicable and enforceable requirement under the Act. [Section 403]

Topic	Preexisting Law	P.L. 107-188
Emergency powers	SDWA Section 1431 grants the EPA Administrator emergency powers to take such actions as deemed necessary to protect persons served by a public water system upon receipt of information that a contaminant that is present in, or is likely to enter, a public water system or an underground source of drinking water may present an imminent and substantial endangerment to health of those persons.	Amends SDWA Section 1431 to specify that EPA's emergency powers include the authority to act when there is a threatened or potential terrorist attack or other intentional act to disrupt the provision of safe drinking water or to impact the safety of a community's drinking water supply. [Section 403]
Penalties for tampering with public water systems	SDWA Section 1432 authorizes criminal and civil penalties for persons who tamper, attempt to tamper, or threaten to tamper with public water supplies. Provides that any person who tampers with a public water system shall be imprisoned for not more than 5 years, or fined, or both. Any person who attempts to tamper, or threatens to tamper, with a system shall be imprisoned for not more than 3 years. Provides that EPA may bring a civil action and that the appropriate federal court may impose a penalty of not more than $50,000 for tampering or not more than $20,000 for such attempt or threat.	Amends SDWA Section 1432 to increase criminal and civil penalties for tampering, attempting to tamper, or making threats to tamper with public water supplies. The maximum prison sentence for tampering is increased from 5 to 20 years. The maximum prison sentence for attempting to tamper, or making threats to tamper, is increased from 3 to 10 years. The maximum fine that may be imposed for tampering is increased from $50,000 to $1 million. The maximum fine for attempting to tamper, or threatening to tamper, is increased from $20,000 to $100,000. [Section 403]
Technical assistance	SDWA Section 1442(b) authorizes EPA to provide technical assistance and to make grants to states and public water systems to assist in responding to and alleviating emergency situations.	Amends SDWA Section 1442(d) to authorize appropriations to carry out Section 1442(b) of not more than $35 million for FY2002, and such sums as may be necessary for each fiscal year thereafter. [Section 403]
Reauthorization of the Prescription Drug User Fee Act (FFDCA Sections 735–736)		
Types of fees	FFDCA Section 736(a) authorizes the Secretary to assess and collect three types of fees. First, a human drug application and supplement fee is due upon submission of the application or supplement. The Secretary may refund 75% of the fee if the application is not accepted. In the event the application is withdrawn after being filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on it. The fee is waived for orphan drug applications and for supplements to drug applications that propose a new use for children. Second, annual establishment fees are assessed on each manufacturer of an approved drug for each fiscal year that an establishment manufactures the drug. Third, annual product fees are assessed on certain drugs registered under the FFDCA. Both establishment and product fees are due on Jan. 31 of each year.	Amends FFDCA Section 736(a) by requiring the annual establishment and product fees to be paid by October 1. Reduces by 50% the application and supplement fee for applications that contain no clinical data to review, and for filing a supplement. Eliminates the waiver for supplements for pediatric indications. Clarifies that the sponsor of the drug application is responsible for paying the annual product fee. Exempts from the product fee those products that are listed in the "Orange Book" with a potency described in terms of per 100mL, or which are the same as another approved products. [Section 504(a)]

