

SECTION FOUR: MEDICAL AND LIABILITY ISSUES

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Table 1: Congressional Grants of Authority Regarding Information Sharing to Respond to an Emergency or Major Disaster Involving Weapons of Mass Destruction

Reference & Section	Affected Entity	Principal Focus
U.S. Constitution		
Amendment X	States	Powers not delegated to the USG are reserved for the States
Amendment XI	States	Immunity of States from suits brought by foreign persons and from citizens of another State
Presidential Documents		
Executive Order 12196	Federal	Occupational safety and health programs for Federal employees; unique military exception to the Occupational Safety and Health Act
Executive Order 12333	Federal intelligence agencies	United States Intelligence Activities
Executive Order 13284	Federal Intelligence agencies	Amends Executive Order 12333
U.S. Code		
10 U.S.C. §1089, Gonzales Act	DoD	Liability of military health care practitioner
10 U.S.C. §1094	DoD	Portability of licenses for military health care personnel
10 U.S.C. § 2733, Military Claims Act	DoD	Authorizes claims against the United States for loss, damage, injury or death incident to military service
28 U.S.C. §2671, et seq., Federal Tort Claims Act	Federal	Federal government immunity and liability
28 U.S.C. §1346(b).	District Courts	Choice of law for the Federal Tort Claims Act
29 U.S.C. §651, et seq., OSHA	Federal, State employers	Mandates protection of safety and health of workers in the workplace
42 U.S.C. §1320d, et seq., HIPAA	States, Federal health care providers	Ensuring the privacy of protected health information
42 U.S.C. §1983	Federal, State employees & gov't	Imposes liability for actions that violate the rights of individuals under the Constitution or Federal law
42 U.S.C. §5148	Federal	Stafford Act immunity from liability provision
50 U.S.C. §401, et seq.	Federal	National Security Act authorizes release of certain information
Pub. L. 107-188, Bioterrorism Act	Federal, State	Various measures to enhance public health emergency measures
Pub. L. 107-296, Homeland Security Act of 2002 (6 U.S.C. §101, et seq.)	States	Creation of the Department of Homeland Security and other measures to enhance homeland security
Pub. L. 108-20, Smallpox Emergency Personnel Protection Act of 2003	Federal, States, Localities	Provides for injury/death compensation resulting from adverse reaction to the smallpox vaccine for certain categories of persons
Code of Federal Regulations		
29 CFR Part 1903.15	Federal, State	Providing proposed penalties for violations of regulations
29 CFR Part 1910.120	Federal, State employers	Protecting employees from exposure to hazardous substances
29 CFR Part 1910.1030	Federal, State employers	Protecting employees from occupational exposure to blood or other potentially infectious materials
42 CFR Part 70	HHS	Interstate quarantine regulations
42 CFR Part 71	HHS	Foreign quarantine regulations
45 CFR Part 160	States, Federal health care providers	<i>Standards for the Privacy of Individually Identifiable Health Information</i> implements HIPAA
45 CFR Part 164, Subparts A & E	States, Federal health care providers	Security and privacy standards for health information

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Reference & Section	Affected Entity	Principal Focus
Agency Directives/Instructions/Manuals		
DoDI 6205.2, Immunization Requirements	DoD, Military Depts	Sets out program and procedures for immunizing military and dependents
DoDD 6205.03, DoD Immunization Program for Biological Warfare Defense	DoD, Military Depts	Cited within AFI 44-119; sets out evaluation of biological warfare threats and procedures for immunization against such agents
Case Law		
Jacobson v. Commonwealth of Massachusetts	States	States may, consistent with the constitution mandate vaccinations
Berkovitz v. U.S.	Federal	Establishes 2-part test for discretionary function FTCA exception
Florida Dept. of State v. Treasure Salvors, Inc.	States	Sovereign immunity applies to suit of citizen against his/her State
Dureiko v. United States	Federal	Failure to live up to contractual requirement voids discretionary function immunity
Sunrise Village Mobile Home Park, L.C. v. United States	Federal	Liability for non-discretionary functions of Federal employees
United States v. Varig Airlines	Federal	Elaboration of discretionary function exception
United States v. Gaubert	Federal	Elaboration of discretionary function exception
Bivens v. Six Unknown Federal Agents	Federal	Authorizes suit for violation of constitutionally protected interests
Model Laws		
Model State Emergency Health Powers Act	States	Suggests standards for preparing for and responding to public health emergencies
State Laws		
NC Session Law 2003-227	States	NC's First Responder Vaccination Program
NYS Exec. Law, Ch. 18, Art. 2-B	States	Emergency Management Assistance Compact; other emergency management provisions
63 OK Stat. §682.1	States	OK's First Responder Vaccination Program
VA Code Ann. §44-146.13 et seq.	States	Commonwealth of VA Emergency Services and Disaster Law of 2000

I. Health Information Privacy Protection Act (HIPPA)

Title II of The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Department of Health and Human Services (HHS) to establish national standards for electronic health care transactions and deals with privacy and security of personal, private health information.¹ The law strives for administrative simplification by way of standardized electronic transactions involving health information, requiring standard formats, code sets, and identifiers.² It also specifies criminal penalties for wrongful disclosure of individually identifiable health information, which is a violation of Federal Law.³ In 1999, HHS was directed by Congress to develop privacy and security rules pursuant to Title II of HIPAA.

In response to the congressional mandate, HHS issued in 2001 *Standards for Privacy of Individually Identifiable Health Information*, or the Privacy Rule, which required most covered entities to comply with its provisions by April 14, 2003.⁴ Small health plans must comply by April 14, 2004. The Privacy Rule articulates the policies, procedures, and process for safeguarding the "protected health information" of individuals maintained by covered entities, which are specified health care providers, health plans, including health insurance companies, and health care clearinghouses.⁵ "Protected health information" is defined as individually identifiable health information related to tests, diagnoses, and treatment that is maintained or transferred in hard copy or electronically or communicated orally.⁶ Third parties hired by these covered entities, e.g., lawyers and accountants, may be given access to the protected information but covered entities must contractually require those parties to abide by the same restrictions on use or disclosure of the information. The Privacy Rule guarantees to patients access to their medical records and gives them greater control over the use and disclosure of their protected health information as well as options to address the compromise of that information. The protection afforded to patients lasts as long as the information is in the possession of the covered entity or its business associate.

Although the Privacy Rule preempts State law to the extent there is a conflict with State law, the regulations are a national minimum requirement. States may ask the Secretary of Health for an exemption from preemption for several reasons. Stronger, more restrictive State laws regulating health plans and otherwise protecting personal health information could be exempted. In addition, exemptions may be granted for specified public health functions. For instance, the Secretary of Health could determine that the health laws of the State serve "a compelling need related to public health, safety, or welfare" or the law "provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention."⁷ Finally, covered entities may disclose protected health information to federal officials without authorization if necessary for national security reasons, as specified in the

¹ 42 U.S.C. §1320d, *et seq.* (2002).

² 42 U.S.C. §1320d-2.

³ 42 U.S.C. §1320d-6.

⁴ 45 CFR Part 160; 45 CFR Part 164, Subparts A and E (2002).

⁵ That is, health care providers who transmit certain financial and administrative health information electronically.

⁶ 45 CFR Part 160.103.

⁷ 45 CFR Part 160.203.

National Security Act⁸ and Executive Order 12333.⁹

For these reasons, HIPAA and the Privacy Rule do not significantly limit the right of public health officials to use or disclose protected health information to manage a public health crisis such as might occur with bioterrorism. Pursuant to the exceptions under the rule, State rules requiring disclosure to public health officials information about a person who, for instance, is suspected to or does carry a communicable disease would not be preempted by the Privacy Rule. Under HIPAA, the disclosure of such information to public health authorities would not require authorization and would not be actionable absent such authorization as State law on liability for such disclosure would govern.¹⁰

Section 607 of the Model State Emergency Health Powers Act, discussed more fully in **Paragraph III-E** below, suggests standards for access to and disclosure of protected health information. Access to information of persons subject to treatment, quarantine, and other efforts of the public health authority during a public health emergency, should be strictly limited to those who have a need to know the information for purposes of treatment, epidemiological research, or investigating the causes of transmission.¹¹ The public health authority may not disclose protected health information without "individual written, specific informed consent" unless the information is disclosed to: the individual; his or her immediate family or personal representative; federal authorities pursuant to federal law; pursuant to a court order to protect the public; or to identify a deceased person or the cause of death.

II. Vaccinations / Treatment During an Actual or Potential Bioterrorist Event

The constitutionality of compulsory vaccinations is well settled in the law. States may require widespread vaccinations, e.g., immunization against some diseases for children who attend public school, to ensure a healthy environment. To satisfy public policy and medical ethics concerns, public health entities generally obtain informed consent from individuals, to include parents of children under the legal age of consent, before administering the vaccination or treatment. In addition, exemptions from the treatment or vaccination are provided. While States may be able to compel the vaccination of children, adult immunization programs are much more difficult to administer.

Vaccination programs for emergency responders and health care providers are imperative, not only to treatment, but also to containment measures should a biological incident occur. These programs are generally not compulsory, but are strongly encouraged, especially for first responders. Recently, President George W. Bush signed into law the "Smallpox Emergency

⁸ 50 U.S.C. §401, *et seq.* (2002).

⁹ Executive Order 12333, "United States Intelligence Activities," December 4, 1981.

¹⁰ 45 CFR Part 164.512. It also defines a public health authority is defined as one authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority.

¹¹ The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities for the Centers for Disease Control, *The Model State Emergency Health Powers Act*, December 21, 2002 (herein MSEHPA)

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Personnel Protection Act of 2003¹² as an initial measure to not only encourage emergency personnel to receive this vaccination, but also to provide an avenue for compensation should the vaccination cause injury.

The Department of Defense (DoD) has a differing approach to compulsory vaccinations, especially regarding deployed or deploying troops. As discussed in Section C below, however, this approach has come under fire with the announcement of the smallpox vaccination. DoD is attempting to address the concerns expressed by its employees, as it encourages its personnel to take the necessary precautions to protect themselves.

A. Compulsory Vaccination Issues

States may prescribe specified public health measures pursuant to their police powers. The Supreme Court, in *Jacobson v. Commonwealth of Massachusetts*, held that States may establish reasonable regulations, such as the mandatory smallpox vaccinations at issue, to protect the public health and safety.¹³ Generally, the emergency management statutes of the States authorize the Governor and the public health authority to take measures necessary to protect the public during a bioterrorist event or other public health emergency. All States have compulsory vaccination measures, though the scope and applicability of the laws vary, and all States have provided exemptions for medical reasons. The vast majority of States created exemptions from compulsory vaccination for religious reasons, fewer have exemptions for philosophical reasons.¹⁴ Most State laws are older and were passed in response to the emergence of a specific disease. The laws are usually insufficient to deal with a broader range of infectious diseases and do not reflect the current state of medical thinking on the diseases and treatment for the diseases.

When it comes to adults, the ability to require vaccinations is even more limited. Except for first responders and health care workers (discussed in the next section), vaccinations for adults are only recommendations, not compulsory. Although the majority of adults were immunized as children, a common misconception is that these immunizations last for a lifetime. As a result, the National Immunization Program under the Centers for Disease Control (CDC) engages in awareness efforts to encourage adults to update their vaccinations.¹⁵ Even under this program, the list of recommended vaccinations does not include those that would protect against diseases that could potentially be used as biological weapons.¹⁶ Thus, the impact of a biological agent could be widespread due to the limited use of protective vaccinations.

B. Protecting First Responders and Health Care Workers

Even health care workers and first responders can be compelled to be vaccinated only in limited circumstances. In order to provide effective treatment and containment by such personnel, it is critical that they be protected from potential biologic agents that could be used as weapons

¹² Pub. Law 108-20, Smallpox Emergency Personnel Protection Act, April 30, 2003.

¹³ 197 U.S. 11 (1905).

¹⁴ See generally, Gostin, et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 Columbia L. Rev. 59 (1999).

¹⁵ National Immunization Program, Adult Immunization Schedule; available at: <http://www.cdc.gov/nip/recs/adult-schedule.htm#chart>.

¹⁶ *Id.*

against the general population.

1. State Measures

Several States recently have passed laws that address concerns of liability resulting from administering the smallpox vaccine. These include Virginia, North Carolina, Indiana, and Arkansas. Other States, such as North Carolina, Oklahoma, Mississippi, and Arkansas have passed laws creating vaccination programs for first responders who may be exposed to infectious diseases when responding to a bioterrorist attack. North Carolina and Oklahoma, for example, have passed similar laws that authorize the establishment of a program that would allow emergency responders access to vaccines on a voluntary basis for those responders who may be exposed to infectious diseases. The laws in these states require compulsory vaccination only for those first responders who have "occupational exposure" to blood-borne pathogens and, by standards established by the Occupational Safety and Health Administration (OSHA), must be immunized. The vaccinations must be recommended by the Public Health Service.¹⁷ Those employees, who are vaccinated, may not use the OSHA standards as a basis for a tort claim for injuries resulting from the vaccination.

2. OSHA Standards for Protecting Health Workers

The Occupational Safety and Health Act of 1970 mandates minimum safety and health conditions for places of employment and the enforcement of standards created pursuant to the Act.¹⁸ OSHA regulations are designed to protect workers from health and safety hazards in the workplace, at the State and Federal levels. The regulations apply to health care workers who may be exposed to contagious diseases and to hazards from chemical, radiological and/or explosive devices in the course of responding to emergencies involving such hazards.

The OSHA Standards are found at 29 C.F.R. Part 1910. The Hazardous Waste Operations and Emergency Response Standard¹⁹ requires employers to plan for emergencies involving hazardous substances when their employees may be required to handle such substances. Hospitals must have in place adequate emergency response plans, equipment, and trained personnel if they plan to treat victims in emergencies involving hazardous substances.²⁰ The regulations also require hospitals to provide their workers protection against blood-borne pathogens, defined as "pathogenic microorganisms that are present in human blood and can cause disease in humans."²¹ Failure to comply with OSHA standards may result in criminal penalties and civil fines.²²

Executive Order 12196 sets out the occupational safety and health programs for Federal employees. Significantly, it does not require compliance with OSHA requirements for military personnel or "uniquely military equipment, systems, and operations."²³

¹⁷ NC Session Law 2003-227, June 11, 2003; 63 OK Stat. §682.1.

¹⁸ 29 U.S.C. §651, *et seq.* (2002).

¹⁹ 29 CFR Part 1910.

²⁰ 29 CFR §1910.120.

²¹ 29 CFR §1910.130.

²² 29 CFR §1903.15.

²³ Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees," February 26, 1980.

3. Smallpox Emergency Personnel Protection Act of 2003²⁴

Earlier this year, Congress passed and the President signed into law the Smallpox Emergency Personnel Protection Act of 2003. This act is the latest in a series of events promoted by the President to encourage renewed use of the smallpox vaccine to protect health care providers and first responders.

The primary goal of the act is to "provide benefits and other compensation for certain individuals with injuries resulting from administration of smallpox countermeasures, and for other purposes."²⁵ Thus, if a person qualifying as a covered individual suffers injury or death as a result of smallpox vaccination, they or their families and dependents may be compensated for losses suffered. Under this act, a 'covered individual' spans the gamut from health care workers, firefighters, law enforcement and emergency medical personnel to persons who volunteer to be a member of a smallpox emergency response plan.²⁶ The Smallpox Emergency Response Plan was announced by the White House at the end of 2002 and gave the Department of Health and Human Services the authority to "form volunteer Smallpox Response Teams who can provide critical services to their fellow Americans in the event of a smallpox attack."²⁷ The plan recommended that such volunteers receive smallpox vaccinations, but that widespread vaccination of the general population was not considered necessary.²⁸

This Act further encouraged not only health care workers and first responders to receive the vaccination, but also those who were considering volunteering for the smallpox response teams. By providing an avenue for injury compensation, it is hoped that more people will be encouraged to volunteer for the vaccinations, thus providing an adequate core of individuals who could safely respond to a biological attack using smallpox.

C. Federal Agency Vaccination Policies

The Departments of Defense and State have different requirements for their personnel when it comes to vaccinations. The personnel employed by these agencies are most likely to be in situations in which they may be exposed to biological weapons. Unlike the civilian population, the Department of Defense has the ability to compel its personnel to be vaccinated.

Under Department of Defense Instruction (DoDI) 6205.2, the Department of Defense established the department's immunization policies for all military and civilian employees and their family members. One goal of the instruction is to address "military-unique peacetime and contingency requirements such as global deployment and defense against potential biological warfare agents."²⁹ As part of this program, the Military Departments are tasked with "developing appropriate immunization procedures" in consultation with various Armed Services medical activities as well as to "develop and implement general principles and specific procedures to be

²⁴ Pub. L. 108-20, *supra* note 12.

²⁵ *Id.*

²⁶ *Id.* at §2.

²⁷ Protecting Americans: Smallpox Vaccination Program, available at <http://www.whitehouse.gov/news/releases/2002/12/20021213-1.html>

²⁸ *Id.*

²⁹ DoDI 6205.2 "Immunization Requirements," October 9, 1986.

followed in the prophylactic immunization programs of the Armed Forces."³⁰

This immunization policy is further defined in Department of Defense Directive (DoDD) 6205.3, "DoD Immunization Program for Biological Warfare Defense."³¹ Under this directive, more specific procedures regarding biological warfare are added to the general immunization program established under DoDI 6205.2.

In order to require immunizations under this directive, the Commanders of the Unified Commands provide the Chairman of the Joint Chiefs of Staff (CJCS) with an assessment of potential biological warfare threats within their theater of operation. In consultation with various military Commanders and Chiefs, the CJCS validates and prioritizes the biological warfare threats, which is forwarded to the Secretary of the Army (the designated DoD Executive Agent (EA)), who then provides recommendations and protocols to enhance protection against the biologic agents. Once the recommendations are made, the Assistant Secretary of Defense for Health Affairs (ASD (HA)) directs the Secretaries of the Military Departments to begin immunization of the specified DoD personnel for the specific biological warfare threat agents.³² In general, personnel potentially subject to this directive include:

- a. Personnel assigned to high-threat areas;
- b. Personnel predesignated for immediate contingency deployment (crisis response);
- c. Personnel identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area.³³

Unlike the civilian population, the personnel designated pursuant to the recommendations of the ASD (HA) must be vaccinated, with only limited exception. With the recent establishment of the Unified Combatant Command, NORTHCOM, personnel within the United States may be considered to be assigned to "high-threat areas" and therefore may be subject to required immunizations.

