



## HR 3448

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Congress: 107 (2001–2003, Ended)

Chamber: House
Policy Area: Health
Introduced: Dec 11, 2001

Current Status: Became Public Law No: 107-188.

Latest Action: Became Public Law No: 107-188. (Jun 12, 2002)

Law: 107-188 (Enacted Jun 12, 2002)

Official Text: https://www.congress.gov/bill/107th-congress/house-bill/3448

#### **Sponsor**

Name: Rep. Tauzin, W. J. (Billy) [R-LA-3]

Party: Republican • State: LA • Chamber: House

## Cosponsors (70 total)

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Rep. McCarthy, Karen [D-MO-5]	D · MO		Dec 11, 2001
Rep. McKeon, Howard P. "Buck" [R-CA-25]	R · CA		Dec 11, 2001

Rep. Pallone, Frank, Jr. [D-NJ-6]         D · NJ         Dec 11, 2001           Rep. Pickering, Charles W. "Chip" [R-MS-3]         R · MS         Dec 11, 2001           Rep. Platts, Todd Russell [R-PA-19]         R · PA         Dec 11, 2001           Rep. Pryce, Deborah [R-OH-15]         R · OH         Dec 11, 2001           Rep. Radanovich, George [R-CA-19]         R · CA         Dec 11, 2001           Rep. Roybal-Allard, Lucille [D-CA-33]         D · CA         Dec 11, 2001           Rep. Rush, Bobby L. [D-IL-1]         D · D. IL         Dec 11, 2001           Rep. Sawyer, Tom [D-OH-14]         D · OH         Dec 11, 2001           Rep. Saxion, Jim [R-NJ-3]         R · NJ         Dec 11, 2001           Rep. Schiff, Adam B. [D-CA-27]         D · CA         Dec 11, 2001           Rep. Schrock, Edward L. [R-VA-2]         R · VA         Dec 11, 2001           Rep. Schimkus, John [R-IL-20]         R · WI         Dec 11, 2001           Rep. Sensenbrenner, F. James, Jr. [R-WI-9]         R · WI         Dec 11, 2001           Rep. Smithkus, John [R-IL-20]         R · IL         Dec 11, 2001           Rep. Smith, Christopher H. [R-NJ-4]         R · NJ         Dec 11, 2001           Rep. Smith, Christopher H. [R-NJ-4]         R · NJ         Dec 11, 2001           Rep. Strickland, Ted [D-OH-6]         <	Cosponsor	Party / State	Role	Date Joined
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Rep. Smith, Lamar [R-TX-21]       R · TX       Dec 11, 2001         Rep. Strickland, Ted [D-OH-6]       D · OH       Dec 11, 2001         Rep. Stupak, Bart [D-MI-1]       D · MI       Dec 11, 2001         Rep. Sununu, John E. [R-NH-1]       R · NH       Dec 11, 2001         Rep. Terry, Lee [R-NE-2]       R · NE       Dec 11, 2001         Rep. Towns, Edolphus [D-NY-10]       D · NY       Dec 11, 2001         Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Slaughter, Louise McIntosh [D-NY-28]	$D \cdot NY$		Dec 11, 2001
Rep. Strickland, Ted [D-OH-6]       D · OH       Dec 11, 2001         Rep. Stupak, Bart [D-MI-1]       D · MI       Dec 11, 2001         Rep. Sununu, John E. [R-NH-1]       R · NH       Dec 11, 2001         Rep. Terry, Lee [R-NE-2]       R · NE       Dec 11, 2001         Rep. Towns, Edolphus [D-NY-10]       D · NY       Dec 11, 2001         Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Smith, Christopher H. [R-NJ-4]	$R \cdot NJ$		Dec 11, 2001
Rep. Stupak, Bart [D-MI-1]       D · MI       Dec 11, 2001         Rep. Sununu, John E. [R-NH-1]       R · NH       Dec 11, 2001         Rep. Terry, Lee [R-NE-2]       R · NE       Dec 11, 2001         Rep. Towns, Edolphus [D-NY-10]       D · NY       Dec 11, 2001         Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Smith, Lamar [R-TX-21]	$R \cdot TX$		Dec 11, 2001
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Rep. Terry, Lee [R-NE-2]       R · NE       Dec 11, 2001         Rep. Towns, Edolphus [D-NY-10]       D · NY       Dec 11, 2001         Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Stupak, Bart [D-MI-1]	D · MI		Dec 11, 2001
Rep. Towns, Edolphus [D-NY-10]       D · NY       Dec 11, 2001         Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Sununu, John E. [R-NH-1]	$R \cdot NH$		Dec 11, 2001
Rep. Upton, Fred [R-MI-6]       R · MI       Dec 11, 2001         Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Terry, Lee [R-NE-2]	$R \cdot NE$		Dec 11, 2001
Rep. Vitter, David [R-LA-1]       R · LA       Dec 11, 2001         Rep. Walden, Greg [R-OR-2]       R · OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Towns, Edolphus [D-NY-10]	$D \cdot NY$		Dec 11, 2001
Rep. Walden, Greg [R-OR-2]       R ⋅ OR       Dec 11, 2001         Rep. Watt, Melvin L. [D-NC-12]       D ⋅ NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D ⋅ CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R ⋅ KY       Dec 11, 2001	Rep. Upton, Fred [R-MI-6]	$R \cdot MI$		Dec 11, 2001
Rep. Watt, Melvin L. [D-NC-12]       D · NC       Dec 11, 2001         Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Vitter, David [R-LA-1]	$R \cdot LA$		Dec 11, 2001
Rep. Waxman, Henry A. [D-CA-29]       D · CA       Dec 11, 2001         Rep. Whitfield, Ed [R-KY-1]       R · KY       Dec 11, 2001	Rep. Walden, Greg [R-OR-2]	$R \cdot OR$		Dec 11, 2001
Rep. Whitfield, Ed [R-KY-1] R · KY Dec 11, 2001	Rep. Watt, Melvin L. [D-NC-12]	D · NC		Dec 11, 2001
	Rep. Waxman, Henry A. [D-CA-29]	D · CA		Dec 11, 2001
Rep. Wilson, Heather [R-NM-1] R · NM Dec 11, 2001	Rep. Whitfield, Ed [R-KY-1]	$R \cdot KY$		Dec 11, 2001
	Rep. Wilson, Heather [R-NM-1]	$R \cdot NM$		Dec 11, 2001