Topic	Preexisting Law	P.L. 107-188
Fee amounts	Under FFDCA Section 736(b), the application fee shall be $250,704 in FY1998, $256,338 in FY1999 and in FY2000, $267,606 in FY2001, and $258,451 in FY2002. The fee for an application that contains no clinical data to review, or for filing a supplement, is 50% of the application fee. Total establishment fee revenues shall be $35.6 million in FY1998, $36.4 million in FY1999 and in FY2000, $38 million in FY2001, and $36.7 million in FY2002. Total product fee revenues must equal the total establishment fee revenues.	Amends FFDCA Section 736(b) by substituting a table setting out application/supplement, establishment, and product fee revenue, and total fee revenue, for FY2003 through FY2007. If subsequent legislation requires the Secretary to fund the additional costs of retirement of federal personnel, fee revenue amounts may be increased to fully fund the portion of the added costs attributable to the process of review of drug applications. [Section 504(b)]
Fee adjustments	FFDCA Section 736(c) requires the Secretary each fiscal year to adjust fees and total fee revenues for inflation using either the average urban Consumer Price Index (CPI) or the increase in the civil service base pay for federal employees in Washington DC, whichever is greater. Each year's adjustment is added on a compounded basis to the sum of all the adjustments made for prior fiscal years. Requires the Secretary to adjust the annual establishment and product fees to ensure that the total amount collected equals that collected from application/supplement fees. Total fees collected for a fiscal year, as adjusted, may not exceed the total costs of reviewing drug applications for that year.	Amends FFDCA Section 736(c) as follows: (i) requires the inflation adjustment to use the CPI for the 12-month period ending June 30 of the year preceding the fiscal year for which the fees are being established or the civil service base pay as stated in the current law, whichever is greater; (ii) beginning in FY2004, creates a new workload adjustment (in addition to the inflation adjustment) to reflect changes in review workload; (iii) creates a new final year adjustment that permits the FDA, if necessary, to make a one-time fee increase in FY2007 to ensure that the agency has enough funds to operate for up to 3 months in FY2008 if there is a delay in reauthorizing PDUFA at the end of FY2007; and (iv) requires that the application/supplement, establishment, and product fees be established 60 days before the start of the fiscal year, based on the revenue amounts set out in Section 736(b) and the adjustments enumerated above. [Section 504(c)]
Fee waiver or reduction	FFDCA Section 736(d) permits the Secretary to reduce or waive one or more fees to protect public health or to remove barriers to innovation. Brand-name drug makers may seek a waiver if the fee would put them at an economic disadvantage relative to a generic drug manufacturer. The Secretary may also waive the application fee for first-time drug applications from small businesses with fewer than 500 employees.	Amends FFDCA Section 736(d) by eliminating the waiver for brand-name drug manufacturers that claim the fee would put them at an economic disadvantage relative to generic drug producers. [Section 504(d)]
Assessment of fees	Under FFDCA Section 736(f), fees may only be assessed for a fiscal year if the FDA's annual appropriation for salaries and expenses for that year is equal to or greater than its FY1997 appropriation, multiplied by whichever inflation adjustment factor is applicable for the fiscal year in question. This "trigger" ensures that PDUFA fees are not a substitute for the agency's annual appropriations.	Changes the title of Section 736(f) but leaves the trigger as is. [Section 504(e)]

Topic	Preexisting Law	P.L. 107-188
Crediting and availability of fees	FFDCA Section 736(g) permits FDA to transfer collected fees to its salaries and expenses account, without fiscal year limitation, to be used solely for reviewing drug applications. Fees must be collected in an amount equal to that specified in the annual appropriations act and may only be collected and available to defray the increase in application review costs over the costs for such activities in FY1997, adjusted for inflation. This second "trigger" is intended to ensure that PDUFA fees are used to accelerate the drug application review process and not substitute for "normal level" expenses. Authorizes the following appropriations for fees: $106.8 million for FY1997; $109.2 million for FY1999 and for FY2000; $114 million for FY2001; and $110.1 million for FY2002, adjusting as specified above. Collected fees that exceed the authorized amount must be subtracted from the amount of fees authorized to be collected in the subsequent fiscal year.	Amends FFDCA Section 736(g) by providing FDA a 5% margin of error for meeting the requirements of the second trigger. The intent of this modification is to relieve FDA of the need to overspend each year, which the agency has done consistently to ensure that its expenditures do not fall below the trigger amount and cause it to lose the authority to collect fees. Authorizes the following appropriations for fees: $222.9 million for FY2003; $231million for FY2004; $252 million for FY2005; $259.3 million for FY2006; and $259.3 million for FY2007, adjusting as specified above. [Section 504(f)]
Accountability and reports	The Food and Drug Administration Modernization Act of 1997 (FDAMA; P.L. 105-115, Section 104) required the Secretary to provide Congress with an annual performance report and an annual fiscal report.	Requires the Secretary to consult with Congress and interested public and private stakeholders in developing recommendations for the next PDUFA reauthorization. Requires the Secretary to publish the recommendations in the *Federal Register* for public comment. Requires the Secretary to provide Congress with an annual performance report and an annual fiscal report [Section 505]
Reports of postmarketing studies	FFDCA Section 506B establishes annual reporting requirements for drug sponsors who enter into agreements with the Secretary to conduct a postmarketing study.	Amends FFDCA Section 506B to require the Secretary, in the event a sponsor fails to complete an agreed upon study, to post a statement on the FDA's Web site to that effect. Give the Secretary the authority to require sponsors who fail to complete studies of fast-track drugs and biological products for serious and life-threatening illnesses to notify health care practitioners of the sponsor's failure to complete the study and of unanswered questions relating to the clinical benefits and safety of the product. [Section 506]
Effective date and sunset	FDAMA Sections 106–107 reauthorized PDUFA from October 1, 1997 through September 30, 2002, with required annual reports due no later than 120 days thereafter.	The amendments made by this subtitle take effect on October 1, 2002, and sunset on September 30, 2007. The annual reporting requirements of Section 505 remain effective for an additional 120 days. [Sections 508–509]