In 1997, DoD mandated that all military personnel in the Persian Gulf Region be vaccinated against anthrax.³⁴ The Department's authority to do so derived from the directives outlined above. As part of the Smallpox Emergency Response Plan announced by the President, both the Departments of Defense and State announced that they would be immunizing their personnel, with DoD again acting under the authority of the directives outlined above.³⁵

The Department of State does not have any compulsory vaccination procedures, but it has established a "chemical and biological countermeasure program."³⁶ Under this program, the Department provides chemical antidotes and antibiotics to various overseas posts that are located

³⁰ *Id.*

³¹ DoDD 6205.3 "DoD Immunization Program for Biological Warfare Defense," November 26, 1993.

³² *Id.* at F. 1.-4.

³³ *Id.* at D. 1. a.-c.

³⁴ Press Release: Anthrax Vaccine, Military Use in the Persian Gulf Region, Washington, DC. U.S. Dept. of Defense Sept 8, 1998, cited in JAMA vol. 287, No. 17 at 2243. May 1, 2002.

³⁵ Protecting Americans: Smallpox Vaccination Program, *supra* note 27.

³⁶ Chemical-Biological Agents Fact Sheet, Dept. of State, Bureau of Consular Affairs. Available at: <http://travel.state.gov/cbw.html>.

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in high-threat areas.³⁷ Also, the White House has stated that personnel working for the Department of State abroad in high threat areas are not required to be vaccinated, but are strongly encouraged to participate in the smallpox vaccination program.³⁸

D. Quarantine Procedures

In order to contain infectious diseases, the federal government has enacted regulations regarding quarantine procedures. In 42 CFR Part 70, interstate quarantine regulations are established and in Part 71, foreign quarantine procedures are outlined.³⁹

Under Part 70 of these regulations, the federal government may restrict the movement of persons suspected of carrying specified communicable diseases in order to prevent the interstate spread of disease. The diseases for which quarantine is authorized are listed in an Executive Order of the President, the most recent of which is Executive Order 13295, issued on April 4, 2003.⁴⁰ In addition, an individual in the communicable stage of a disease may not travel from one State to another without obtaining a permit from the health officer of the destination State, assuming that such a permit is required under the law of the destination State. Furthermore, individuals in the communicable period of certain diseases (cholera, plague, smallpox, typhus, or yellow fever) may not travel on board an interstate conveyance without obtain a permit from the Director of CDC.⁴¹

Additionally, if the Director of the Centers for Disease Control and Prevention (Director) believes that the State or local government is not taking adequate measures to contain a communicable disease, the Director may "take such measures to prevent such spread of the diseases as he/she deems reasonably necessary."⁴² These regulations exempt military personnel from the disease reporting and travel permit requirements, provided that they are traveling under competent orders and precautions to prevent the possible transmission of infection to others have been taken.⁴³

Part 71 provides regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States. Generally it covers the various means of transport, including military transport. Specifically, "[u]pon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States."⁴⁴ Additionally, the Federal government "may require detention of a carrier until the completion of the measures...that are necessary to prevent the introduction or spread of a communicable disease."⁴⁵ Thus, the governmental authority to prevent the entry of contaminated persons, containers, or animals is quite broad, including the ability to prevent entry as well as require inspections and/or disinfection procedures. With respect to individuals arriving from foreign

³⁷ *Id.*

³⁸ *Id.*

³⁹ 42 CFR Part 70 (2002); 42 CFR Part 71 (2002).

⁴⁰ Executive Order 13295, "Revised List of Quarantinable Communicable Diseases," April 4, 2003.

⁴¹ 42 CFR Part 70, *id.* at 70.5.

⁴² *Id.* at 70.2.

⁴³ *Id.* at 70.8.

⁴⁴ 42 CFR Part 71.31(a).

⁴⁵ *Id.* at 71.31(b).

countries, as in Part 70, the Federal government has authority to quarantine individuals with specified communicable diseases that have been previously listed in an Executive Order of the President.

III. Standardization of Emergency Response

A. Federal Organization for Public Health Emergency Response

An issue that directly affects emergency responders is the standardization of equipment and procedures for responding to disasters and emergencies. Of particular concern is the lack of standard equipment for responding to events that involve or may involve chemical or biological agents. In addition, there is a concern that differing standards for communications equipment could hamper the efforts to render emergency response support across entities and jurisdictions. The Bioterrorism Act, passed in the wake of the domestic anthrax mailings, attempted to address what is a significant gap in emergency response today: the lack of standardized measures and a centralized authority to encourage the adoption of such.

Section 102 establishes within the Department of Health and Human Services (HHS) an Assistant Secretary for Public Health Emergency Preparedness. The Assistant Secretary is an appointee reporting directly to the Secretary, responsible for coordinating between HHS and other U.S. agencies, departments, and offices, and between the HHS and State and local entities responsible for emergency preparedness. He is also responsible for coordinating HHS activities relating to bioterrorism and other public health emergencies, including the National Disaster Medical System (NDMS), and coordinating HHS's efforts to enhance State and local preparedness for a bioterrorism attack or other public health emergency. NDMS is a federally coordinated system that the Secretary may activate to provide healthcare and other services to the victims of a public health emergency when local capabilities are overwhelmed. HHS, the Federal Emergency Management Agency (FEMA, now within the Department of Homeland Security (DHS)), DoD, and the Department of Veterans Affairs work in collaboration with States, localities, and the private sector to ensure resources are available for effective response to a bioterrorism attack or other public health emergency.

A WMD attack could devastate a community to the point that the local health care supply becomes inundated and therefore ineffective. The NDMS is one attempt to ameliorate this potential problem. The NDMS is an organization composed of Federal government agencies, State and local governments, private businesses, and civilian volunteers assembled in order to share resources. The NDMS works to ensure that these resources exist and are available in the event of a disaster that could possibly overpower the local health care resources. The general purpose is to enable the coordination of Federal, State and local emergency medical response to ensure that responders have the means to provide support to State and local authorities during a major disaster or emergency. In addition, the NDMS supports the military and Veterans Health Administration medical systems in providing treatment for those evacuated to the United States from overseas conflicts.⁴⁶ The Office of Emergency Preparedness (OEP) in HHS heads up NDMS. OEP coordinates Federal health, medical and health related social services and recovery to major emergencies and Federally declared disasters. In a WMD attack, OEP is directly

⁴⁶Available at <http://ndms.dhhs.gov/NDMS/ndms.html>.

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accountable for Federal health and medical action. FEMA (DHS), the Federal interagency community, and OEP operate together while OEP serves as the lead Federal agency for health and medical services within the Federal Response Plan.⁴⁷

B. Bioterrorism Preparedness Plans and Other Measures

The Bioterrorism Act includes significant amendments to the Public Health Service Act (42 U.S.C. §201, et seq.) aimed at ensuring that the United States, from the Federal to the local levels, in the public and private sector, will be prepared in the event of domestic bioterrorism or other public health emergency. Section 101 of the Bioterrorism Act adds Title 28 to the Public Health Service Act (PHSA), mandating that the Secretary of Health and Human Services (Secretary) develop and implement a national strategy for and to coordinate Federal, State, and local activities on bioterrorism and other public health emergency preparedness and response. The coordinated national preparedness plan must address Federal assistance to States and localities to:

- Ensure appropriate detection and response capacities at the State and local levels, including:
 - Surveillance and reporting mechanisms
 - Laboratory readiness
 - Training and equipment for emergency responders
- Develop and maintain vaccines against biological agents and other medical countermeasures
- Coordinate Federal, State, and local planning, preparedness, and response activities for all phases of a public health emergency
- Improve the readiness of the response capabilities of health care facilities.

The Secretary must report to the Congress biennially on, among other things, progress on the plan and its goals. The Secretary must also make recommendations to Congress on any additional legislative authorities necessary for implementing the plan and for protecting the public health in an emergency. The comprehensive reports required of the Secretary by Congress, such as studies of vulnerabilities of rural communities, medically underserved communities, and vulnerable sections of the population, e.g., children, as well as studies of volunteer and private sector involvement in emergency response, indicate a Congressional intent to comprehensively address the challenging issues in national preparedness and response to public health emergencies.

Section 137 authorizes the Secretary to make grant awards. This section also authorizes the Secretary to enter into cooperative agreements with States and localities to facilitate their preparing and implementing bioterrorism and other public health emergency preparedness and response plans. The activities eligible States and localities may conduct using the award include: purchasing supplies, equipment, and countermeasures; conducting exercises that test their health emergency response capabilities; developing and implementing specified medical care components of the State plans; training public health laboratory and other health care personnel; developing and enhancing participation in relevant information sharing systems; enhancing ability to communicate with the public in a public health emergency; contamination prevention

⁴⁷Available at <http://ndms.dhhs.gov/>.

planning; training and planning for the protection of responders; and triage and transportation management.

C. Working Group to Facilitate Standardization

Section 108 of the Bioterrorism Act requires that the Secretary of HHS establish a Working Group on Bioterrorism and Other Public Health Emergencies (Working Group), in coordination with the heads of the Departments of Justice, Defense, Energy, Labor, and Veterans Affairs, the Environmental Protection Agency, Federal Emergency Management Agency, and the Central Intelligence Agency, and other appropriate Federal officials.⁴⁸ The Working Group is responsible for assisting in and making recommendations on, among other things, the following:

- Safety, training, and protective measures for medical and other emergency responders;
- Facilitating the availability of priority countermeasures;
- Developing common equipment standards to protect against biological agents;
- Developing and improving joint planning and training programs, between medical and other first responders, hospitals and other health facilities, for managing the consequences of public health emergencies;
- Developing Federal, State, and local strategies for communicating with the public;
- Revising the Federal Response Plan as necessary to clarify Federal responsibilities for investigating "suspicious outbreaks of disease;" and
- Enhancing Federal coordination with and support of State and local emergency medical services.

The intent is to ensure that emergency responders nationwide are afforded access to the same training, equipment, and other resources, and to implement similar standards, strategies, and processes so that the effectiveness of emergency responders is enhanced.

D. Managing the Strategic National Stockpile

Subtitle B of the Bioterrorism Act mandates that the Secretary of HHS, in coordination with the Secretary of Veterans Affairs and in consultation with the Working Group, maintain a stockpile of drugs, vaccines, and other medical products and devices. In the event of a bioterrorist attack or other public health emergency, the Secretary may use the stockpile as appropriate to secure the health of the U.S. population. For example, the Stockpile must contain an adequate amount of smallpox vaccine and potassium iodide. The Act assigns the decision to deploy the National Stockpile to the Department of Homeland Security.⁴⁹ The President, under Section 127, must make available to State and local governments, from the national stockpile, potassium iodide in sufficient amounts to protect populations within 20 miles of a nuclear power plant. Under Section 122, the Secretary may accelerate approval, pursuant to the Food, Drug and Administration Act, of priority countermeasures.

⁴⁸ Pub. L. 107-188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002, June 12, 2002.

⁴⁹ *Id.* at §121(a)(1)-(2).

E. Isolation and Quarantine Measures Suggested by Model State Emergency Health Powers Act (MSEHPA)

Regulations for responding to public health emergencies are inconsistent from State to State. Not only do the triggers for and declaration and implementation of public health emergency measures vary, but also the penalties for violating laws such as quarantine laws range from misdemeanor to felony depending on the State. As a remedy for this major disparity between State regulations, State officials are being urged to survey their quarantine and other public health emergency regulations. The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, at the request of the Centers for Disease Control and Prevention (CDC), has also developed the Model State Emergency Health Powers Act (MSEHPA), to assist States in determining which legal authorities would be necessary to prevent, detect, manage, and contain public health emergencies.

The Model State Emergency Health Powers Act (MSEHPA) grants broad powers to State and local public health authorities to prevent, detect, manage, and contain public health emergencies, including those involving bioterrorism, while also promoting the common good and respecting individual rights to liberty, privacy, and bodily integrity. The purposes of the model law are: to require the implementing State to develop a public health emergency response plan; to authorize data collection and reporting for the protection of people and management of property and access to communications; to authorize access to health information in specified circumstances in order to facilitate early detection of a public health crisis; to authorize State and local officials to use, appropriate, and destroy property when necessary for the care of patients; to authorize officials to provide care, treatment, and vaccination to those who are ill or who have been exposed to communicable diseases; and to isolate and quarantine individuals as necessary to prevent the spread of contagious diseases; and to ensure that in exercising public health emergency authorities, State and local officials do not unduly interfere with civil rights and liberties.⁵⁰

Article II of the MSEHPA requires the Governor to appoint a Public Health Emergency Planning Commission, which would develop a plan for responding to a public health emergency. The Plan must be comprehensive in scope, addressing all aspects of response to include: coordination of the response; training health providers; communicating with the public; storing essential materials; evacuation, quarantine, and treatment; operation of the judicial system to hear isolation and quarantine matters; and identifying cultural or religious norms to which responders should be sensitive.

Article III of the model law is concerned with measures for early identification and tracking of public health emergencies. Section 301 requires health care providers, coroners, medical examiners, and pharmacists to report electronically, or in writing, on conditions and activities that "may be potential causes of a public health emergency." Veterinarians, livestock owners, veterinary diagnostic laboratories and other animal caretakers must also report similar information for animals that have or might have diseases that could cause a public health emergency. These reports should include as much detail as possible to identify the illness, the patient or animal, and the location of the patient or animal. To ascertain the existence of, investigate, and track cases that might cause a public health emergency, Section 302 authorizes the State or local public health authority to identify and interview individuals believed to have

⁵⁰ MSEHPA, §102.

been exposed to a potentially contagious illness and to close, evacuate, or decontaminate potentially contaminated facilities or materials. Section 303 provides for expeditious sharing of information regarding a case of a reportable illness or condition. The information shared with the public health authority is restricted to only that necessary to treat, control, investigate, or prevent a public health emergency. Article IV of the MSEHPA details the requirements for declaring a state of public health emergency and the content and effects of such a declaration, which includes the activation of the Governor's emergency powers and those of the public health authority. Powers of the governor include mobilizing the militia, honoring interstate emergency compacts, and use of resources necessary to manage the emergency.

Article V details special powers in relation to managing property that is obtained during a state of public health emergency. Section 501 authorizes the evacuation, closure, and decontamination of facilities and the destruction and decontamination of materials where there is "reasonable cause to believe" that the facilities and materials pose a danger to public health. Section 502 authorizes the public health authority to access and control facilities and property, to include hospitals and communications devices, as well as materials, roads, and public areas. Section 503 details measures for the safe disposal of public waste. This includes the authority of the public health authority to require facilities to handle such waste in a specified manner. Section 504 provides for the safe disposal of human remains, authorizing the public health authority to adopt the necessary measures to ensure such remains are disposed of in the manner necessary to respond to the public health emergency. This section addresses specifically the problem of managing mass casualties. Subsection (d) of the model act would authorize the public health authority to compel any business or facility authorized under State law to embalm, bury, cremate, or transport human remains, to accept and dispose of human remains in a public health emergency as a condition of continued licensure in the State. Control of health care supplies, to include serums, vaccines, and antibiotics, is the subject of Section 505. It also addresses compensation to property owners for any takings by the State. Compensation for the taking of private property is addressed in Section 805.

Article VI sets out the special powers relating to protection of persons that would apply during a public health emergency. It is these provisions of the MSEHPA that have been most controversial as they give the public health authority sweeping power to institute compulsory measures in the interest of securing the public health. Among other things, the MSEHPA provides for medical examination and testing of persons and the isolation and/or quarantine of individuals, who may be infected with or may have been exposed to a contagious disease, but who refuse testing.⁵¹ Section 603 authorizes the public health agency to vaccinate and otherwise treat exposed or infected persons to protect them and to prevent the spread of a contagious or possibly contagious disease. The vaccination or treatment must not, however, "be such as is reasonably likely to lead to serious harm to the affected individual." In deference to those who refuse vaccination or treatment for reasons of religion, health, or conscience, the model Act would allow the public health authority to isolate or quarantine them.

Intra-State quarantine is a public health measure reserved to the States under the 10th Amendment of the Constitution, which reserves to the States the police power, or the authority to protect the health and welfare of citizens within the States. Where the communicable disease

⁵¹ MSEHPA, §602.

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remains or is likely to remain intra-State, quarantine authority rests with State officials and each State has its own quarantine statute. Isolation and quarantine authority are provided for in Section 604 of the MSEHPA, which adheres to the classic definitions of isolation and quarantine. Generally, the Governor of a State must declare a public health emergency in order to initiate quarantine under the MSEHPA. The trigger for such a declaration could be events, such as bioterrorism or outbreaks of either a novel or previously eradicated infectious agent, which bear a high probability of death or injury in a population. Isolation is defined as:

the physical separation and confinement of an individual or groups of individuals who are infected or reasonably believed to be infected with a contagious or possibly contagious disease from non-isolated individuals, to prevent or limit the transmission of the disease to non-isolated individuals.

Quarantine is defined as:

The physical separation and confinement of an individual or group of individuals, who are or may have been exposed to a contagious or possibly contagious disease and who do not show signs or symptoms of a contagious disease, from non-quarantined individuals, to prevent or limit the transmission of the disease to the non-quarantined individuals.⁵²

Essentially, isolation is concerned with separating and confining those infected or believed to be infected with a contagious disease and quarantine affects those exposed or believed to be exposed to such a disease.

The MSEHPA suggests the following set of standardized conditions and principles for instituting quarantine and isolation measures:

- Isolation and quarantine conditions must be "by the least restrictive means necessary" to contain contagion.
- Isolated persons must be confined separately from quarantine persons.
- Isolated and quarantined persons must be regularly monitored to determine if they still must be isolated or quarantined.
- An isolated or quarantined person, who is determined to be infected or is reasonably believed to be infected, must be separated from other isolated or quarantined persons.
- When isolated or quarantined persons pose no substantial risk of transmitting a contagious disease to others, the public health authority must immediately release them.
- The basic needs of quarantined persons must be addressed systematically and competently.
- The public health authority must isolate and quarantine individuals in safe and hygienic premises.
- The religious/cultural beliefs of quarantined and isolated persons must be respected to the extent possible.

The model law provides for isolation and quarantine via court order as well as, in extreme circumstances, immediate isolation and quarantine with subsequent due process, e.g., quarantine

⁵² MSEHPA, §§104 (h) and (o), respectively.

a group of individuals and provide due process once the quarantine has commenced. Temporary isolation or quarantine without notice and a hearing may only be continued if the public health authority seeks a court order for its continuance within ten (10) days after the measure is instituted.⁵³ The MSEHPA also aims to standardize penalties for violation of quarantine. Section 604 of the MSEHPA states that violating a quarantine order constitutes a misdemeanor. In recognition of the fact that individuals may resist isolation and quarantine efforts, Section 605 of the model law allows individuals to petition a court for relief from isolation or quarantine.