# **Committee Activity**

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 11, 2001

# **Subjects & Policy Tags**

**Policy Area:** 

Health

## **Related Bills**

Bill	Relationship	Last Action
107 SCONRES 117	Related bill	Jun 4, 2002: Motion to reconsider laid on the table Agreed to without objection.
107 HRES 427	Procedurally related	May 22, 2002: Motion to reconsider laid on the table Agreed to without objection.
107 HR 3310	Related bill	Dec 10, 2001: Referred to the Subcommittee on Health.
107 S 1765	Related bill	Dec 5, 2001: Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 255.
107 S 1715	Related bill	${f Nov~15,2001:}$ Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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

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

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

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

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

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

Directs the Secretary to provide for the establishment of an integrated system or systems of public health alert

communications and surveillance networks between and among: (1) Federal, State, and local public health officials; (2) public and private health-related laboratories, hospitals, and other health care facilities; and (3) any other entities determined appropriate by the Secretary. Authorizes appropriations.

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

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

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

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

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

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

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

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

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

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

appropriations for such provisions.

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

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

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

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

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

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

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

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

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

Subtitle C: Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies - Directs the Secretary, to enhance the security of the United States with respect to bioterrorism and other public health emergencies, to make awards of grants or cooperative agreements to eligible entities to enable such entities to conduct activities, including: (1) developing coordinated Statewide plans and community-wide plans for responding to bioterrorism and other public health emergencies; (2) addressing deficiencies in public health needs; (3) purchasing or upgrading equipment supplies, pharmaceuticals or other priority countermeasures to enhance preparedness for and response to bioterrorism or other public health emergencies; (4) conducting exercises to test the capability and timeliness of public health emergency response activities; (5) developing and implementing the trauma care and burn center care components of the State plans for the provision of emergency medical services; (6) improving training or workforce development to enhance public health laboratories; (7) training public health and health care personnel; (8) developing, enhancing, coordinating, or improving participation in systems by which disease detection and