Topic	Preexisting Law	P.L. 107-188
Miscellaneous Provisions		
Digital television	Section 201 of the Telecommunications Act of 1996 (P.L. 104-104) provided that digital television licenses issued by the Federal Communications Commission (FCC) should be limited to existing broadcasters. On April 3, 1997, the FCC allotted digital television spectrum to all eligible broadcasters existing at that time.	Requires the FCC to allot a digital channel to any requesting full-power television station that had an application pending for an analog television station construction permit as of October 24, 1991, and which had its application granted after April 3, 1997. Any station receiving digital spectrum under this provision is required to complete construction of its digital facility within 18 months, without the possibility of an extension. Stations are also prohibited from operating an analog signal on their designated digital channel. [Section 531]
Medicare + Choice	Section 1853 of the Social Security Act (SSA) requires the Centers for Medicare and Medicaid Services (CMS) to announce the annual Medicare + Choice (M+C) payment rates on March 1 of each year that will be applicable on January 1 of the following year. Section 1854 requires that each M+C organization must submit to the Secretary for approval, for each of its M+C plans, specific information about the adjusted community rate (ACR), M+C premiums, cost sharing, and additional benefits (if any) no later than July 1 of each year, also for the following year. Section 1851 permits individuals to make and change election to an M+C plan on an ongoing basis. Beginning in 2002, elections and changes to elections are available on a more limited basis. Individuals can make or change elections each November, during the annual coordinated election period. Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2002 (or first 3 months of any subsequent year). Special enrollment rules apply to newly eligible aged beneficiaries. Special enrollment periods apply to enrollees under limited situations, such as a change in place of residence.	Moves the CMS annual announcement of M+C payment rates from no later than March 1 to no later than the second Monday in May, effective only in 2003 and 2004. Moves the deadline for plans to submit information about ACRs, M+C premiums, cost sharing, and additional benefits (if any) from no later than July 1 to no later than the second Monday in September in 2002, 2003, and 2004. Changes the annual coordinated election period from the month of November to November 15 – December 31 in 2002, 2003, and 2004. Allows Medicare beneficiaries to make and change election to an M+C plan on an ongoing basis through 2004. Beginning in 2005, individuals would only be able to make changes on the more limited basis, originally scheduled to be phased in beginning in 2002. [Section 532]

Appendix A. Bioterrorism-Related Hearings 107th Congress

Senate Appropriations Subcommittee on Labor, HHS, and Education

October 3, 2001	Bioterrorism: Public health preparedness and response
October 23, 2001	Public health response to anthrax attack
November 2, 2001	Smallpox: Public health preparedness and response
November 29, 2001	Funding for bioterrorism preparedness

Senate Appropriations Subcommittee on VA-HUD and Independent Agencies

November 28, 2001	Anthrax decontamination

Senate Armed Services Subcommittee on Emerging Threats and Capabilities

October 25, 2001	Bioterrorism and the Dark Winter exercise

Senate Commerce, Science and Transportation Committee

February 5, 2002	Bioterrorism: Countermeasures R&D (Subcommittee on Science, Technology, and Space)

Senate Environment and Public Works Committee

December 4, 2001	Anthrax decontamination

Senate Foreign Relations Committee

September 5, 2001	Bioterrorism threat and the spread of infectious diseases

Senate Governmental Affairs Committee

July 23, 2001	Bioterrorism: FEMA's role and public health preparedness (Subcommittee on National Security, Proliferation and Federal Services)
October 17, 2001	Bioterrorism: Federal agency preparedness
October 30-31, 2001	Anthrax in the mail: Protecting postal workers and the public
April 18, 2002	Public health preparedness

Senate Health, Education, Labor, and Pensions Committee

September 26, 2001	Psychological trauma of terrorism
October 9, 2001	Bioterrorism: Public health preparedness and response
November 2, 2001	Kids and terrorism (Subcommittee on Children and Families)

Senate Judiciary Committee

November 6, 2001	Law enforcement and the domestic bioterrorism threat (Subcommittee on Technology, Terrorism and Government Information)

House Appropriations Subcommittee on Labor, HHS, and Education

May 1, 2002	HHS bioterrorism preparedness

House Energy and Commerce Committee

October 10, 2001	Bioterrorism preparedness and response (Subcommittee on Oversight and Investigations)
November 1, 2001	Public health early-warning surveillance systems (Subcommittee on Oversight and Investigations)
November 7, 2001	Physical security and NIH and CDC facilities (Subcommittee on Oversight and Investigations)
November 15, 2001	Bioterrorism: Public health preparedness and response