That the MSEHPA makes failure to obey quarantine a misdemeanor offense raises issues as regards military aid in enforcing quarantine and the Posse Comitatus Act. Since failure to obey would be a punishable offense, any effort to enforce compliance to an isolation or quarantine order could be viewed as law enforcement. For States implementing the MSEHPA or a law based on it, the military role in a quarantine event would be of a supportive nature. Enforcement of the quarantine "law" would be the responsibility of State and local law enforcement authorities and the State National Guard. Absent other statutory or Constitutional authority, the role of the military would be logistical and/or operational support, e.g., food distribution, operational maintenance of critical infrastructure, and transport of goods.

The Centers for Disease Control and Prevention, through the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, has been encouraging states to review the powers listed in the MSEHPA. Such consistency may simplify the legal issues that may arise in the event of a quarantine that extends beyond a State's borders as well as those issues attendant to Federal assistance to States in emergency situations. These organizations were correct in anticipating that dissemination of the MSEHPA would enable the standardization of State public health emergency authorities, especially the methods for instituting quarantine measures and the penalties for resistance to or violations of quarantine regulations. State and local lawmakers and health officials nationwide have considered the Model Act as a guide for public health law reform in their states. Thirty-two states and the District of Columbia have passed laws that incorporate provisions from or related to the Act.⁵⁴ Significantly, the majority of States did not include the blanket authority Section 601 of the model law afforded to public health authorities to "use every available means" to contain the spread of infectious disease.

IV. Licensure of Health Care Professionals Responding to a Public Health Emergency

It is important to expeditious emergency response that licensure requirements are met and are ascertainable for those responding to a WMD emergency, including out-of-State doctors who are called upon because of lack of sufficient resources in the State.

A. Federal Licensure

Federalism concerns may prevent Congress from mandating that States recognize the credentials of health professionals from other States in a public health emergency. Currently, the

⁵³ MSEHPA, §605.

⁵⁴ These States are: AL, AZ, CT, DE, FL, GA, HI, IA, ID, IL, LA, ME, MD, MN, MO, MT, NV, NH, NM, NC, OK, OR, PA, RI, SC, SD, TN, UT, VT, VA, WI, and WY.

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Bioterrorism Act (Pub. L. 107-188, Public Health Security and Bioterrorism Act of 2002) addresses licensure issues in a few ways. In recognition of the problem that some states do not recognize the licenses of other States, or do so only through formal, time-intensive processes, Congress authorizes the Secretary to "encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services, to provide such health services in the State."⁵⁵

The law also requires the Secretary of HHS to create and maintain an emergency verification system for the advance registration of health professionals in order to verify their credentials, licenses, and privileges when those professionals volunteer to provide health care services during a public health emergency. This database would allow immediate access to information on doctors in the area of a bioterrorism event. Also under the Bioterrorism Act, licensed physicians, who respond in a State other than the one in which they are licensed, are granted the same authorities and protections as individuals licensed in that State. Similarly, the MSEHPA, Emergency Management Assistance Compact (EMAC) legislation, and existing interstate Mutual Aid Agreements, will ensure that in the future, mechanisms will be in place for reciprocity and indemnification of out-of-State health care providers.

B. State Licensure

Many States have in place comprehensive emergency management acts that address licensure requirements. The State legislatures have recognized that State resources may be overwhelmed in a disaster or emergency and have attempted to address the need for the portability of licenses and certificates for health care professionals of other States who provide emergency assistance. For instance, the New York law on natural and man-made disasters requires the State to enter into an Emergency Management Assistance Compact and to formulate the interstate mutual aid agreements necessary to implement the compact.⁵⁶ With respect to the portability of licenses, the law provides:

Whenever any person holds a license, certificate or other permit issued by any state party to the compact evidencing the meeting of qualifications for professional, mechanical or other skills, and when such assistance is requested by the receiving party state, such person shall be deemed licensed, certified, or permitted by the state requesting assistance to render aid involving such skill to meet a declared emergency or disaster, subject to such limitations and conditions as the governor of the requesting state may prescribe by executive order or otherwise.⁵⁷

Virginia's emergency services law exempts from liability licensed workers from another State that render aid within the State in the event of a disaster or emergency. It provides:

If any person holds a license, certificate, or other permit issued by any state, or political subdivision thereof, evidencing the meeting of qualifications for professional, mechanical, or other skills, the person may gratuitously render aid involving that skill in this Commonwealth during a disaster, and such person shall not be liable for negligently causing the death of, or injury to, any person or for the loss of, or damage to, the property of any person resulting from

⁵⁵ Pub. L. 107-188, *supra* note 48 at §107.

⁵⁶ NYS Exec. Law, Chapter 18, Article 2-B, §29-g.4.

⁵⁷ *Id.*, §29-g.5.

such gratuitous service.⁵⁸

Section 608 of the Model State Emergency Health Powers Act suggests a standard method of addressing the licensing and appointment of health personnel during a public health emergency. This includes the power to authorize the coroner or medical examiner to appoint emergency assistance. It suggests authorizing the public health authority, during the period of the state of public health emergency, to require in-State health care providers to assist in emergency health response measures as a condition of practicing in the State. It also authorizes the appointment of out-of-State health care providers to assist with emergency response, and to waive the licensing, fees, and other administrative requirements for practicing within the State.

C. Licensure of Military Personnel

Portability of licenses for military health care professionals is addressed by 10 U.S.C. §1094, which provides:

Notwithstanding any law regarding the licensure of health care providers, a health-care professional described in paragraph (2) may practice the health profession or professions of the health-care professional in any State, the District of Columbia, or a Commonwealth, territory, or possession of the United States, regardless of whether the practice occurs in a health care facility of the Department of Defense, a civilian facility affiliated with the Department of Defense, or any other location authorized by the Secretary of Defense.

In essence, 10 U.S.C. §1094(d) allows military physicians with a valid license to respond in any State, Commonwealth, the District of Columbia, or Territory in execution of and acting within the scope of orders of the Secretary of Defense. Department of Defense Instruction 6025.16 provides for the interstate portability of licensure for military medical responders.⁵⁹ This type of DoD Instruction is rare in the Federal government. For example, the Federal Bureau of Investigation, which also has medical personnel such as physicians and medical examiners, has no similar authority ensuring the portability of the licenses of FBI doctors. To augment the efficacy of §1094, 10 U.S.C. §1089, known as the Gonzales Act, is the only avenue available to sue a military practitioner. The Gonzales Act allows such suit in cases of a "negligent or a wrongful act or omission" by the medical personnel.⁶⁰

D. Liability of Medical Responders

Issues of liability for public and private sector emergency responders – agencies and workers — are very complicated. The protection of public health is a police power reserved to the States pursuant to the 10th Amendment. Emergency responders in the first instance are State and local workers, but variance among states with respect to liability precludes a uniform approach to liability. The Federal government, however, is primarily responsible for regulating interstate commerce and international areas and has some authority pursuant to the Interstate Commerce Clause of the Constitution for Federal assistance to States. Issues of liability are therefore

⁵⁸ Commonwealth of VA Emergency Services and Disaster Law of 2000 (2002), §44-146.13, *et seq.* (2002), §44-146.23(c).

⁵⁹ DoDI 6025.16, cited in: AFI 44-119, Attachment 30. Jun. 4, 2001. Available at: <http://www.e-publishing.af.mil/pubfiles/af/44/afi44-119/afi44-119.pdf>.

⁶⁰ 10 U.S.C. §1089(a).

relevant at both levels. Pursuant to some State laws, protection from liability is absolute; pursuant to others, protection is minimal.

1. Federal Liability

a) Federal Tort Claims Act

At the Federal level, the Federal Tort Claims Act (FTCA)⁶¹ waives the broad sovereign immunity of the Federal government for the negligent acts of its employees performed in the scope of their duties, and makes the Federal government liable for tort claims "under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."⁶² Thus, the Federal government retains sovereign immunity for governmental functions, *i.e.*, those functions that could not be performed by a private citizen. In addition, although district courts have exclusive jurisdiction over cases brought pursuant to the FTCA, the Courts must apply the law of the place in which the act or omission occurred.⁶³ The Act limits the type and amount of damages that may be awarded in a civil action against the government brought pursuant to the FTCA.⁶⁴ Finally, as a prerequisite to bringing suit in court for any damage, injury, or death caused by an employee of the Government acting within the scope of his employment, the individual must have filed a claim with the appropriate Federal agency and been denied.⁶⁵

The exceptions articulated in 28 U.S.C. §2860 qualifies the waiver of sovereign immunity provided in the FTCA. Three exceptions are particularly applicable when considering the liability of emergency responders. Subsection (f) specifically prohibits the bringing of "any claim for damages caused by the imposition or establishment of quarantine by the United States." Second, 28 U.S.C. §2860(a) prohibits suit against the Federal government for acts or omissions of its agencies and employees if the claim arose when they exercised due care in the execution of a statute or regulation.

b) Discretionary Function Exception

Third, in addition to the due care exception, 28 U.S.C. §2860(a) includes the "discretionary function exception." This exception prohibits suit against the government for acts or omissions of its agencies and employees if the claim arose in the exercise or performance or failure to exercise or perform a discretionary function.

⁶¹ 28 U.S.C. 2671, *et seq.* (2002).

⁶² 28 U.S.C. §1346(b). The Federal government is liable for the acts or omissions of an independent contractor only to the extent that the government exercised supervision over the contractor's daily activities and was authorized to control the details of the contractor's performance. *U.S. v. Orleans*, 425 U.S. 807 (1976).

⁶³ 28 U.S.C. §1346 (b).

⁶⁴ 28 U.S.C. §2674.

⁶⁵ 28 U.S.C. §2675. The Federal Employees Liability Reform and Tort Compensation Act (FELRTCA) provides for the substitution of a defendant employee with the Federal government once the Attorney General determines that the employee was acting within the scope of his or her employment. 28 U.S.C. §2679(d)(1). See however, *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*, 403 U.S. 388 (1971), which authorizes suit against individual Federal employees for claims based on injury to a constitutionally protected interest.

In the case *Berkovitz v. United States*, the Supreme Court addressed the discretionary function exception in the FTCA.⁶⁶ The case involved the two-month old Berkovitz child who, after taking an oral dose of the polio vaccine, became substantially paralyzed and required a respirator to breathe. In denying the claim against the National Institutes of Health, the Supreme Court stated:

The determination of whether the discretionary function exception bars a suit against the Government is guided by several established principles. This Court stated in *Varig* that "it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case." *Id.*, at 813. In examining the nature of the challenged conduct, a court must first consider whether the action is a matter of choice for the acting employee. This inquiry is mandated by the language of the exception; conduct cannot be discretionary unless it involves an element of judgment or choice. See *Dalehite v. United States*, 346 U.S. 15, 34 (1953) (stating that the exception protects "the discretion of the executive or the administrator to act according to one's judgment of the best course"). Thus, the discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow. In this event, the employee has no rightful option but to adhere to the directive. And if the employee's conduct cannot appropriately be the product of judgment or choice, then there is no discretion in the conduct for the discretionary function exception to protect. *Cf. Westfall v. Erwin*, 484 U.S. 292, 296-297 (1988) (recognizing that conduct that is not the product of independent judgment will be unaffected by threat of liability).

Moreover, assuming the challenged conduct involves an element of judgment, a court must determine whether that judgment is of the kind that the discretionary function exception was designed to shield. The basis for the discretionary function exception was Congress' desire to "prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *United States v. Varig Airlines*, *supra*, at 814. The exception, properly construed, therefore protects only governmental actions and decisions based on considerations of public policy. See *Dalehite v. United States*, *supra*, at 36 ("Where there is room for policy judgment and decision there is discretion"). In sum, the discretionary function exception insulates the Government from liability if the action challenged in the case involves the permissible exercise of policy judgment.⁶⁷

Berkovitz thus requires Courts to conduct a two-part inquiry before finding that the discretionary function is applicable in a particular case. First, the conduct must involve "an element of judgment or choice" and not be a course of action prescribed by a Federal law, regulation, or policy. Second, the court must find that the judgment exercised by the employee "is of a kind that the discretionary function exception was designed to shield," that is, "grounded in social, economic, and political policy."⁶⁸

c) Stafford Act

The Stafford Act addresses generally liability in the area of emergency response and

⁶⁶ *Berkovitz by Berkovitz v. U.S.*, 486 U.S. 531 (1988).

⁶⁷ *Berkovitz*, 486 U.S. 531, 536-37.

⁶⁸ *Id.*, at 537, citing *United States v. Varig Airlines*, 467 U.S. 797, 814 (1984). See also, *Gaubert v. United States*, 499 U.S. 315 (1991). For cases discussing principles of liability for non-discretionary work of Federal employees, see e.g., *Sunrise Village Mobile Home Park, L.C. v. United States*, 42 Fed. Cl. 392 (1998).

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consequence management. Section 5148 provides for nonliability of the Federal Government and provides:

The Federal Government shall not be liable for any claim based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty on the part of a Federal agency or an employee of the Federal Government in carrying out the provisions of this Act.⁶⁹

The language mirrors that of the discretionary function exception found in the FTCA, providing broad immunity from liability for acts or omissions of Federal agencies and employees engaged in emergency relief efforts that involves an element of judgment or choice.

In *Dureiko v. United States*, the Federal Circuit Court determined that a government agency loses the protection of the discretionary function exception by entering into a contract.⁷⁰ The plaintiffs had entered into an agreement with the Federal government after Hurricane Andrew to lease to FEMA spaces in their mobile home park in return for an agreement from the government to clean up any damages resulting from the hurricane to specified standards and without causing additional damage. That agreement was breached when a government contractor allegedly inflicted substantial damage on the mobile home park. The tort claims of the plaintiff were dismissed, because the emergency relief efforts were deemed a discretionary function protected from liability under the Stafford Act. The plaintiffs' suit in the Court of Federal Claims, based on a contract claim, was dismissed on the same grounds. The Federal Circuit reversed that ruling, however, holding that the government entered into a contract to repair the park to certain standards and the alleged breach of contract was not a discretionary function. The Court stated, "Although FEMA's initial decision to contract with Pine Isle necessarily involved 'an element of judgment or choice,' FEMA's subsequent compliance (or non-compliance) with the contract did not."

d) Liability Protection under the Homeland Security Act

With the initiative of the President to immunize health workers against smallpox after the terrorist attacks on September 11th, the question of mass vaccinations has been a major issue in the health care arena. Whether Federal and State governments have the authority to compel individuals to accept vaccination and treatment, and what liability attaches and to whom, should individuals become ill or die as a result of such vaccinations are two of the most important questions. In particular, health care providers and pharmaceutical companies expressed deep concern about liability that might arise from participation in the smallpox vaccination initiative.

Section 304 of the Homeland Security Act addresses, among other things, the administration of smallpox countermeasures by the Secretary of HHS in response to an actual or potential terrorist incident or other public health emergency. The section authorizes the Secretary of HHS to declare a public health emergency that "makes advisable the administration of a covered countermeasure to a category or categories of individuals."⁷¹ The Act provides an exclusive remedy against the United States for injury or death resulting from the administration of the smallpox countermeasure. It thereby provides protection from liability for those who

⁶⁹ 42 U.S.C. §5148.

⁷⁰ *Dureiko v. United States*, No. 99-5043 (Fed. Cir. April 14, 2000).

⁷¹ Pub. L. 107-296, Homeland Security Act of 2002, §304(c).

manufacture, distribute, or administer smallpox countermeasures to an individual during the period of the public health emergency declared by the Secretary. However, the United States may recover damages from any covered person who failed to fulfill his or her obligations under a contract with the United States or who carried out his or her obligation in a grossly negligent, reckless, or illegal manner.⁷²

e) Military Claims Act

The Military and Civilian Personnel Claims Act compensates for personal injury, death, or property damage incident to military service.⁷³ Claims that may be brought pursuant to the Military Claims Act include those brought for the negligent or wrongful act or omission of a Federal employee acting within the scope of his or her duty and claims based on noncombatant activities of the military department. The latter could include claims arising out of exercises, exhibitions and aircraft operations. Although the Military Claims Act is applicable worldwide, it applies only "under such regulations as the Secretary [of the military department] concerned may prescribe."⁷⁴ In addition, the Military Claims Act does not apply to any tort claim to which the FTCA applies.⁷⁵ Thus, it is applicable overseas when the FTCA does not apply, and, domestically, on military bases. Like the FTCA, the Military Claims Act is not applicable to certain claims. These include certain governmental activities, such as combat activities or enemy action. In particular, claims that are governed by the Federal Tort Claims Act are not cognizable under the Military Claims Act. Also excluded, among others, are claims arising out of enemy action or combat activities. Finally, the Act prohibits payment of a claim if the claimant or the claimant's agent or employee contributed to his or her personal property damage, injury, or death through negligent or wrongful acts. If there is such contributory fault, the claim may be allowed only "to the extent that the law of the place where the act or omission complained of occurred would permit recovery from a private individual under like circumstances."⁷⁶

2. State Liability for Emergency Response Measures Resulting in Damage, Injury, or Death

The Eleventh Amendment to the U.S. Constitution provides, "The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state." The Amendment provides protection to States against claims filed by foreign persons or residents of another State. In *Florida Department of State v. Treasure Salvors, Inc.*, the Supreme Court held that this sovereign immunity also held against suits filed against the State by its own citizens.⁷⁷ This case is indicative of how states have statutorily immunized from liability their employees who cause property damage, injury, or death while performing governmental functions such as law enforcement.

Governmental functions are distinguished from ministerial functions or functions the government

⁷² *Id.*

⁷³ 10 U.S.C. § 2733 (2002) (herein the Military Claims Act).

⁷⁴ 10 U.S.C. §2733 (a).

⁷⁵ 10 U.S.C. §2733 (b)(2).

⁷⁶ 10 U.S.C. §2733 (b)(4).

⁷⁷ *Florida Dept. of State v. Treasure Slavors, Inc.*, 458 U.S. 670, 685 (1982).