information about biological attacks and other public health emergencies can be rapidly communicated; (9) enhancing communication to the public of information on bioterrorism and other public health emergencies, including through the use of 2-1-1 call centers; (10) addressing the health security needs of children and other vulnerable populations with respect to bioterrorism and other public health emergencies; (11) providing training and developing methods to enhance the safety of workers and workplaces in the event of bioterrorism; (12) preparing and planning for contamination prevention efforts related to public health that may be implemented in the event of a bioterrorist attack; (13) preparing a plan for triage and transport management in the event of bioterrorism or other public health emergencies; (14) enhancing the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies; (15) enhancing the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon; (16) enhancing training and planning to protect the health and safety of personnel involved in responding to a biological attack; (17) improving surveillance, detection, and response activities to prepare for emergency response activities including biological threats or attacks; and (18) developing, enhancing, and coordinating or improving the ability of existing telemedicine programs to provide health care information and advice as part of the emergency public health response to bioterrorism or other public health emergencies. Authorizes appropriations.

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

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

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

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

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

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

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

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

(Sec. 154) Directs the Secretary of Veterans Affairs to take appropriate actions to enhance the readiness of Department

of Veterans Affairs medical centers to protect the patients and staff of such centers from chemical or biological attack or otherwise to respond to such an attack and so as to enable such centers to fulfill their obligations as part of the Federal response to public health emergencies. Authorizes appropriations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

methodologies whose purpose is to test food in order to rapidly detect the adulteration of the food.

Sets forth reporting requirements and authorizes appropriations.

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

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

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

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

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

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

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

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

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

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

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

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

Subtitle B: Protection of Drug Supply - Amends the FFDCA to mandate annual registration, through electronic means,

of foreign manufacturers (as well as the importers) engaged in the import of drug and device products into United States.

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

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

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

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

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

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

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

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

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

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

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

**Title V: Additional Provisions - Subtitle A: Prescription Drug User Fees - Prescription Drug User Fee Amendments** of 2002 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning definitions and the authority

to assess and use drug fees. Extends authorizations of appropriations.

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

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

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

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

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

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

**Subtitle C: Additional Provisions** - Directs the Federal Communications Commission, at the request of an eligible licensee or permittee, in order to further promote the orderly transition to digital television, and to promote the equitable allocation and use of digital channels by television broadcast permittees and licensees, within 90 days of enactment, to allot, if necessary, and assign a paired digital television channel to that licensee or permittee, subject to stated conditions.

Sets forth licensee and permittee requirements.