House Government Reform Committee

May 1, 2001	Management of medical stockpiles (Subcommittee on National Security, Veterans Affairs and International Relations)
July 23, 2001	Federal response to a bioterrorism attack: Dark Winter (Subcommittee on National Security, Veterans Affairs and International Relations)
October 5, 2001	Bioterrorism: Federal, state, and local preparedness (Subcommittee on Government Efficiency, Financial Management and Intergovernmental Relations)
October 12, 2001	Assessing the threat of bioterrorism (Subcommittee on National Security, Veterans Affairs and International Relations)
October 23, 2001	Vaccine research and development (Subcommittee on National Security, Veterans Affairs and International Relations)
October 30, 2001	Anthrax and postal worker safety

November 7, 2001	DOD medical readiness for chemical and biological warfare (Subcommittee on National Security, Veterans Affairs and International Relations)
November 14, 2001	Medical care for bioterrorism victims
November 29, 2001	Risk communication: National security and public health (Subcommittee on National Security, Veterans Affairs and International Relations)
December 14, 2001	Bioterrorism response: Information sharing between local, state, and federal governments (Subcommittee on Technology and Procurement Policy)
February 28, 2002	Anthrax antitoxin research
March 1, 2002	Federal, state, and local response to biological and chemical attack (Subcommittee on Government Efficiency, Financial Management and Intergovernmental Relations)
March 21, 2002	Combating terrorism (Subcommittee on National Security, Veterans Affairs and International Relations)

House International Relations Committee

December 5, 2001	Bioterrorism and potential sources of anthrax

House Science Committee

November 8, 2001	Anthrax decontamination
December 5, 2001	Bioterrorism: Federal preparedness and response

House Veterans' Affairs Committee

April 10, 2002	Bioterrorism legislation (H.R. 3253, H.R. 3254)

Appendix B. Bioterrorism-Related Web Sites

Department of Health and Human Services

Information on public health preparedness	[http://www.hhs.gov/hottopics/healing]
DHHS Office of Emergency Preparedness	[http://www.oep.dhhs.gov]
DHHS Office of Public Health Preparedness	[http://www.hhs.gov/ophp]
Metropolitan Medical Response Systems	[http://www.mmrs.hhs.gov]
National Pharmaceutical Stockpile Program	[http://www.cdc.gov/nceh/nps/default.htm]
Centers for Disease Control and Prevention	[http://www.bt.cdc.gov]
Health Resources and Services Admin.	[http://www.hrsa.gov/bioterrorism.htm]
Food and Drug Administration	[http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html]
National Institutes of Health	[http://www.niaid.nih.gov/publications/bioterrorism.htm]
National Library of Medicine	[http://www.nlm.nih.gov/medlineplus/biologicalandchemicalweapons.html]

Department of Defense

U.S. Army Medical Research Institute of Infectious Diseases	[http://www.usamriid.army.mil]
DOD Anthrax Vaccine Immunization Program	[http://www.anthrax.osd.mil]
Nuclear, Biological, Chemical Medical Reference Site	[http://www.nbc-med.org/others]

State and Local Health Departments

Many health departments have included information on bioterrorism and public health preparedness on their Web sites. For links to state and local health departments, go to [http://www.apha.org/state_local/afflinks.htm].

Professional Associations

American College of Emergency Physicians	[http://www.acep.org/1,4634,0.html]
American College of Physicians	[http://www.acponline.org/bioterro]
American Hospital Association	[http://www.hospitalconnect.com/aha/key_issues/disaster_readiness/index.html]

American Medical Association	[http://www.ama-assn.org/ama/pub/category/6671.html]
American Society for Microbiology	[http://www.asmusa.org/pasrc/bioprep.htm]
Association for Professionals in Infection Control and Epidemiology	[http://www.apic.org/bioterror]
Association of State and Territorial Health Officials	[http://www.astho.org]
Council of State and Territorial Epidemiologists	[http://www.cste.org]
Federation of American Scientists, Chemical & Biological Arms Control Program	[http://fas.org/bwc/index.html]
Nat. Assoc. of County & City Health Officials	[http://www.naccho.org/files/documents/responds_to_bioterrorism.html]

Academic Resources

Johns Hopkins Center for Civilian Biodefense Studies	[http://www.hopkins-biodefense.org]
The Henry L. Stimson Center	[http://www.stimson.org/cbw]
Monterey Institute of International Studies	[http://www.cns.miis.edu]
Chemical and Biological Arms Control Institute	[http://www.cbaci.org]
UCLA Center for Public Health and Disaster Relief	[http://www.ph.ucla.edu/cphdr]
University of Minnesota Center for Infectious Disease Research and Policy	[http://www1.umn.edu/cidrap]
St. Louis University Center for the Study of Bioterrorism and Emerging Infections	[http://bioterrorism.slu.edu]
Columbia University Center for Public Health Preparedness	[http://cpmcnet.columbia.edu/dept/sph/CPHP/index.html]
University of North Carolina Center for Public Health Preparedness	[http://www.sph.unc.edu/bioterrorism]