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performs in its proprietary capacity. Proprietary functions include profit-making enterprises such as hospitals and recreational facilities. Certain aspects of emergency response, such as firefighting and law enforcement, are inherently governmental in nature. Exceptions to State immunity include suits brought to compel compliance with State or Federal laws and suits that Congress mandates should be heard in Federal court.

a) State Tort Claims Act

Almost all States have tort claims acts mirroring the Federal Tort Claims Act that waives the sovereign immunity States hold. These acts immunize the discretionary functions of government officials and employees. Like the FTCA, the State laws generally provide that immunity does not apply when government employees are negligent in the conduct of routine activities. In such cases, the injured party should recover as if a private person did the action or omission. In addition, the discretionary function immunity does not apply where the employee failed to meet standards specified in Federal or State statutes or regulations. Emergency response actions such as the issuance of warnings and hazardous materials response, have been held to be discretionary functions. Most do not confer immunity for grossly negligent or willful acts. In addition, the statutes generally allow only limited compensatory damages in actions against the government.

b) Emergency Management Statutes

All States have emergency management statutes that govern their emergency and disaster response. In order to allow government employees to perform their jobs without fear of liability for actions within the scope of their employment, each of these statutes have provisions similar to that in the Stafford Act which provide immunity from lawsuits arising out of actions taken pursuant to the emergency management statute. The statutes vary from State to State: some have very broad immunity, others provide more restricted immunity. In most States, immunity requires an official declaration of a state of emergency.

New York's provision regarding liability of out-of-State emergency responders provides:

Officers or employees of a party state rendering aid in another state pursuant to this compact shall be considered agents of the requesting state for tort liability and immunity purposes and no party state or its officers or employees rendering aid in another state pursuant to this compact shall be liable on account or any act or omission in good faith on the part of such forces while so engaged or on account of the maintenance or use of any equipment or supplies in connection therewith. Good faith shall not include willful misconduct, gross negligence or recklessness.⁷⁸

Virginia's emergency statute has a more expansive liability provision. It exempts from liability the State, localities, its public and private agencies and employees, and Federal agencies, for emergency services activities, not involving willful misconduct, that are undertaken pursuant to the emergency services statute.⁷⁹ It preserves the rights of the injured party under the State's Workers' Compensation Act, pension laws, and acts of Congress. Immunity also extends to persons who voluntarily surrender real estate "for the purpose of sheltering persons, of emergency access, or of other uses relating to emergency services," should those persons negligently cause property loss or damage, injury, or death during an actual or impending

⁷⁸ NYS Exec. Law, Chapter 18, Article 2-B, §29-g.6.

⁷⁹ Commonwealth of VA Emergency Services and Disaster Law of 2000 (2002), §44-146.13, *et seq.* (2002), §44-146.23(c).

emergency. It exempts from liability emergency workers from other States with proper licenses or other permits from those States, as well as volunteers. In addition, it specifically addresses actions taken with respect to hazardous substances, exempting from liability negligently caused damage, injury or death that may result from rendering assistance or advice on an actual or threatened discharge of a hazardous substance, or actions taken in "preventing, cleaning up, treating, or disposing of" or attempting to do the same for any hazardous substance discharge.⁸⁰ On the other hand, States such as Alabama preserve the State's immunity in its entirety.

The Model State Emergency Health Powers Act suggests standard ways of dealing with several liability issues. First, Section 607(b)(3) provides that out-of-State emergency health care providers appointed to assist with the public health emergency:

shall not be held liable for any civil damages as a result of medical care or treatment related to the response to the public health emergency unless such damages result from providing, or failing to provide, medical care or treatment under circumstances demonstrating a reckless disregard for the consequences so as to affect the life or health of the patient.

In essence, the model law sets a high standard, that of "reckless disregard," for liability to attach to out-of-State medical responders. Simple negligence would not suffice.

Similar to the immunity from liability provided in the Stafford Act, Section 804 of the MSEHPA also provides for State immunity from liability, "except in cases of gross negligence or willful misconduct," for injury, death, or property damage resulting from compliance with the public health emergency law. In addition, Section 804 provides for immunity from liability for private persons who allow the public health authorities to use their real property for sheltering persons during the emergency and negligently cause injury, death, or property damage those persons. Also, persons, firms, and corporations cannot be civilly liable for the death or injury resulting from rendering assistance or advice or performing a contract at the request of the State, unless the death or injury resulted from gross negligence or willful misconduct. The only exception from the immunity from liability for private parties is for that party whose act or omission contributed to or caused the public health emergency.

In light of the immunity discussed above, which can only be waived by statute, suits brought alleging the negligent act or omission of State agencies and employees during emergency response actions are rarely successful. Thus, assertion of immunity by the States generally have been upheld in the following types of suits: those based on a failure to adequately prepare for or warn of a danger, unless the government had notice of the danger and the danger was not readily apparent to the populace at risk; for failure to enter into a mutual aid agreement; and for the malfunction of emergency systems.

V. Summary

In the event of a WMD incident, there are many significant medical and liability issues to consider when determining the appropriate method to manage the crisis. Not only are there

⁸⁰ *Id.* §44-146.23(e).

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issues regarding vaccination requirements and liability resulting from vaccinations, but also locating the appropriately vaccinated personnel to respond to a given WMD incident. Additionally, standardized response procedures and interstate recognition of medical licenses are necessary to facilitate timely and complete responses to crises with defined roles and actions for all participants in the responding chains of command.

As discussed throughout this section, there has been a recent concerted effort to coordinate bioterrorism responses across Federal, State, and local agencies. The passage of the Bioterrorism Act of 2002 and the development of the Model State Emergency Health Powers Act (MSEHPA) are especially important to facilitating WMD crisis management efforts. By allocating roles and procedures at various levels of government, consequence management activities can be efficiently carried out.

VI. Appendix: Citation Excerpts

United States Constitution, 1787
Amendment X, Rights Reserved to States, 1791
The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.
Amendment XI, Suits Against a State, 1795
The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state.

42 U.S.C. §1983, 2002
Civil Action for Deprivation of Rights
Sec. 1983. Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia.
Source: http://uscode.house.gov/usc.htm
UPDATE: None

42 U.S.C. §5148, 2002
Nonliability of Federal Government
Sec. 5148. The Federal Government shall not be liable for any claim based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty on the part of a Federal agency or an employee of the Federal Government in carrying out the provisions of this chapter
Source: http://uscode.house.gov/uscode-cgi/fastweb.exe?search
UPDATE: None

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Executive Order 12196, February 26, 1980, as amended by Executive Order 12608, September 9, 1987

Occupational Safety and Health Programs for Federal Employees

This document is included in its entirety on the Deskbook CD-ROM.

By the authority vested in me as President by the Constitution and statutes of the United States of America, including Section 7905 of Title 5 of the United States Code and in accord with Section 19 of the Occupational Safety and Health Act of 1970, as amended (29 U.S.C. 668), it is ordered:

1-1. *Scope of this Order.*

1-101. This order applies to all agencies of the Executive Branch except military personnel and uniquely military equipment, systems, and operations.

1-102. For the purposes of this order, the term "agency" means an Executive department, as defined in 5 U.S.C. 101, or any employing unit or authority of the Federal government, other than those of the judicial and legislative branches. Since section 19 of the Occupational Safety and Health Act ("the Act") covers all Federal employees, however, the Secretary of Labor ("the Secretary") shall cooperate and consult with the heads of agencies in the legislative and judicial branches of the government to help them adopt safety and health programs.

1-2. *Heads of Agencies.*

1-201. The head of each agency shall:

(a)Furnish to employees places and conditions of employment that are free from recognized hazards that are causing or are likely to cause death or serious physical harm.

(b)Operate an occupational safety and health program in accordance with the requirements of this order and basic program elements promulgated by the Secretary

(c)Designate an agency official with sufficient authority to represent the interest and support of the agency head to be responsible for the management and administration of the agency occupational safety and health program.

(d)Comply with all standards issued under section 6 of the Act, except where the Secretary approves compliance with alternative standards. When an agency head determines it necessary to apply a different standard, that agency head shall, after consultation with appropriate occupational safety and health committees where established, notify the Secretary and provide justification that equivalent or greater protection will be assured by the alternate standard.

(e)Assure prompt abatement of unsafe or unhealthy working condition. Whenever an agency cannot promptly abate such conditions, it shall develop an abatement plan setting forth a timetable for abatement and a summary of interim steps to protect employees.

Employees exposed to the conditions shall be informed of the provisions of the plan. When a hazard cannot be abated without assistance of the General Services Administration or other Federal lessor agency, an agency shall act with the lessor agency to secure abatement.

(f)Establish procedures to assure that no employee is subject to restraint, interference, coercion, discrimination or reprisal for filing a report of an unsafe or unhealthy working condition, or other participation in agency occupational safety and health program activities.

(g)Assure that periodic inspections of all agency workplaces are performed by personnel with equipment and competence to recognize hazards.

(h)Assure response to employee reports of hazardous conditions and require inspections within twenty-four hours for imminent dangers, three working days for potential serious conditions, and twenty working days for other conditions. Assure the right to anonymity of those making the reports.

(i)Assure that employee representatives accompany inspections of agency workplaces.

(j)Operate an occupational safety and health management information system, which shall include the maintenance of such records as the Secretary may require.

(k)Provide safety and health training for supervisory employees, employees responsible for conducting occupational safety and health inspections, all members of occupational safety and health committees where established, and other employees.

(l)Submit to the Secretary an annual report on the agency occupational safety and health program that includes information the Secretary prescribes.

UPDATE: None

Executive Order 12333, December 4, 1981

United States Intelligence Activities

This document is included in its entirety on the Deskbook CD-ROM.

Part 2 - Conduct of Intelligence Activities

2.1Need. Accurate and timely information about the capabilities, intentions and activities of foreign powers, organizations, or persons and their agents is essential to informed decision making in the areas of national defense and foreign relations. Collection of such information is a priority objective and will be pursued in a vigorous, innovative and responsible manner that is consistent with the Constitution and applicable law and respectful of the principles upon which the United States was founded.

2.2Purpose. This Order is intended to enhance human and technical collection techniques, especially those undertaken abroad, and the acquisition of significant foreign intelligence, as well as the detection and countering of international terrorist activities and espionage conducted by foreign powers. Set forth below are certain general principles that, in addition to and consistent with applicable laws, are intended to achieve the proper balance between the acquisition of essential information and protection of individual interests. Nothing in this Order shall be construed to apply to or interfere with any authorized civil or criminal law enforcement responsibility of any department or agency.

2.3Collection of Information. Agencies within the Intelligence Community are authorized to collect, retain or disseminate information concerning United States persons only in accordance with procedures established by the head of the agency concerned and approved by the Attorney General, consistent with the authorities provided by Part 1 of this Order. Those procedures shall permit collection, retention and dissemination of the following types of information:

- (a) Information that is publicly available or collected with the consent of the person concerned;
- (b) Information constituting foreign intelligence or counterintelligence, including such information concerning corporations or other commercial organizations. Collection within the United States of foreign intelligence not otherwise obtainable shall be undertaken by the FBI or, when significant foreign intelligence is sought, by other authorized agencies of the Intelligence Community, provided that no foreign intelligence collection by such agencies may be undertaken for the purpose of acquiring information concerning the domestic activities of United States persons;
- (c) Information obtained in the course of a lawful foreign intelligence, counterintelligence, international narcotics or international terrorism investigation;
- (d) Information needed to protect the safety of any persons or organizations, including those who are targets, victims or hostages of international terrorist organizations;
- (e) Information needed to protect foreign intelligence or counterintelligence sources or methods from unauthorized disclosure. Collection within the United States shall be undertaken by the FBI except that other agencies of the Intelligence Community may also collect such information concerning present or former employees, present or former intelligence agency contractors or their present or former employees, or applicants for any such employment or contracting;
- (f) Information concerning persons who are reasonably believed to be potential sources or contacts for the purpose of determining their suitability or credibility;
- (g) Information arising out of a lawful personnel, physical or communications security investigation;
- (h) Information acquired by overhead reconnaissance not directed at specific United States persons;
- (i) Incidentally obtained information that may indicate involvement in activities that may violate federal, state, local or foreign laws; and
- (j) Information necessary for administrative purposes.

In addition, agencies within the Intelligence Community may disseminate information, other than information derived from signals intelligence, to each appropriate agency within the Intelligence Community for purposes of allowing the recipient agency to determine whether the information is relevant to its responsibilities and can be retained by it.

2.4Collection Techniques. Agencies within the Intelligence Community shall use the least intrusive collection techniques feasible within the United States or directed against United States persons abroad. Agencies are not authorized to use such techniques as electronic surveillance, unconsented physical search, mail surveillance, physical surveillance, or monitoring devices unless they are in accordance with procedures established by the head of the agency concerned and approved by the Attorney General. Such procedures shall protect constitutional and other legal rights and limit use of such information to lawful governmental purposes. These procedures shall not authorize:

- (a) The CIA to engage in electronic surveillance within the United States except for the purpose of training, testing, or conducting countermeasures to hostile electronic surveillance;
- (b) Unconsented physical searches in the United States by agencies other than the FBI, except for:
 - (1) Searches by counterintelligence elements of the military services directed against military personnel within the United States or

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Executive Order 12333, December 4, 1981

abroad for intelligence purposes, when authorized by a military commander empowered to approve physical searches for law enforcement purposes, based upon a finding of probable cause to believe that such persons are acting as agents of foreign powers; and
(2) Searches by CIA of personal property of non-United States persons lawfully in its possession.

(c) Physical surveillance of a United States person in the United States by agencies other than the FBI, except for:

(1) Physical surveillance of present or former employees, present or former intelligence agency contractors or their present or former employees, or applicants for any such employment or contracting; and

(2) Physical surveillance of a military person employed by a nonintelligence element of a military service.

(d) Physical surveillance of a United States person abroad to collect foreign intelligence, except to obtain significant information that cannot reasonably be acquired by other means.

2.5Attorney General Approval. The Attorney General hereby is delegated the power to approve the use for intelligence purposes, within the United States or against a United States person abroad, of any technique for which a warrant would be required if undertaken for law enforcement purposes, provided that such techniques shall not be undertaken unless the Attorney General has determined in each case that there is probable cause to believe that the technique is directed against a foreign power or an agent of a foreign power. Electronic surveillance, as defined in the Foreign Intelligence Surveillance Act of 1978, shall be conducted in accordance with that Act, as well as this Order.

2.6Assistance to Law Enforcement Authorities. Agencies within the Intelligence Community are authorized to:

(a) Cooperate with appropriate law enforcement agencies for the purpose of protecting the employees, information, property and facilities of any agency within the Intelligence Community;

(b) Unless otherwise precluded by law or this Order, participate in law enforcement activities to investigate or prevent clandestine intelligence activities by foreign powers, or international terrorist or narcotics activities;

(c) Provide specialized equipment, technical knowledge, or assistance of expert personnel for use by any department or agency, or, when lives are endangered, to support local law enforcement agencies. Provision of assistance by expert personnel shall be approved in each case by the General Counsel of the providing agency; and

(d) Render any other assistance and cooperation to law enforcement authorities not precluded by applicable law.

2.7Contracting. Agencies within the Intelligence Community are authorized to enter into contracts or arrangements for the provision of goods or services with private companies or institutions in the United States and need not reveal the sponsorship of such contracts or arrangements for authorized intelligence purposes. Contracts or arrangements with academic institutions may be undertaken only with the consent of appropriate officials of the institution.

2.8Consistency With Other Laws. Nothing in this Order shall be construed to authorize any activity in violation of the Constitution or statutes of the United States.

2.9Undisclosed Participation in Organizations Within the United States. No one acting on behalf of agencies within the Intelligence Community may join or otherwise participate in any organization in the United States on behalf of any agency within the Intelligence Community without disclosing his intelligence affiliation to appropriate officials of the organization, except in accordance with procedures established by the head of the agency concerned and approved by the Attorney General. Such participation shall be authorized only if it is essential to achieving lawful purposes as determined by the agency head or designee. No such participation may be undertaken for the purpose of influencing the activity of the organization or its members except in cases where:

(a) The participation is undertaken on behalf of the FBI in the course of a lawful investigation; or

(b) The organization concerned is composed primarily of individuals who are not United States persons and is reasonably believed to be acting on behalf of a foreign power.

2.10Human Experimentation. No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines.

2.11Prohibition on Assassination. No person employed by or acting on behalf of the United States Government shall engage in, or conspire to engage in, assassination.

2.12Indirect Participation. No agency of the Intelligence Community shall participate in or request any person to undertake activities forbidden by this Order.

UPDATE

Executive Order 13284, February 28, 2003

Executive Order 12333, December 4, 1981

Amendment of Executive Orders, and Other Actions, in Connection With the Establishment of the Department of Homeland Security

Sec. 18. Executive Order 12333 of December 4, 1981 ("United States Intelligence Activities"), is amended in Part 3.4(f) by:

- (a) striking "and" at the end of subpart 3.4(f)(6);
- (b) striking the period and inserting "; and" at the end of subpart 3.4(f)(7); and
- (c) adding a new subpart 3.4(f)(8) to read as follows: "(8) Those elements of the Department of Homeland Security that are supervised by the Department's Under Secretary for Information Analysis and Infrastructure Protection through the Department's Assistant Secretary for Information Analysis, with the exception of those functions that involve no analysis of foreign intelligence information."

Sec. 19. Functions of Certain Officials in the Department of Homeland Security.

The Secretary of Homeland Security, the Deputy Secretary of Homeland Security, the Under Secretary for Information Analysis and Infrastructure Protection, Department of Homeland Security, and the Assistant Secretary for Information Analysis, Department of Homeland Security, each shall be considered a "Senior Official of the Intelligence Community" for purposes of Executive Order 12333, and all other relevant authorities, and shall:

- (a) recognize and give effect to all current clearances for access to classified information held by those who become employees of the Department of Homeland Security by operation of law pursuant to the Homeland Security Act of 2002 or by Presidential appointment;
 - (b) recognize and give effect to all current clearances for access to classified information held by those in the private sector with whom employees of the Department of Homeland Security may seek to interact in the discharge of their homeland security-related responsibilities;
 - (c) make all clearance and access determinations pursuant to Executive Order 12968 of August 2, 1995, or any successor Executive Order, as to employees of, and applicants for employment in, the Department of Homeland Security who do not then hold a current clearance for access to classified information; and
 - (d) ensure all clearance and access determinations for those in the private sector with whom employees of the Department of Homeland Security may seek to interact in the discharge of their homeland security-related responsibilities are made in accordance with Executive Order 12829 of January 6, 1993.
- Sec. 20. Pursuant to the provisions of section 1.4 of Executive Order 12958 of April 17, 1995 ("Classified National Security Information"), I hereby authorize the Secretary of Homeland Security to classify information originally as "Top Secret." Any delegation of this authority shall be in accordance with section 1.4 of that order or any successor Executive Orders.