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

#### **Actions Timeline**

- Jun 12, 2002: Signed by President.
- Jun 12, 2002: Signed by President.
- Jun 12, 2002: Became Public Law No: 107-188.
- Jun 12, 2002: Became Public Law No: 107-188.
- Jun 7, 2002: Presented to President.
- Jun 7, 2002: Presented to President.
- Jun 4, 2002: Pursuant to the provisions of S. Con. Res. 117, enrollment corrections on H.R. 3448 have been made.
- May 23, 2002: Conference report considered in Senate. (consideration: CR S4772-4775; S4780-4786)
- May 23, 2002: Conference report agreed to in Senate: Senate agreed to conference report by Yea-Nay Vote. 98 0. Record Vote Number: 124.
- May 23, 2002: Senate agreed to conference report by Yea-Nay Vote. 98 0. Record Vote Number: 124.
- May 23, 2002: Message on Senate action sent to the House.
- May 22, 2002: Rule H. Res. 427 passed House.
- May 22, 2002: Mr. Tauzin brought up conference report H. Rept. 107-481 for consideration under the provisions of H. Res. 427. (consideration: CR H2844-2860)
- May 22, 2002: Rules Committee Resolution H. Res. 427 Reported to House. Rule provides for consideration of the conference report to H.R. 3448 with 1 hour of general debate. Previous question shall be considered as ordered without intervening motions.
- May 22, 2002: DEBATE The House proceeded with one hour of debate on the conference report.
- May 22, 2002: The previous question was ordered without objection.
- May 22, 2002: Conference report agreed to in House: On agreeing to the conference report Agreed to by the Yeas and Nays: 425 1 (Roll no. 189).
- May 22, 2002: Motions to reconsider laid on the table Agreed to without objection.
- May 22, 2002: On agreeing to the conference report Agreed to by the Yeas and Nays: 425 1 (Roll no. 189).
- May 22, 2002: Conference papers: message on House action held at the desk in Senate.
- May 21, 2002: Conference papers: Senate report and manager's statement held at the desk in Senate.
- May 21, 2002: Conference report filed: Conference report H. Rept. 107-481 filed.(text of conference report: CR H2691-2732)
- May 21, 2002: Conference report H. Rept. 107-481 filed. (text of conference report: CR H2691-2732)
- Feb 28, 2002: Mr. Tauzin asked unanimous consent that the House disagree to the Senate amendment, and agree to a conference.
- Feb 28, 2002: On motion that the House disagree to the Senate amendment, and agree to a conference Agreed to without objection.
- Feb 28, 2002: Ms. Eshoo moved that the House instruct conferees. (consideration: CR H638; text: CR H638)
- Feb 28, 2002: DEBATE The House proceeded with one hour of debate on the motion to instruct conferees. The instructions contained in the motion require the managers on the part of the House to work diligently to reconcile differences between the two Houses; to recognize importance of, and not disrupt flow of funding for bioterrorism and other public health emergencies; to recognize the need to establish a national system for tracking the possession and use of deadly biolgical agents; to recognize the need to prioritize Federal and State resources; to acknowledge the need to work with the Administration; and to provide for vulnerability assessments, emergency response plans, and other actions with respect to public drinking water supplies.
- Feb 28, 2002: POSTPONED VOTE At the conclusion of debate on the motion to instruct conferees, the Chair put the question on adoption of the motion and by voice vote, announced that the ayes had prevailed. Mr. Tauzin subsequently demanded the yeas and nays and further proceedings on adoption of the motion were postponed until later in the legislative day.
- Feb 28, 2002: On motion that the House instruct conferees Agreed to by the Yeas and Nays: 412 0 (Roll no. 46). (consideration: CR H638-641)
- Feb 28, 2002: Motion to reconsider laid on the table Agreed to without objection.
- Feb 28, 2002: The Speaker appointed conferees from the Committee on Energy and Commerce for consideration of the House bill and the Senate amendment, and modifications committed to conference: Tauzin, Bilirakis, Gillmor, Burr, Shimkus, Dingell, Waxman, and Brown (OH).
- Feb 28, 2002: The Speaker appointed conferees Provided that Mr. Pallone is appointed in lieu of Mr. Brown of Ohio for

consideration of Title IV of the House bill, and modifications committed to conference.

- Feb 28, 2002: The Speaker appointed conferees from the Committee on Agriculture for consideration of Title II of the House bill and sec. 216 and title V of the Senate amendment, and modifications committed to conference: Combest, Lucas (OK), Chambliss, Stenholm, and Holden.
- Feb 28, 2002: The Speaker appointed conferees from the Committee on the Judiciary for consideration of Title II of the House bill and secs. 216 and 401 of the Senate amendment, and modifications committed to conference: Sensenbrenner, Smith (TX), and Conyers.
- Jan 23, 2002: Message on Senate action sent to the House.
- Dec 20, 2001: Measure laid before Senate by unanimous consent. (consideration: CR S13902-13911)
- Dec 20, 2001: Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- Dec 20, 2001: Passed Senate with an amendment by Unanimous Consent.
- Dec 20, 2001: Senate insists on its amendment, asks for a conference, appoints conferees Kennedy, Dodd, Harkin, Mikulski, Jeffords, Gregg, Frist, Enzi and Hutchinson.
- Dec 18, 2001: Received in the Senate, read twice.
- Dec 12, 2001: Considered as unfinished business. (consideration: CR H9310-9311)
- Dec 12, 2001: Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 418 2 (Roll no. 493).(text: CR 12/11/2001 H9195-9209)
- Dec 12, 2001: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 418 2 (Roll no. 493). (text: CR 12/11/2001 H9195-9209)
- Dec 12, 2001: Motion to reconsider laid on the table Agreed to without objection.
- Dec 11, 2001: Introduced in House
- Dec 11, 2001: Introduced in House
- Dec 11, 2001: Referred to the Subcommittee on Health.
- Dec 11, 2001: Referred to the House Committee on Energy and Commerce.
- Dec 11, 2001: Mr. Tauzin moved to suspend the rules and pass the bill.
- Dec 11, 2001: Considered under suspension of the rules. (consideration: CR H9195-9217)
- Dec 11, 2001: DEBATE The House proceeded with forty minutes of debate on H.R. 3448.
- Dec 11, 2001: At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.