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10 U.S.C. §1089 (2002)

Defense of Certain Suits Arising Out of Medical Malpractice

(a) The remedy against the United States provided by sections 1346(b) and 2672 of title 28 for damages for personal injury, including death, caused by the negligent or wrongful act or omission of any physician, dentist, nurse, pharmacist, or paramedical or other supporting personnel (including medical and dental technicians, nursing assistants, and therapists) of the armed forces, the National Guard while engaged in training or duty under section 316, 502, 503, 504, or 505 of title 32, the Department of Defense, the Armed Forces Retirement Home, or the Central Intelligence Agency in the performance of medical, dental, or related health care functions (including clinical studies and investigations) while acting within the scope of his duties or employment therein or therefore shall hereafter be exclusive of any other civil action or proceeding by reason of the same subject matter against such physician, dentist, nurse, pharmacist, or paramedical or other supporting personnel (or the estate of such person) whose act or omission gave rise to such action or proceeding. This subsection shall also apply if the physician, dentist, nurse, pharmacist, or paramedical or other supporting personnel (or the estate of such person) involved is serving under a personal services contract entered into under section 1091 of this title.

(b) The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or the estate of such person) for any such injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon such person or an attested true copy thereof to such person's immediate superior or to whomever was designated by the head of the agency concerned to receive such papers and such person shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the action or proceeding is brought, to the Attorney General and to the head of the agency concerned.

(c) Upon a certification by the Attorney General that any person described in subsection (a) was acting in the scope of such person's duties or employment at the time of the incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the District Court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merits that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State court.

(d) The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28, and with the same effect.

(e) For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to any cause of action arising out of a negligent or wrongful act or omission in the performance of medical, dental, or related health care functions (including clinical studies and investigations).

(f)(1) The head of the agency concerned may, to the extent that the head of the agency concerned considers appropriate, hold harmless or provide liability insurance for any person described in subsection (a) for damages for personal injury, including death, caused by such person's negligent or wrongful act or omission in the performance of medical, dental, or related health care functions (including clinical studies and investigations) while acting within the scope of such person's duties if such person is assigned to a foreign country or detailed for service with other than a Federal department, agency, or instrumentality or if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 1346(b) of title 28, for such damage or injury.

(2) With respect to the Secretary of Defense and the Armed Forces Retirement Home Board, the authority provided by paragraph (1) also includes the authority to provide for reasonable attorney's fees for persons described in subsection (a), as determined necessary pursuant to regulations prescribed by the head of the agency concerned.

(g) In this section, the term "head of the agency concerned" means -

- (1) the Director of Central Intelligence, in the case of an employee of the Central Intelligence Agency;
- (2) the Secretary of Transportation, in the case of a member or employee of the Coast Guard when it is not operating as a service in the Navy;
- (3) the Armed Forces Retirement Home Board, in the case of an employee of the Armed Forces Retirement Home; and
- (4) the Secretary of Defense, in all other cases.

Source: <http://uscode.house.gov/usc.htm>

10 U.S.C. §1089 (2002)
UPDATE
Pub. L. 107-296, Homeland Security Act of 2002
Amended by sec. 1704(b)(1), 116 Stat. 2314.

10 U.S.C. §1094 (2002)
Licensure Requirement for Health-Care Professionals
<p>(a)(1) A person under the jurisdiction of the Secretary of a military department may not provide health care independently as a health-care professional under this chapter unless the person has a current license to provide such care. In the case of a physician, the physician may not provide health care as a physician under this chapter unless the current license is an unrestricted license that is not subject to limitation on the scope of practice ordinarily granted to other physicians for a similar specialty by the jurisdiction that granted the license.</p> <p>(2) The Secretary of Defense may waive paragraph (1) with respect to any person in unusual circumstances. The Secretary shall prescribe by regulation the circumstances under which such a waiver may be granted.</p> <p>(b) The commanding officer of each health care facility of the Department of Defense shall ensure that each person who provides health care independently as a health-care professional at the facility meets the requirement of subsection (a).</p> <p>(c)(1) A person (other than a person subject to chapter 47 of this title) who provides health care in violation of subsection (a) is subject to a civil money penalty of not more than \$5,000.</p> <p>(2) The provisions of subsections (c) and (e) through (h) of section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) shall apply to the imposition of a civil money penalty under paragraph (1) in the same manner as they apply to the imposition of a civil money penalty under that section, except that for purposes of this subsection -</p> <p>(A) a reference to the Secretary in that section is deemed a reference to the Secretary of Defense; and</p> <p>(B) a reference to a claimant in subsection (e) of that section is deemed a reference to the person described in paragraph (1).</p> <p>(d)(1) Notwithstanding any law regarding the licensure of health care providers, a health-care professional described in paragraph (2) may practice the health profession or professions of the health-care professional in any State, the District of Columbia, or a Commonwealth, territory, or possession of the United States, regardless of whether the practice occurs in a health care facility of the Department of Defense, a civilian facility affiliated with the Department of Defense, or any other location authorized by the Secretary of Defense.</p> <p>(2) A health-care professional referred to in paragraph (1) is a member of the armed forces who -</p> <p>(A) has a current license to practice medicine, osteopathic medicine, dentistry, or another health profession; and</p> <p>(B) is performing authorized duties for the Department of Defense.</p> <p>(e) In this section:</p> <p>(1) The term "license" -</p> <p>(A) means a grant of permission by an official agency of a State, the District of Columbia, or a Commonwealth, territory, or possession of the United States to provide health care independently as a health-care professional; and</p> <p>(B) includes, in the case of such care furnished in a foreign country by any person who is not a national of the United States, a grant of permission by an official agency of that foreign country for that person to provide health care independently as a health-care professional.</p> <p>(2) The term "health-care professional" means a physician, providing direct patient care as may be designated by the Secretary of Defense in regulations.</p>
Source: http://uscode.house.gov/usc.htm
UPDATE: None

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10 U.S.C. §2733 (2002)

Military Personnel and Civilian Employees Claims Act (Military Claims Act)

Property loss; personal injury or death: incident to noncombat activities of Department of Army, Navy, or Air Force

(a) Under such regulations as the Secretary concerned may prescribe, he, or, subject to appeal to him, the Judge Advocate General of an armed force under his jurisdiction, or the chief Counsel of the Coast Guard, as appropriate, if designated by him, may settle, and pay in an amount not more than \$100,000, a claim against the United States for -

(1) damage to or loss of real property, including damage or loss incident to use and occupancy;

(2) damage to or loss of personal property, including property bailed to the United States and including registered or insured mail damaged, lost, or destroyed by a criminal act while in the possession of the Army, Navy, Air Force, Marine Corps, or Coast Guard, as the case may be; or

(3) personal injury or death;

either caused by a civilian officer or employee of that department, or the Coast Guard, or a member of the Army, Navy, Air Force, Marine Corps, or Coast Guard, as the case may be, acting within the scope of his employment, or otherwise incident to noncombat activities of that department, or the Coast Guard.

(b) A claim may be allowed under subsection (a) only if -

(1) it is presented in writing within two years after it accrues, except that if the claim accrues in time of war or armed conflict or if such a war or armed conflict intervenes within two years after it accrues, and if good cause is shown, the claim may be presented not later than two years after the war or armed conflict is terminated;

(2) it is not covered by section 2734 of this title or section 2672 of title 28;

(3) it is not for personal injury or death of such a member or civilian officer or employee whose injury or death is incident to his service;

(4) the damage to, or loss of, property, or the personal injury or death, was not caused wholly or partly by a negligent or wrongful act of the claimant, his agent, or his employee; or, if so caused, allowed only to the extent that the law of the place where the act or omission complained of occurred would permit recovery from a private individual under like circumstances; and

(5) it is substantiated as prescribed in regulations of the Secretary concerned.

For the purposes of clause (1), the dates of the beginning and ending of an armed conflict are the dates established by concurrent resolution of Congress or by a determination of the President.

(c) Payment may not be made under this section for reimbursement for medical, hospital, or burial services furnished at the expense of the United States.

(d) If the Secretary concerned considers that a claim in excess of \$100,000 is meritorious, and the claim otherwise is payable under this section, the Secretary may pay the claimant \$100,000 and report any meritorious amount in excess of \$100,000 to the Secretary of the Treasury for payment under section 1304 of title 31.

(e) Except as provided in subsection (d), no claim may be paid under this section unless the amount tendered is accepted by the claimant in full satisfaction.

(f) For the purposes of this section, a member of the National Oceanic and Atmospheric Administration or of the Public Health Service who is serving with the Navy or Marine Corps shall be treated as if he were a member of that armed force.

(g) Under regulations prescribed by the Secretary concerned, an officer or employee under the jurisdiction of the Secretary may settle a claim that otherwise would be payable under this section in an amount not to exceed \$25,000. A decision of the officer or employee who makes a final settlement decision under this section may be appealed by the claimant to the Secretary concerned or an officer or employee designated by the Secretary for that purpose.

(h) Under such regulations as the Secretary of Defense may prescribe, he or his designee has the same authority as the Secretary of a military department under this section with respect to the settlement of claims based on damage, loss, personal injury, or death caused by a civilian officer or employee of the Department of Defense acting within the scope of his employment or otherwise incident to noncombat activities of that department

Source: <http://uscode.house.gov/usc.htm>

UPDATE: None

28 U.S.C. §1346 (2002)

United States as Defendant

Sec. 1346. United States as defendant

(a) The district courts shall have original jurisdiction, concurrent with the United States Court of Federal Claims, of:

(1) Any civil action against the United States for the recovery of any internal-revenue tax alleged to have been erroneously or illegally assessed or collected, or any penalty claimed to have been collected without authority or any sum alleged to have been excessive or in any manner wrongfully collected under the internal-revenue laws;

(2) Any other civil action or claim against the United States, not exceeding \$10,000 in amount, founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort, except that the district courts shall not have jurisdiction of any civil action or claim against the United States founded upon any express or implied contract with the United States or for liquidated or unliquidated damages in cases not sounding in tort which are subject to sections 8(g)(1) and 10(a)(1) of the Contract Disputes Act of 1978. For the purpose of this paragraph, an express or implied contract with the Army and Air Force Exchange Service, Navy Exchanges, Marine Corps Exchanges, Coast Guard Exchanges, or Exchange Councils of the National Aeronautics and Space Administration shall be considered an express or implied contract with the United States.

(b)(1) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

(2) No person convicted of a felony who is incarcerated while awaiting sentencing or while serving a sentence may bring a civil action against the United States or an agency, officer, or employee of the Government, for mental or emotional injury suffered while in custody without a prior showing of physical injury.

(c) The jurisdiction conferred by this section includes jurisdiction of any set-off, counterclaim, or other claim or demand whatever on the part of the United States against any plaintiff commencing an action under this section.

(d) The district courts shall not have jurisdiction under this section of any civil action or claim for a pension.

(e) The district courts shall have original jurisdiction of any civil action against the United States provided in section 6226, 6228(a), 7426, or 7428 (in the case of the United States district court for the District of Columbia) or section 7429 of the Internal Revenue Code of 1986.

(f) The district courts shall have exclusive original jurisdiction of civil actions under section 2409a to quiet title to an estate or interest in real property in which an interest is claimed by the United States.

(g) Subject to the provisions of chapter 179, the district courts of the United States shall have exclusive jurisdiction over any civil action commenced under section 453(2) of title 3, by a covered employee under chapter 5 of such title.

Source: <http://uscode.house.gov/usc.htm>

UPDATE: None

Domestic WMD Incident Management Legal Deskbook

28 U.S.C. §2671, et seq., 2002

Federal Tort Claims Act

This document is included in its entirety on the Deskbook CD-ROM.

Section 2674. Liability of United States

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.

If, however, in any case wherein death was caused, the law of the place where the act or omission complained of occurred provides, or has been construed to provide, for damages only punitive in nature, the United States shall be liable for actual or compensatory damages, measured by the pecuniary injuries resulting from such death to the persons respectively, for whose benefit the action was brought, in lieu thereof.

With respect to any claim under this chapter, the United States shall be entitled to assert any defense based upon judicial or legislative immunity which otherwise would have been available to the employee of the United States whose act or omission gave rise to the claim, as well as any other defenses to which the United States is entitled.

With respect to any claim to which this section applies, the Tennessee Valley Authority shall be entitled to assert any defense which otherwise would have been available to the employee based upon judicial or legislative immunity, which otherwise would have been available to the employee of the Tennessee Valley Authority whose act or omission gave rise to the claim as well as any other defenses to which the Tennessee Valley Authority is entitled under this chapter.

Section 2675. Disposition by Federal agency as prerequisite; evidence

(a) An action shall not be instituted upon a claim against the United States for money damages for injury or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, unless the claimant shall have first presented the claim to the appropriate Federal agency and his claim shall have been finally denied by the agency in writing and sent by certified or registered mail. The failure of an agency to make final disposition of a claim within six months after it is filed shall, at the option of the claimant any time thereafter, be deemed a final denial of the claim for purposes of this section. The provisions of this subsection shall not apply to such claims as may be asserted under the Federal Rules of Civil Procedure by third party complaint, cross-claim, or counterclaim.

(b) Action under this section shall not be instituted for any sum in excess of the amount of the claim presented to the federal agency, except where the increased amount is based upon newly discovered evidence not reasonably discoverable at the time of presenting the claim to the federal agency, or upon allegation and proof of intervening facts, relating to the amount of the claim.

(c) Disposition of any claim by the Attorney General or other head of a federal agency shall not be competent evidence of liability or amount of damages.

Section 2680. Exceptions

The provisions of this chapter and section 1346(b) of this title shall not apply to—

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

(b) Any claim arising out of the loss, miscarriage, or negligent transmission of letters or postal matter.

(c) Any claim arising in respect of the assessment or collection of any tax or customs duty, or the detention of any goods or merchandise by any officer of customs or excise or any other law-enforcement officer.

(d) Any claim for which a remedy is provided by sections 741-752, 781-790 of Title 46, relating to claims or suits in admiralty against the United States.

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(e) Any claim arising out of an act or omission of any employee of the Government in administering the provisions of sections 1-31 of Title 50, Appendix.

(f) Any claim for damages caused by the imposition or establishment of a quarantine by the United States.

[(g) Repealed. Sept. 26, 1950, c. 1049, § 13(5), 64 Stat. 1043.]

(h) Any claim arising out of assault, battery, false imprisonment, false arrest, malicious prosecution, abuse of process, libel, slander, misrepresentation, deceit, or interference with contract rights: Provided, That, with regard to acts or omissions of investigative or law enforcement officers of the United States Government, the provisions of this chapter and section 1346(b) of this title shall apply to any claim arising, on or after the date of the enactment of this proviso, out of assault, battery, false imprisonment, false arrest, abuse of process, or malicious prosecution. For the purpose of this subsection, "investigative or law enforcement officer" means any officer of the United States who is empowered by law to execute searches, to seize evidence, or to make arrests for violations of Federal law.

(i) Any claim for damages caused by the fiscal operations of the Treasury or by the regulation of the monetary system.

(j) Any claim arising out of the combatant activities of the military or naval forces, or the Coast Guard, during time of war.

(k) Any claim arising in a foreign country.

(l) Any claim arising from the activities of the Tennessee Valley Authority.

(m) Any claim arising from the activities of the Panama Canal Company.

(n) Any claim arising from the activities of a Federal land bank, a Federal intermediate credit bank, or a bank for cooperatives.

Source: <http://uscode.house.gov/usc.htm>

UPDATE: None

**Domestic WMD Incident Management
Legal Deskbook**

29 U.S.C. §651, et seq. (2002)

Occupational Safety and Health Act

This document is included in its entirety on the Deskbook CD-ROM.

Sec. 654. Duties of employers and employees

(a) Each employer -

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his own actions and conduct.

Sec. 655. Standards

(a) Promulgation by Secretary of national consensus standards and established Federal standards; time for promulgation; conflicting standards

Without regard to chapter 5 of title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

(b) Procedure for promulgation, modification, or revocation of standards

The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this chapter, the Secretary may request the recommendations of an advisory committee appointed under section 656 of this title. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health and Human Services, together with all pertinent factual information developed by the Secretary or the Secretary of Health and Human Services, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefore and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of

29 U.S.C. §651, et seq. (2002)

health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)

(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: Provided, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance, (ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefore, (iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard, (iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and (v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means. A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health and Human Services certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health and Human Services designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health and Human Services, such examinations may be furnished at the expense of the Secretary of Health and Human Services. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health and Human Services, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.

(c) Emergency temporary standards

(1) The Secretary shall provide, without regard to the requirements of chapter 5 of title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines

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(A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and

(B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

(d) Variances from standards; procedures

Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Statement of reasons for Secretary's determinations; publication in Federal Register

Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this chapter, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Judicial review

Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) Priority for establishment of standards

In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health and Human Services regarding the need for mandatory standards in determining the priority for establishing such standards

Source: <http://www4.law.cornell.edu/uscode/29/ch15.html>

UPDATE

Pub. L. 108-7, Consolidated Appropriations Resolution 2003

New note added to 29 U.S.C. §670

42 U.S.C. §1320d, et seq. (2002)

Administrative Simplification

Sec. 1320d. - Definitions

For purposes of this part:

(4) Health information

The term "health information" means any information, whether oral or recorded in any form or medium, that -

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

(6) Individually identifiable health information

The term "individually identifiable health information" means any information, including demographic information collected from an individual, that -

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and -

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

Sec. 1320d-1. - General requirements for adoption of standards

(a) Applicability

Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1320d-2(a)(1) of this title.

(b) Reduction of costs

Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) Role of standard setting organizations

(1) In general

Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) Special rules

(A) Different standards

The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if -

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5.

(B) No standard by standard setting organization

If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part -

(i) paragraph (1) shall not apply; and

(ii) subsection (f) of this section shall apply.

(3) Consultation requirement

(A) In general

A standard may not be adopted under this part unless -

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f) of this section, consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) Organizations described

The organizations referred to in subparagraph (A) are the following:

(i) The National Uniform Billing Committee.

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(ii) The National Uniform Claim Committee.

(iii) The Workgroup for Electronic Data Interchange.

(iv) The American Dental Association.

(d) Implementation specifications

The Secretary shall establish specifications for implementing each of the standards adopted under this part.

(e) Protection of trade secrets

Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

(f) Assistance to Secretary

In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 242k(k) of this title, and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) Application to modifications of standards

This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1320d-3(b) of this title in the same manner as it applies to an initial standard adopted under section 1320d-3(a) of this title.

Sec. 1320d-2. - Standards for information transactions and data elements

(a) Standards to enable electronic exchange

(1) In general

The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for -

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

(2) Transactions

The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

(A) Health claims or equivalent encounter information.

(B) Health claims attachments.

(C) Enrollment and disenrollment in a health plan.

(D) Eligibility for a health plan.

(E) Health care payment and remittance advice.

(F) Health plan premium payments.

(G) First report of injury.

(H) Health claim status.

(I) Referral certification and authorization.

(3) Accommodation of specific providers

The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

(b) Unique health identifiers

(1) In general

The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

(2) Use of identifiers

The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

(c) Code sets

(1) In general

The Secretary shall adopt standards that -

(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) of this section from among the code sets that have been developed by private and public entities; or

(B) establish code sets for such data elements if no code sets for the data elements have been developed.

(2) Distribution

The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1320d-3(b) of this title.

(d) Security standards for health information

42 U.S.C. §1320d, et seq. (2002)

(1) Security standards

The Secretary shall adopt security standards that -

(A) take into account -

- (i) the technical capabilities of record systems used to maintain health information;
- (ii) the costs of security measures;
- (iii) the need for training persons who have access to health information;
- (iv) the value of audit trails in computerized record systems; and
- (v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

(2) Safeguards

Each person described in section 1320d-1(a) of this title who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards -

(A) to ensure the integrity and confidentiality of the information;

(B) to protect against any reasonably anticipated -

- (i) threats or hazards to the security or integrity of the information; and
- (ii) unauthorized uses or disclosures of the information; and

(C) otherwise to ensure compliance with this part by the officers and employees of such person.

(e) Electronic signature

(1) Standards

The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1) of this section.

(2) Effect of compliance

Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1) of this section.

(f) Transfer of information among health plans

The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan

Sec. 1320d-5. - General penalty for failure to comply with requirements and standards

(a) General penalty

(1) In general

Except as provided in subsection (b) of this section, the Secretary shall impose on any person who violates a provision of this part a penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

(2) Procedures

The provisions of section 1320a-7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1320a-7a of this title.

(b) Limitations

(1) Offenses otherwise punishable

A penalty may not be imposed under subsection (a) of this section with respect to an act if the act constitutes an offense punishable under section 1320d-6 of this title.

(2) Noncompliance not discovered

A penalty may not be imposed under subsection (a) of this section with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

(3) Failures due to reasonable cause

(A) In general

Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) of this section if -

- (i) the failure to comply was due to reasonable cause and not to willful neglect; and
- (ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) Extension of period

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42 U.S.C. §1320d, et seq. (2002)

(i) No penalty

The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(4) Reduction In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) of this section that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved

Sec. 1320d-6. - Wrongful disclosure of individually identifiable health information

(a) Offense

A person who knowingly and in violation of this part -

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b) of this section.

(b) Penalties

A person described in subsection (a) of this section shall -

(1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both

Source: <http://www4.law.cornell.edu/>

UPDATE: None

50 U.S.C. §401, et seq. (2002)
National Security Act
<i>This document is included in its entirety on the Deskbook CD-ROM.</i>
Purpose: To provide programs, policies, procedures, and roles for various agencies and departments relating to national security.
UPDATE
Pub. L. 107-306 Intelligence Authorization Act for Fiscal Year 2003, 2002
New note added by secs. 109, 352, 402, 801, 901, and 1001-1011 Note amended by secs. 401, 841, and 811 Amended by secs. 321, 324, 342, 353, 811, 821, 822, 841, and 903 New section added or section amended generally by secs. 311, 313, 331, 341, 342, 343, 502, 811, 823, 827, 902, and 904
Pub. L. 107-248, Department of Defense Appropriations Act for FY2003
New note added by secs. 8058(b) and 8042
Pub. L. 107-296, The Homeland Security Act of 2002
Amended by sec. 897(a)
Pub. L. 108-87 Department of Defense Appropriations Act for FY 2004
New note added by secs. 8042 and 8057(b)

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Pub. L. 107-188 (2002)

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

This document is included in its entirety on the Deskbook CD-ROM.

SEC. 107. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

Part B of title III of the Public Health Service Act, as amended by section 106 of this Act, is amended by inserting after section 319H the following section:

SEC. 319I. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

(a) IN GENERAL- The Secretary shall, directly or through an award of a grant, contract, or cooperative agreement, establish and maintain a system for the advance registration of health professionals for the purpose of verifying the credentials, licenses, accreditations, and hospital privileges of such professionals when, during public health emergencies, the professionals volunteer to provide health services (referred to in this section as the 'verification system'). In carrying out the preceding sentence, the Secretary shall provide for an electronic database for the verification system.

(b) CERTAIN CRITERIA- The Secretary shall establish provisions regarding the promptness and efficiency of the system in collecting, storing, updating, and disseminating information on the credentials, licenses, accreditations, and hospital privileges of volunteers described in subsection (a).

(c) OTHER ASSISTANCE- The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification system developed under subsection (a).

(d) COORDINATION AMONG STATES- The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State.

(e) RULE OF CONSTRUCTION- This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(f) AUTHORIZATION OF APPROPRIATIONS- For the purpose of carrying out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.'

SEC. 121. STRATEGIC NATIONAL STOCKPILE.

(a) STRATEGIC NATIONAL STOCKPILE-

(1) IN GENERAL- The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in coordination with the Secretary of Veterans Affairs, shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency.

(2) PROCEDURES- The Secretary, in managing the stockpile under paragraph (1), shall--

(A) consult with the working group under section 319F(a) of the Public Health Service Act;

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure; and

(F) ensure the adequate physical security of the stockpile.

(b) SMALLPOX VACCINE DEVELOPMENT-

(1) IN GENERAL- The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by the Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION- Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) DISCLOSURES- No Federal agency shall disclose under section 552, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(d) DEFINITION- For purposes of subsection (a), the term 'stockpile' includes--

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to the Secretary supplies described in subsection (a).

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(e) AUTHORIZATION OF APPROPRIATIONS-

(1) STRATEGIC NATIONAL STOCKPILE- For the purpose of carrying out subsection (a), there are authorized to be appropriated \$640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(2) SMALLPOX VACCINE DEVELOPMENT- For the purpose of carrying out subsection (b), there are authorized to be appropriated \$509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

UPDATE: None

**Domestic WMD Incident Management
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Pub. L. 107-296 (2002)

Homeland Security Act of 2002

This document is included in its entirety on the Deskbook CD-ROM.

SEC. 304. CONDUCT OF CERTAIN PUBLIC HEALTH-RELATED ACTIVITIES.

(a) IN GENERAL- With respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats carried out by the Department of Health and Human Services (including the Public Health Service), the Secretary of Health and Human Services shall set priorities, goals, objectives, and policies and develop a coordinated strategy for such activities in collaboration with the Secretary of Homeland Security to ensure consistency with the national policy and strategic plan developed pursuant to section 302(2).

(b) EVALUATION OF PROGRESS- In carrying out subsection (a), the Secretary of Health and Human Services shall collaborate with the Secretary in developing specific benchmarks and outcome measurements for evaluating progress toward achieving the priorities and goals described in such subsection.

(c) ADMINISTRATION OF COUNTERMEASURES AGAINST SMALLPOX- Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding the following:

(p) ADMINISTRATION OF SMALLPOX COUNTERMEASURES BY HEALTH PROFESSIONALS-

(1) IN GENERAL- For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

(2) DECLARATION BY SECRETARY CONCERNING COUNTERMEASURE AGAINST SMALLPOX-

(A) AUTHORITY TO ISSUE DECLARATION-

(i) IN GENERAL- The Secretary may issue a declaration, pursuant to this paragraph, concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals.

(ii) COVERED COUNTERMEASURE- The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (8)(A)) for purposes of administration to individuals during the effective period of the declaration.

(iii) EFFECTIVE PERIOD- The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

(iv) PUBLICATION- The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

(B) LIABILITY OF UNITED STATES ONLY FOR ADMINISTRATIONS WITHIN SCOPE OF DECLARATION- Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual only if--

(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

(ii)(I) the individual was within a category of individuals covered by the declaration; or

(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

(C) PRESUMPTION OF ADMINISTRATION WITHIN SCOPE OF DECLARATION IN CASE OF ACCIDENTAL VACCINIA INOCULATION-

(i) IN GENERAL- If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual--

(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

(II) shall (unless such presumption is rebutted) be deemed for purposes of this subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

(ii) CIRCUMSTANCES IN WHICH PRESUMPTION APPLIES- The presumption and deeming stated in clause (i) shall apply if--

(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph (A) or by the date 30 days after the close of such period; or

(II) the individual resides or has resided with an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccinia after such date.

(3) EXCLUSIVITY OF REMEDY- The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses.

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`(4) CERTIFICATION OF ACTION BY ATTORNEY GENERAL- Subsection (c) applies to actions under this subsection, subject to the following provisions:

`(A) NATURE OF CERTIFICATION- The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

`(B) CERTIFICATION OF ATTORNEY GENERAL CONCLUSIVE- The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

`(5) DEFENDANT TO COOPERATE WITH UNITED STATES-

`(A) IN GENERAL- A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

`(B) CONSEQUENCES OF FAILURE TO COOPERATE- Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate--

`(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

`(ii) the United States shall not be liable based on the acts or omissions of such person; and

`(iii) the Attorney General shall not be obligated to defend such action.

`(6) RECOURSE AGAINST COVERED PERSON IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION-

`(A) IN GENERAL- Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

`(B) VENUE- The United States may maintain an action under this paragraph against such person in the district court of the United States in which such person resides or has its principal place of business.

`(7) DEFINITIONS- As used in this subsection, terms have the following meanings:

`(A) COVERED COUNTERMEASURE- The term 'covered countermeasure' or 'covered countermeasure against smallpox', means a substance that is--

`(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

`(II) vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and

`(ii) specified in a declaration under paragraph (2).

`(B) COVERED PERSON- The term 'covered person', when used with respect to the administration of a covered countermeasure, includes any person who is--

`(i) a manufacturer or distributor of such countermeasure;

`(ii) a health care entity under whose auspices such countermeasure was administered;

`(iii) a qualified person who administered such countermeasure; or

`(iv) an official, agent, or employee of a person described in clause (i), (ii), or (iii).

`(C) QUALIFIED PERSON- The term 'qualified person', when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered.'

Source: <http://thomas.loc.gov/bss/d107/d107laws.html>

UPDATE: None

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Pub. L. 108-20 (2003)

Smallpox Emergency Personnel Protection Act of 2003

This document is included in its entirety in Appendix B on the Deskbook CD-ROM.

SEC. 2. SMALLPOX EMERGENCY PERSONNEL PROTECTION.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following part:

Part C--Smallpox Emergency Personnel Protection

SEC. 261. GENERAL PROVISIONS.

(a) Definitions.--For purposes of this part:

(1) Covered countermeasure.--The term 'covered countermeasure' means a covered countermeasure as specified in a Declaration made pursuant to section 224(p). (2) Covered individual.--The term 'covered individual' means an individual--

(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties; (B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in paragraph (7)) approved by the Secretary; (C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and (D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before the enactment of this part).

(3) Covered injury.--The term 'covered injury' means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 262, to have been sustained by an individual as the direct result of--

(A) administration to the individual of a covered countermeasure during the effective period of the Declaration; or (B) accidental vaccinia inoculation of the individual in circumstances in which-- (i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period; (ii) smallpox vaccine has not been administered to the individual; and (iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.

(4) Declaration.--The term 'Declaration' means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003.

(5) Effective period of the declaration.--The term 'effective period of the Declaration' means the effective period specified in the Declaration, unless extended by the Secretary.

(6) Eligible individual.--The term 'eligible individual' means an individual who is (as determined in accordance with section 262)--

(A) a covered individual who sustains a covered injury in the manner described in paragraph (3)(A); or (B) an individual who sustains a covered injury in the manner described in paragraph (3)(B).

(7) Smallpox emergency response plan.--The term 'smallpox emergency response plan' or 'plan' means a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

UPDATE: None

29 CFR Part 1903.15 (2003)

Occupational Safety and Health Standards: Proposed Penalties

§ 1903.15 Proposed penalties.

(a) After, or concurrent with, the issuance of a citation, and within a reasonable time after the termination of the inspection, the Area Director shall notify the employer by certified mail or by personal service by the Compliance Safety and Health Officer of the proposed penalty under section 17 of the Act, or that no penalty is being proposed. Any notice of proposed penalty shall state that the proposed penalty shall be deemed to be the final order of the Review Commission and not subject to review by any court or agency unless, within 15 working days from the date of receipt of such notice, the employer notifies the Area Director in writing that he intends to contest the citation or the notification of proposed penalty before the Review Commission.

UPDATE: None

29 CFR Parts 1910.120 & 1910.1030 (2003)
Occupational Safety and Health Standards
<i>These Parts are included in their entirety on the Deskbook CD-ROM.</i>
Purpose: Establishes various procedures and policies with regards to Hazardous Substances and Blood-borne Pathogens.
UPDATE: None

42 CFR Part 71 (2002)
Foreign Quarantine
<i>This document is included in its entirety in Appendix B on the Deskbook CD-ROM.</i>
Purpose: Regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or possessions of the United States.
UPDATE: None

45 CFR Part 164 (2002)
Security and Privacy
<i>This document is included in its entirety in Appendix B on the Deskbook CD-ROM.</i>
Purpose: Outlines regulations for information dissemination regarding medical and other health records.
Source: http://www.hipaaprivacyworkgroups.com/Regs/
UPDATE: None

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42 CFR Part 70 (2002)

Interstate Quarantine

This document is included in its entirety on the Deskbook CD-ROM.

Sec. 70.1 General definitions.

As used in this part, terms shall have the following meaning:

(a) Communicable diseases means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(b) Communicable period means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(c) Conveyance means any land or air carrier, or any vessel as defined in paragraph (h) of this section.

(d) Incubation period means the period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(e) Interstate traffic means:

(1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession--

(i) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(f) Possession means any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(g) State means any State, the District of Columbia, Puerto Rico, and the Virgin Islands.

(h) Vessel means any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

Sec. 70.2 Measures in the event of inadequate local control.

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

Sec. 70.3 All communicable diseases.

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession, or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

Sec. 70.4 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

Sec. 70.5 Certain communicable diseases; special requirements.

The following provisions are applicable with respect to any person who is in the communicable period of cholera, plague, smallpox, typhus or yellow fever, or who, having been exposed to any such disease, is in the incubation period thereof:

(a) Requirements relating to travelers.

42 CFR Part 70 (2002)

- (1) No such person shall travel from one State or possession to another, or on a conveyance engaged in interstate traffic, without a written permit of the Surgeon General or his/her authorized representative.
- (2) Application for a permit may be made directly to the Surgeon General or to his/her representative authorized to issue permits.
- (3) Upon receipt of an application, the Surgeon General or his/her authorized representative shall, taking into consideration the risk of introduction, transmission, or spread of the disease from one State or possession to another, reject it, or issue a permit that may be conditioned upon compliance with such precautionary measures as he/she shall prescribe.
- (4) A person to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances as required by its terms.
- (b) Requirements relating to operation of conveyances.
- (1) The operator of any conveyance engaged in interstate traffic shall not knowingly:
- (i) Accept for transportation any person who fails to present a permit as required by paragraph (a) of this section; or
 - (ii) Transport any person in violation of conditions prescribed in his/her permit.
- (2) Whenever a person subject to the provisions of this section is transported on a conveyance engaged in interstate traffic, the operator thereof shall take such measures to prevent the spread of the disease, including submission of the conveyance to inspection, disinfection and the like, as an officer of the Public Health Service designated by the Surgeon General for such purposes deems reasonably necessary and directs.

Sec. 70.6 Apprehension and detention of persons with specific diseases.

Regulations prescribed in this part are not applicable to the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of the following diseases: Anthrax, chancroid, cholera, dengue, diphtheria, granuloma inguinale, infectious encephalitis, favus, gonorrhea, leprosy, lymphogranuloma venereum, meningococcus meningitis, plague, poliomyelitis, psittacosis, relapsing fever, ringworm of the scalp, scarlet fever, streptococcic sore throat, smallpox, syphilis, trachoma, tuberculosis, typhoid fever, typhus, and yellow fever.

Sec. 70.7 Responsibility with respect to minors, wards, and patients.

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

Sec. 70.8 Members of military and naval forces.

The provisions of Secs. 70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: Provided, That in the case of persons otherwise subject to the provisions of Sec. 70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

UPDATE

Executive Order 13295, Revised List of Quarantinable Communicable Diseases, April 4, 2003

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)), it is hereby ordered as follows:

Section 1. Based upon the recommendation of the Secretary of Health and Human Services (the "Secretary"), in consultation with the Surgeon General, and for the purpose of specifying certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, the following communicable diseases are hereby specified pursuant to section 361(b) of the Public Health Service Act:

(a) Cholera; Diphtheria; infectious Tuberculosis; Plague; Smallpox; Yellow Fever; and Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named).

(b) Severe Acute Respiratory Syndrome (SARS), which is a disease associated with fever and signs and symptoms of pneumonia or other respiratory illness, is transmitted from person to person predominantly by the aerosolized or droplet route, and, if spread in the population, would have severe public health consequences.

Sec. 2. The Secretary, in the Secretary's discretion, shall determine whether a particular condition constitutes a communicable disease

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of the type specified in section 1 of this order.

Sec. 3. The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the Secretary.

Sec. 4. This order is not intended to, and does not, create any right or benefit enforceable at law or equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

Sec. 5. Executive Order 12452 of December 22, 1983, is hereby revoked.

GEORGE W. BUSH

THE WHITE HOUSE,

April 4, 2003.

45 CFR Part 160 (2002)

General Administrative Requirements

This document is included in its entirety on the Deskbook CD-ROM

Subpart A - General Provisions

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. 104-191), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

§ 160.103 Definitions. Except as otherwise provided, the following definitions apply to this subchapter:

Covered entity means:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

- (1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or
- (2) Is administered by an entity other than the employer that established and maintains the plan.

Health information means any information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Subpart B - Preemption of State Law

§ 160.203 General rule and exceptions. A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

- (1) Is necessary:
 - (i) To prevent fraud and abuse related to the provision of or payment for health care;
 - (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;
 - (iii) For State reporting on health care delivery or costs; or
 - (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or
- (2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

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45 CFR Part 160 (2002)

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

- (1) The State law for which the exception is requested;
- (2) The particular standard, requirement, or implementation specification for which the exception is requested;
- (3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;
- (4) How health care providers, health plans, and other entities would be affected by the exception;
- (5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and
- (6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations. An exception granted under this subpart remains in effect until:

- (a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or
- (b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Source: <http://www.hipaaprivacyworkgroups.com/Regs/>

UPDATE: None

DoDI 6205.2, October 9, 1986

Immunization Requirements

This document is included in its entirety on the Deskbook CD-ROM

1. PURPOSE

This Instruction addresses immunization policies for all members of the Armed Forces, civilian employees of the Department of Defense, and all eligible beneficiaries of the military health care system as established by reference (a). It requires implementation of programs that minimize individual illness and disability, days lost from work, and impairment of operational capabilities from conditions that are preventable through immunization. Immunization requirements contained in this Instruction complement immunization, preventive medicine, and health promotion requirements listed in references (a) through (j) and implement the Public Health Service plans for attaining the immunization objectives for the nation.

2. APPLICABILITY AND SCOPE This Instruction:

- 2.1. Applies to the Office of the Secretary of Defense (OSD), the Military Departments (including their National Guard and Reserve components), the Organization of the Joint Chiefs of Staff (OJCS), and the Defense Agencies (hereafter referred to collectively as "DoD Components").
- 2.2. Addresses military-unique peacetime and contingency requirements such as global deployment and defense against potential biological warfare agents.
- 2.3. Provides protection for all eligible beneficiaries against vaccine preventable diseases.

3. POLICY It is DoD policy that:

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- 3.1. The general recommendations of the U.S. Public Health Service, as promulgated by the Centers for Disease Control (CDC) Immunization Practices Advisory Committee (ACIP) and published in CDC's Morbidity and Mortality Weekly Report (MMWR) shall be followed.
- 3.2. For those activities that are unique to the Military, the Military Departments shall develop appropriate immunization procedures in consultation with the Armed Forces Epidemiological Board, Armed Forces Medical Intelligence Center, and Armed Forces Pest Management Board, as required.
- 3.3. Health care beneficiaries shall be advised of the availability and indications for use of immunizing agents for vaccine preventable diseases. Particular emphasis shall be given to those conditions that affect operational readiness, pose a risk in the community and occupational environment, or are unique to a particular geographic or cultural setting.
- 3.4. Communicable disease reporting requirements and adverse vaccine reaction reporting requirements of civil authorities shall be complied with through liaison between the military public health jurisdiction and the appropriate local, state, or federal health jurisdiction.
- 3.5. Persons in specific occupations may need selected vaccines and toxoids in addition to those routinely recommended. Vaccinations shall be provided to all military and civilian employees when it is in the best interest of the Government.

4. RESPONSIBILITIES

4.1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) shall:

- 4.1.1. Monitor and evaluate the implementation and effectiveness of the immunization program, and make appropriate recommendations to the Secretary of Defense and the Secretaries of the Military Departments concerning changes or improvements in the program.
- 4.1.2. Establish a Disease Prevention and Control Coordinating Committee that shall:
 - 4.1.2.1. Provide a forum for discussion and review of procedures developed concerning the prevention and control of infectious diseases in military and civilian personnel and their dependents worldwide; the epidemiologic aspects of military mustering, training, and deployment activities; and the civilian community and public health implications of unique military activities.
 - 4.1.2.2. Identify military-unique requirements for vaccine research, development, and production in consultation with the Armed Forces Medical Intelligence Center, Armed Forces Epidemiological Board, and the Armed Forces Pest Management Board.
 - 4.1.2.3. Review Service implementation of DoD policies stated herein and recommend changes, as needed, to the ASD (HA).
- 4.2. The Assistant Secretary of Defense (Force Management and Personnel) shall promulgate policy for the use of immunizations in the prevention and/or amelioration of occupationally related diseases under DoD Instruction 6055.5 (reference (k)). Coordination shall be maintained between the DoD Disease Prevention and Control Coordinating Committee and the DoD Safety and Occupational Health Policy Council.
- 4.3. The Secretaries of the Military Departments shall:
 - 4.3.1. Develop and implement general principles and specific procedures to be followed in the prophylactic immunization programs of the Armed Forces. Prophylactic immunization includes the use of any vaccine, toxoid, or other immunizing agent for the prevention of

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Immunization Requirements

disease, including the maintenance of immune status by reimmunization.

4.3.2. Maintain a medical consultation capability to promulgate the requirements and recommendations herein, as applicable.

4.3.3. Consistent with the policies of DoD Directive 5000.19 (reference (h)), establish and implement uniform procedures for:

4.3.3.1. The identification, reporting, and epidemiologic evaluation of vaccine-associated adverse reactions and illnesses.

4.3.3.2. The identification, reporting, epidemiologic evaluation, and prevention of all cases of vaccine preventable illness.

5. EFFECTIVE DATE AND IMPLEMENTATION

This Instruction is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.

UPDATE: None

DoDD 6205.3, November 26, 1993

DoD Immunization Program for Biological Warfare Defense

This document is included in its entirety on the Deskbook CD-ROM

A. PURPOSE

This Directive:

1. Establishes policy, assigns responsibilities, and prescribes procedures for members of the Department of Defense against validated biological warfare threats, and prioritization of research, development, testing, acquisition, and stockpiling of biological defense vaccines under reference (a).
2. Provides vaccination guidance that focuses exclusively on defense against biological warfare threats and complements immunization requirements for naturally occurring endemic disease threats outlined in references (b) and (c).
3. Addresses peacetime and contingency requirements for immunization against biological warfare threats against U.S. personnel.
4. Designates the Secretary of the Army as the "DoD Executive Agent" for the DoD Immunization Program for Biological Warfare Defense.
5. Provides direction on levels of acquisition and stockpiling of biological defense vaccines and prioritizes research and development efforts in defending against current and emerging biological warfare threats.

B. APPLICABILITY AND SCOPE

This Directive applies to:

1. The Office of the Secretary of Defense, the Military Departments (including their National Guards), the Chairman of the Joint Chiefs of Staff, the Unified Commands, and the Defense Agencies (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.
2. Essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces.

C. DEFINITIONS

Terms used in this Directive are defined in enclosure 2.

D. POLICY

It is DoD policy that:

1. For immunization, the following personnel, subject to special exceptions approved by the Chairman of the Joint Chiefs of Staff, should be immunized against validated biological warfare threat agents, for which suitable vaccines are available, in sufficient time to develop immunity before deployment to high-threat areas:
 - a. Personnel assigned to high-threat areas.
 - b. Personnel predesignated for immediate contingency deployment (crisis response).
 - c. Personnel identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area.
2. For vaccine research, development, testing, evaluation, acquisition, and stockpiling, efforts for the improvement of existing vaccines and the development of new vaccines against all validated biological warfare threat agents shall be integrated and prioritized. The Department of Defense shall develop a capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threats.

E. RESPONSIBILITIES

1. The Under Secretary of Defense for Acquisition and Technology shall ensure the coordination and integration of the DoD Immunization Program for Biological Warfare Defense with all acquisition-related elements of the DoD Biological Defense Program.
2. The Under Secretary of Defense for Policy shall review all facets of the DoD Immunization Program for Biological Warfare Defense to ensure that it is consistent with DoD policy and is adequately integrated into overall DoD biological defense policies.
3. The Assistant Secretary of Defense for Health Affairs shall:
 - a. Serve as the advisor to the Secretary of Defense as in DoD Directive 5136.1 (reference (d)) on the DoD Immunization Program for Biological Warfare Defense.
 - b. In consultation with the DoD Executive Agent, the Secretaries of the Military Departments, and the Chair of the Armed Forces Epidemiological Board, identify vaccines available to protect against biological threat agents designated by the Chairman of the Joint Chiefs of Staff and recommend appropriate immunization protocols.
 - c. Issue instructions to the Military Departments and the other appropriate DoD Components on the immunization of DoD personnel, under the guidelines of this Directive, and monitor and evaluate the implementation of those instructions.
4. The Secretary of the Army, as the DoD Executive Agent for the Immunization Program for Biological Warfare Defense, shall:

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a. Besides those responsibilities in the Deputy Secretary of Defense Memorandum and the Joint Service Agreement (references (e) and (f)), do the following to enhance the DoD Immunization Program for Biological Warfare Defense, and report annually through the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to the Secretary of Defense the capability to carryout those policies:

(1) Vaccine Research and Development

Priorities developed in coordination with the ASD(HA), the Chairman of the Joint Chiefs of Staff, and the Secretaries of the Military Departments shall include the development of vaccines against validated biological warfare threat agents for which none exist, improvement of vaccines that are unacceptable in the time they take to produce immunity or in the level of immunity they produce or are inadequate because of the number of doses required to achieve immunity, assessment of the effectiveness of vaccines against biological warfare threat agents in their likely modes of use (e.g., aerosols), and development of multivalent vaccines that will produce protective immunity after a single vaccination. Vaccines must be either licensed by the Food and Drug Administration (FDA) or have been designated, under FDA requirements, "for use as investigational new drugs (INDs)," as in 21 CFR 50 (reference (g)).

(2) Vaccine Acquisition and Stockpiling

b. Develop and maintain a DoD capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threat agents for which suitable vaccines exist.

c. On an annual basis, provide information and recommendations, in coordination with the Secretaries of the Military Departments and the Chair of the Armed Forces Epidemiological Board, to the ASD(HA) on vaccines to acquire and appropriate immunization schedules that include reimmunization required to develop and maintain protective immunity. Those recommendations should include, but not be limited to the following:

(1) All relevant data on the effectiveness of each vaccine against the corresponding biological warfare threat agent.

(2) The expected type, frequency, and severity of vaccine-associated adverse reactions.

d. Serve as the focal point for the submission of information from the Services, as specified by subsection E.5., below, and monitor the Services' implementation of the DoD Immunization Program for Biological Warfare Defense. Recommend appropriate changes and improvements to the Secretary of Defense through the ASD(HA), and the Secretaries of the Military Departments. Report to the Secretary of Defense annually on the Immunization Program for Biological Warfare Defense.

e. The Executive Agent Acquisition Executive (AE) shall plan, program, and budget for biological defense. The AE shall coordinate directly with the ASD(HA), the Under Secretary of Defense for Policy, the Under Secretary of Defense for Acquisition, the Secretaries of the Departments, and other offices as required to ensure program integration.

5. The Secretaries of the Military Departments shall:

a. Implement, monitor, evaluate, and document the DoD Immunization Program for Biological Warfare Defense in their Department and establish procedures for coordinating and reporting the following information to the Executive Agent:

(1) The identification, reporting, and epidemiologic evaluation of vaccine -associated adverse reactions, in accordance with FDA requirements.

(2) The collection and forwarding of data required by the Executive Agent needed to meet requirements of the FDA for products that are the INDs.

b. Transmit the instructions of the ASD(HA) about the immunization program for biological warfare defense to subordinate units.

c. Program and budget for the required vaccinations for members of their Department and provide the DoD Executive Agent with projected program requirements.

6. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, Defense Intelligence Agency (DIA), annually and as required, shall validate and prioritize the biological warfare threats to DoD personnel and forward that list to the DoD Executive Agent through the ASD(HA).

7. The Commanders of the Unified Commands, annually and as required, shall provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theaters.

8. The Chair of the Armed Forces Epidemiological Board, in consultation with the DoD Executive Agent and the Secretaries of the Military Departments, annually and as required, shall identify to the ASD(HA) vaccines available to protect against validated biological warfare threat agents, and recommend appropriate immunization protocols.

F. PROCEDURES

The DoD Immunization Program for Biological Warfare Defense shall be conducted, as follows:

1. The Commanders of the Unified Commands, annually and as required, shall provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theater.

2. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, DIA, annually, shall validate and prioritize the biological warfare threats to DoD personnel and forward them to the DoD Executive Agent through the ASD(HA).

3. Within 30 days of receiving the validated and prioritized biological warfare threat list from the Chairman of the Joint Chiefs of Staff, the DoD Executive Agent shall, in consultation with the Secretaries of the Military Departments and the Chair of the Armed Forces

DoDD 6205.3, November 26, 1993

Epidemiology Board, provide recommendations to the ASD(HA) on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents.

4. Within 30 days of receiving the coordinated recommendations of the DoD Executive Agent, the ASD(HA) shall direct the Secretaries of the Military Departments to begin immunization of the specified DoD personnel against specific biological warfare threat agents.

5. For biological threats for which the only available vaccine is an ND, it shall be administered under 21 CFR 50 and 312 (reference (g)) and the established ND protocol and/or other applicable legal procedures.

G. INFORMATION REQUIREMENTS

The annual reporting requirements in section E., above, have been assigned Report Control Symbol DD-POL(A) 1921.

H. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. The Secretaries of the Military Departments shall forward one copy of implementing documents to the Assistant Secretary of Defense for Health Affairs within 120 days.

William J. Perry Deputy Secretary of Defense

Enclosures - 2 1. References 2. Definitions

REFERENCES, continued

(e) Deputy Secretary of Defense Memorandum, "Biological Warfare Defense Program," August 26, 1991

(f) Joint Service Agreement, "Joint Service Coordination of Chemical Warfare and Chemical-Biological Defense Requirements, Research, Development, and Acquisition," July 5, 1984

(g) Title 21, Code of Federal Regulations, Parts 50, "Informed Consent of Human Subjects," and 312, "Investigational New Drug Application," current edition

DEFINITIONS

1. Biological Warfare Agent. A microorganism or biological toxin intended to cause disease, injury, or death in humans.

2. Biological Warfare Threat. A biological materiel planned to be deployed to produce casualties in humans.

3. High-Threat Area. A geographic area in the proximity of a nation or nations considered to pose a potential biological threat to DoD personnel by the Chairman of the Joint Chiefs of Staff in consultation with the Commanders in Chief of the Unified Commands and the Director, DIA.

4. Immunity. The capacity to resist the effects of exposure to a specific biological agent or toxin.

5. Immunization. The process of rendering an individual immune. Immunization refers to "the administration of a vaccine to stimulate the immune system to produce an immune response (active immunization)." That process may require weeks to months and administration of multiple doses of vaccine.

6. Programmed Force. The DoD active and Reserve force approved by the Secretary of Defense in the Future Years Defense Program.

7. Vaccination. The administration of a vaccine to an individual for inducing immunity.

8. Vaccine. A preparation that contains one or more components of a biological agent or toxin, and induces an immune response against that agent when administered to an individual.

9. Validated Biological Warfare Threat Agent. A biological warfare agent that is validated as a threat to DoD personnel by the Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified and Specified Commands; the Chiefs of the Military Services; and the Director, DIA.

UPDATE: None

Jacobson v. Commonwealth of Massachusetts, 1905

197 U.S. 11 (1905), U.S. Supreme Court

This document is included in its entirety on the Deskbook CD-ROM.

The authority of the state to enact this statute is to be [197 U.S. 11, 25] referred to what is commonly called the police power,-a power which the state did not surrender when becoming a member of the Union under the Constitution. Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a state to enact quarantine laws and 'health laws of every description;' indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states. According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety. Gibbons v. Ogden, 9 Wheat. 1, 203, 6 L. ed. 23, 71; Hannibal & St. J. R. Co. v. Husen, 95 U.S. 465, 470, 24 S. L. ed. 527, 530; Boston Beer Co. v. Massachusetts, 97 U.S. 25, 24 L. ed. 989; New Orleans Gaslight Co. v. Louisiana Light & H. P. & Mfg. Co. 115 U.S. 650, 661, 29 S. L.

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ed. 516, 520, 6 Sup. Ct. Rep. 252; *Lawson v. Stecle*, 152 U.S. 133, 38 L. ed. 385, 14 Sup. Ct. Rep. 499. It is equally true that the state may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety. The mode or manner in which those results are to be accomplished is within the discretion of the state, subject, of course, so far as Federal power is concerned, only to the condition that no rule prescribed by a state, nor any regulation adopted by a local governmental agency acting under the sanction of state legislation, shall contravene the Constitution of the United States, nor infringe any right granted or secured by that instrument. A local enactment or regulation, even if based on the acknowledged police powers of a state, must always yield in case of conflict with the exercise by the general government of any power it possesses under the Constitution, or with any right which that instrument gives or secures. *Gibbons v. Ogden*, 9 Wheat. 1, 210, 6 L. ed. 23, 73; *Sinnot v. Davenport*, 22 How. 227, 243, 16 L. ed. 243, 247; *Missouri, K. & T. R. Co. v. Haber*, 169 U.S. 613, 626, 42 S. L. ed. 878, 882, 18 Sup. Ct. Rep. 488.

Source: <http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=197&invol=11>

Sunrise Village Mobile Home Park, L.C. v. United States, 1998

No. 96-428C, 42 Fed. Cl. 392, U.S. Court of Federal Claims

This document is included in its entirety on the Deskbook CD-ROM

UNITED STATES COURT OF FEDERAL CLAIMS
42 Fed. Cl. 392

Defendant's motion to dismiss GRANTED.

Plaintiff, mobile home park owner, filed a complaint against the United States seeking damages in excess of \$ 2,000,000. Plaintiff claimed that in the aftermath of a hurricane, the Federal Emergency Management Agency (FEMA) and the Army Corps of Engineers (the Corps) improperly supervised debris removal at plaintiff's mobile home park. Shortly after the hurricane, defendant federal government, acting through FEMA, offered to clean up the park in exchange for the right to lease mobile home sites for persons displaced by the hurricane. Plaintiff argued that defendant's immunity from suit under the Stafford Act, 42 U.S.C.S. § 5148, ceased when it executed a contract with plaintiff. The court disagreed, holding that the intent of Congress was to curtail litigation against the United States arising from disaster relief efforts of FEMA and other agencies, such as the Corps. The acts for which plaintiff sought redress took place shortly after the hurricane and within the scope of federal disaster relief efforts authorized by the president pursuant to the Act. In short, plaintiff's claims failed in the wake of the Act's discretionary function non-liability provision.

The court granted defendant federal government's motion to dismiss the claim for damages because the Federal Emergency Management Agency's actions were within the scope of federal disaster relief efforts and were therefore immune from suit.

Berkovitz v. United States, 1988

486 U.S. 531 (1988), U.S. Supreme Court

This document is included in its entirety on the Deskbook CD-ROM.

BERKOVITZ ET AL. v. UNITED STATES CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

A provision of the Federal Tort Claims Act (FTCA) excepts from statutory liability any claim "based upon [a federal agency's or employee's] exercise or performance or the failure to exercise or perform a discretionary function or duty." Upon contracting a severe case of polio after ingesting a dose of Orimune, an oral polio vaccine manufactured by Lederle Laboratories, petitioner Kevan Berkovitz, a minor, joined by his parents (also petitioners) as guardians, filed an FTCA suit alleging violations of federal law and policy by the National Institutes of Health's Division of Biologic Standards (DBS) in licensing Lederle to produce Orimune, and by the Bureau of Biologics of the Food and Drug Administration (FDA) in approving the release to the public of the particular lot of vaccine containing Berkovitz's dose. The District Court denied the Government's motion to dismiss the suit for lack of subject-matter jurisdiction, but the Court of Appeals reversed. Although rejecting the Government's argument that the discretionary function exception bars all claims arising out of federal agencies' regulatory activities, the court held that the licensing and release of polio vaccines are wholly discretionary actions protected by the exception.

Held:

1. The language, purpose, and legislative history of the discretionary function exception, as well as its interpretation in this Court's decisions, establish that the exception does not preclude liability for any and all acts arising out of federal agencies' regulatory programs, but insulates from liability only those governmental actions and decisions that involve an element of judgment or choice and that are based on public policy considerations. Pp. 535-539.

2. The Court of Appeals erred in holding that the discretionary function exception bars petitioners' claims. Pp. 539-548.

(a) Statutory and regulatory provisions require the DBS, prior to issuing a license for a product such as Orimune, to receive all data which the manufacturer is required to submit, to examine the product, and to make a determination that it complies with safety standards. Thus, a cause of action based on petitioner's allegation that the DBS licensed Orimune without first receiving the required safety data is not barred by the discretionary function exception, since the DBS has no discretion to [486 U.S. 531, 532] issue a license under such circumstances, and doing so would violate a specific statutory and regulatory directive. Petitioners' other claim - that the DBS licensed Orimune even though the vaccine did not comply with certain regulatory safety standards - if interpreted to mean that the DBS issued the license without determining compliance with the standards or after determining a failure to comply, also is not barred by the discretionary function exception, since the claim charges the agency with failing to act in accordance with specific mandatory directives, as to which the DBS has no discretion. However, if this claim is interpreted to mean that the DBS made an incorrect compliance determination, the question of the discretionary function exception's applicability turns on whether the DBS officials making that determination permissibly exercise policy choice, a point that is not clear from the record and therefore must be decided by the District Court if petitioners choose to press this interpretation. Pp. 540-545.

(b) Although the regulatory scheme governing the public release of vaccine lots allows the FDA to determine the appropriate manner in which to regulate, petitioners have alleged that, under the authority granted by the regulations, the FDA has adopted a policy of testing all lots for compliance with safety standards and of preventing the public distribution of any lot that fails to comply, and that, notwithstanding this mandatory policy, the FDA knowingly approved the release of the unsafe lot in question. Accepting these allegations as true, as is necessary in reviewing a dismissal, the holding that the discretionary function exception barred petitioners' claim was improper, since the acts complained of do not involve the permissible exercise of discretion to release a noncomplying lot on the basis of policy considerations. Pp. 545-548.

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The determination of whether the discretionary function exception bars a suit against the Government is guided by several established principles. This Court stated in *Varig* that "it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case." *Id.*, at 813. In examining the nature of the challenged conduct, a court must first consider whether the action is a matter of choice for the acting employee. This inquiry is mandated by the language of the exception; conduct cannot be discretionary unless it involves an element of judgment or choice. See *Dalehite v. United States*, 346 U.S. 15, 34 (1953) (stating that the exception protects "the discretion of the executive or the administrator to act according to one's judgment of the best course"). Thus, the discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow. In this event, the employee has no rightful option but to adhere to the directive. And if the employee's conduct cannot appropriately be the product of judgment or choice, then there is no discretion in the conduct for the discretionary function exception to protect. Cf. *Westfall v. Erwin*, 484 U.S. 292, 296-297 (1988) (recognizing that conduct that is not the

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Berkovitz v. United States, 1988

product of independent judgment will be unaffected by threat of liability).

Moreover, assuming the challenged conduct involves an element of judgment, a court must determine whether that judgment is of the kind that the discretionary function exception was designed to shield. The basis for the discretionary function exception was Congress' desire to "prevent judicial [486 U.S. 531, 537] `second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *United States v. Varig Airlines*, supra, at 814. The exception, properly construed, therefore protects only governmental actions and decisions based on considerations of public policy. See *Dalehite v. United States*, supra, at 36 ("Where there is room for policy judgment and decision there is discretion"). In sum, the discretionary function exception insulates the Government from liability if the action challenged in the case involves the permissible exercise of policy judgment.

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Florida Department of State v. Treasure Salvors, Inc., 1982

458 U.S. 670 (1982), U.S. Supreme Court

This document is included in its entirety on the Deskbook CD-ROM.

FLORIDA DEPARTMENT OF STATE v. TREASURE SALVORS, INC., ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

After respondents had located the wreck of a 17th-century Spanish galleon off the Florida coast, Florida immediately claimed ownership of the galleon pursuant to a Florida statute. Contracts were then entered into between the Florida Division of Archives, as owner of the galleon and its cargo, and respondents, whereby respondents agreed to conduct underwater salvage operations in exchange for the Division's agreement to transfer ownership of 75% of the appraised value of all material recovered from the galleon to respondents. The contracts did not purport to transfer ownership of any property to the Division. Ultimately, many valuable artifacts of the galleon were discovered. In the meantime, in proceedings unrelated to the salvage operations, it was held in *United States v. Florida*, 420 U.S. 531, that, as against Florida, the United States was entitled to the lands, minerals, and other natural resources in the area in which the remains of the galleon had come to rest. Respondents thereafter filed an admiralty in rem action in the Federal District Court for the Southern District of Florida, naming the galleon as defendant but not the State of Florida and seeking a declaration of title to the galleon. Throughout the ensuing proceedings, in which the United States intervened and in which both the District Court and the Court of Appeals on appeal rejected the United States' claim to ownership of the galleon, some of the valuable artifacts remained in the custody of officials of the Florida Division of Archives in Tallahassee, which is located beyond the District Court's territorial jurisdiction. After the Court of Appeals' decision, respondents filed a motion in the District Court for an order commanding the United States Marshal to arrest and take custody of those artifacts and bring them within the court's jurisdiction. The District Court granted the motion and issued a warrant of arrest. Although the warrant was addressed to the state officials, the State itself filed a motion to quash the warrant, but the court denied this motion, ruling that the extraterritorial seizure was proper under Supplemental Admiralty Rule C(5), and issued an order to show cause why the State should not deliver the artifacts into the Marshal's custody. The State then argued that the Eleventh Amendment barred exercise of the District Court's jurisdiction, but the District Court rejected this [458 U.S. 670, 671] argument, holding that the State had waived the Eleventh Amendment as to any claim to the property, and that, apart from any such claim, the Eleventh Amendment did not bar the seizure of the artifacts and subsequent transfer to the Marshal's custody. On the merits, the court also rejected the State's claim to the property based on the salvage contracts with respondents. The Court of Appeals affirmed.

Held:

The judgment is affirmed in part and reversed in part.

621 F.2d 1340, affirmed in part and reversed in part.

JUSTICE STEVENS, joined by THE CHIEF JUSTICE, JUSTICE MARSHALL, and JUSTICE BLACKMUN, concluded that:

1. The Eleventh Amendment did not bar the process issued by the District Court to secure possession of the artifacts held by the state officials. Pp. 683-699.

(a) The Eleventh Amendment, while barring an action directly against the state itself or any agency thereof, does not bar an action against a state official that is based on the theory that the official acted beyond the scope of his statutory authority or, if within that authority, that such authority is unconstitutional. The Eleventh Amendment, however, limits the relief that may be recovered in the latter kind of action; the judgment may not compel the State to use its funds to compensate the plaintiff for his injury. Pp. 683-690.

(b) Here, the process at issue is not barred by the Eleventh Amendment as a direct action against the State, because it was directed only at state officials. Neither the fact that the State elected to defend on behalf of the officials, nor the fact that the District Court purported to adjudicate the State's rights, deprives that court of jurisdiction that had been properly invoked over other parties. Pp. 691-692.

(c) The state officials named in the warrant of arrest do not have a colorable claim to possession of the artifacts, and thus may not invoke the Eleventh Amendment to block execution of the warrant. The salvage contracts, whether valid or not, provide no authority for the officials' refusal to surrender possession of the artifacts, and no statutory provision that even arguably would authorize the officials to retain the artifacts has been advanced. Pp. 692-697.

(d) The relief sought by respondents is not barred by the Eleventh Amendment but is consistent with the principles of *Edelman v. Jordan*, 415 U.S. 651. The warrant of arrest sought possession of specific property. It did not seek any attachment of state funds and would impose no burden on the state treasury. And respondents are not asserting a claim for damages against either the State or its officers. Pp. 697-699.

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2. The proper resolution of the Eleventh Amendment issue does not require - or permit - a determination of the State's ownership of the [458 U.S. 670, 672] artifacts, and hence the Court of Appeals improperly adjudicated the State's right to the artifacts. Pp. 699-700.

JUSTICE BRENNAN while agreeing with the opinion that the State of Florida has not established even a colorable claim to the artifacts, concluded that the Eleventh Amendment is inapplicable in this case because both respondents are Florida corporations and thus the suit was not "commenced or prosecuted against one of the United States by citizens of another State," as the Eleventh Amendment provides. Pp. 700-702.

JUSTICE WHITE, joined by JUSTICE POWELL, JUSTICE REHNQUIST, and JUSTICE O'CONNOR, concurred in the Court's judgment insofar as it reverses the Court of Appeals' determination of the State's ownership of the artifacts. P. 703, n.

STEVENS, J., announced the judgment of the Court and delivered an opinion, in which BURGER, C. J., and MARSHALL and BLACKMUN, JJ., joined. BRENNAN, J., filed an opinion concurring in the judgment in part and dissenting in part, post, p. 700. WHITE, J., filed an opinion concurring in the judgment in part and dissenting in part, in which POWELL, REHNQUIST, and O'CONNOR, JJ., joined, post, p. 702.

Susan Gamble Smathers, Assistant Attorney General of Florida, argued the cause pro hac vice for petitioner. With her on the briefs were Jim Smith, Attorney General, and Sidney H. McKenzie III.

Excerpt ...

A suit generally may not be maintained directly against the State itself, or against an agency or department of the State, unless the State has waived its sovereign immunity. *Alabama v. Pugh*, 438 U.S. 781 . If the State is named directly in the complaint and has not consented to the suit, it must be dismissed from the action. *Id.*, at 782.

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Joseph Dureiko v. United States, 2000

No. 99-5043 (April 14, 2000), U.S. Fed Circuit Court of Appeals

This document is included in its entirety on the Deskbook CD-ROM

JOSEPH DUREIKO, as Trustee, and SOUTHERN PINE ISLE CORPORATION, Plaintiffs-Appellants,
v.
UNITED STATES, Defendant-Appellee.

I. Discretionary Function Exception under the Stafford Act

The Court of Federal Claims dismissed Pine Isle's breach of contract claim because it believed that it lacked subject matter jurisdiction because of the "discretionary function exception" of the Stafford Act. See *Dureiko II*, 42 Fed. Cl. at 576-77. The Stafford Act, also known as the Disaster Relief Act of 1974, immunizes the federal government from liability arising out of its performance of a "discretionary function":

The Federal Government shall not be liable for any claim based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty on the part of a Federal agency or an employee of the Federal Government in carrying out the provisions of this chapter.

42 U.S.C. § 5148.

The trial court noted the Supreme Court's analysis of the analogous and similarly stated discretionary function exception under the FTCA.³ The Supreme Court has enunciated a two-prong test for determining whether the discretionary function exception under the FTCA applies: (1) whether the act involves an element of judgment or choice; and (2) if so, whether that judgment is of the kind that the discretionary function exception was designed to shield. See *United States v. Gaubert*, 499 U.S. 315, 322 (1991); *Berkovitz v. United States*, 486 U.S. 531, 536 (1988). Under the first prong, an act does not involve an element of judgment or choice if it is mandatory, i.e., if "a federal statute, regulation or policy specifically prescribes a course of action for an employee to follow." *Id.* at 536. Under the second prong, because the discretionary function exception serves to "prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort," *United States v. Varig Airlines*, 467 U.S. 797, 814 (1984), the exception "protects only governmental actions and decisions based on considerations of public policy," *Berkovitz*, 486 U.S. at 537.

The Court of Federal Claims relied heavily upon *Dureiko I*, 1996 WL 825402, *Sunrise Village Mobile Home Park v. Phillips & Jordan*, 960 F. Supp. 283 (S.D. Fla. 1996) ("*Sunrise I*"), and *Ornellas v. United States*, 2 Cl. Ct. 378 (1983), for its conclusion that the discretionary function exception barred Pine Isle's contract claim. In the related case of *Dureiko I*, the district court dismissed Pine Isle's tort claims against the United States as barred by the Stafford Act and the FTCA. See *Dureiko I*, 1996 WL 825402, at *2. Similarly, in *Sunrise I*, the district court dismissed another mobile home park's negligence claims against the United States as barred by the FTCA. See *Sunrise I*, 960 F. Supp. at 286-87. Finally, in *Ornellas*, the trial court held that the Stafford Act barred a party's suit for review of the Department of Agriculture's denial of disaster assistance benefits. See *Ornellas*, 2 Cl. Ct. at 380.

Pine Isle contends that the discretionary function exception is inapplicable here, since FEMA failed to act in accordance with multiple mandatory directives. Cf. *Phillips v. United States*, 956 F.2d 1071, 1076-77 (11th Cir. 1992) (holding that the discretionary function exception to the FTCA did not apply to the Corps's failure to comply with its own safety regulations). For example, Pine Isle contends that FEMA failed to comply with the standards prescribed by Task #4. Pine Isle further argues that FEMA ignored the Federal Acquisition Regulations ("FAR"), which require that government contractors "protect from damage all existing improvements and utilities . . . at or near the work site." 48 C.F.R. § 52.236-9 (1999). Pine Isle also notes that the Corps's own Quality Assurance Plan requires that a Quality Assurance Representative "[a]ssure that utility outlets and other features that must not be damaged are marked before removal operations are started." Pine Isle maintains that, once FEMA contracted with Pine Isle for FEMA's cleanup of the Park under these terms in exchange for the right to lease mobile home sites, the contract mandated the government's course of conduct and the discretionary function exception ceased to apply.

The government responds that, because FEMA's cleanup of the Park was authorized, but not mandated, by 42 U.S.C. § 5173, all of its cleanup efforts must be deemed to be discretionary. The government disputes the effect of its contract with Pine Isle, and claims that it would be contrary to the plain language and congressional intent of the Stafford Act to permit Pine Isle to sue the government simply because FEMA chose to administer its relief activities via contract. The government offers the legislative history of the Stafford Act as supportive of its position:

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We have further provided that if the agencies of the Government make a mistake in the administration of the Disaster Relief Act that the Government may not be sued. Strange as it may seem, there are many suits pending in the Court of Claims today against the Government because of alleged mistakes made in the administration of other relief acts, suits aggregating millions of dollars because citizens have averred that the agencies and employees of Government made mistakes. We have put a stipulation in here that there shall be no liability on the part of the Government.

96 Cong. Rec. 11895, 11912 (1950) (statement of Rep. Whittington, Chairman of the House Public Works Committee).

The government contends that it would be anomalous to immunize the decisions of top-level policy-makers, but not lower-level policy implementers carrying out relief policies, plans, and contracts. Finally, the government argues that the Supreme Court's two-prong test for the discretionary function exception under the FTCA collapses to a single inquiry under the Stafford Act, i.e., whether the act in question involves an element of judgment or choice. The government reasons that any act in furtherance of disaster relief necessarily promotes public policy. Cf. *Sunrise I*, 960 F. Supp. at 286 ("Implicit in this statute are the policies of protecting public safety and health and restoring order following a natural disaster.").

We review jurisdictional issues de novo. See *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 481 (Fed. Cir. 1996). On review of a grant of a motion to dismiss, we accept the factual allegations in a complaint as true and ask whether the trial court's dismissal of the complaint was appropriate. See *Berkovitz*, 486 U.S. at 547 (accepting, on review of a motion to dismiss, petitioners' factual allegations regarding the application of the FTCA's discretionary function exception as true). Consequently, we must assume that FEMA and Pine Isle contracted for FEMA's cleanup of the Park in accordance with the standards recited in Tasks #4 and #12 in exchange for Pine Isle's leasing mobile home sites to FEMA.⁴

We agree with Pine Isle that the Court of Federal Claims improperly dismissed its contract claim as barred by the discretionary function exception of the Stafford Act. The Supreme Court's pronouncements on the meaning of the term "discretionary" in the context of the FTCA are clear that "if the employee's conduct cannot appropriately be the product of judgment or choice, then there is no discretion in the conduct for the discretionary function exception to protect." *Berkovitz*, 486 U.S. at 536; see *Gaubert*, 499 U.S. at 322-23. As applied to the alleged facts of this case, once FEMA entered into a contract with Pine Isle, its acts pursuant to this contract no longer involved an element of judgment or choice. Rather, the contract mandated that FEMA's cleanup and restoration of the Park comply with the agreed-upon standards (subsequently reflected in Tasks #4 and #12), and FEMA's failure to do so breached this contract. For purposes of the discretionary function exception of the Stafford Act, we hold that a contract is indistinguishable from a federal statute, regulation, or policy that specifically prescribes a course of action for an employee to follow, since "the employee has no rightful option but to adhere to [its] directive[s]." ⁵ *Berkovitz*, 486 U.S. at 536.

We reject the government's assertion that the plain language and congressional intent of the Stafford Act bar Pine Isle's contract claim. The critical question is, of course, whether FEMA's acts were "discretionary." Although FEMA's initial decision to contract with Pine Isle necessarily involved "an element of judgment or choice," FEMA's subsequent compliance (or non-compliance) with the contract did not.

We are unconvinced by the government's contention that allowing a contract claim in this case would lead to the anomalous result that the acts of top-level policy-makers would be immunized against liability, but those of lower-level policy implementers would not be. The government's argument assumes that the lower-level policy implementers are acting in compliance with the policies conceived by top-level policy-makers. Where, as here, the lower-level policy-implementers are acting contrary to standards established by contract approved by higher-level officials, the discretionary function exception does not bar suit against the government. Cf. *id.* at 544 ("When a suit charges an agency with failing to act in accord with a specific mandatory directive, the discretionary function exception does not apply.").

We note that the government's position, if accepted, would allow it to avoid paying contractors such as Phillips & Jordan for their cleanup efforts. Applying the government's logic, its contract with Phillips & Jordan would also be in furtherance of disaster relief. Yet the government does not explain how this contract differs from the alleged contract with Pine Isle for the leasing of mobile home sites. We cannot agree that Congress intended the discretionary function exception to allow government agencies like FEMA to voluntarily contract with other parties in the course of providing disaster relief assistance, reap the benefits of such contracts but refuse to perform under them, and then claim immunity for liability resulting from its non-performance. Nor do we find anything in the operative language of the Stafford Act that requires this result.

We emphasize that, rather than restricting FEMA's ability to furnish federal disaster relief assistance, our holding actually expands FEMA's options. Were we to hold that the discretionary function exception barred breach of contract claims premised on contracts voluntarily entered into by FEMA and lessors like Pine Isle, parties naturally would be reluctant to contract with FEMA out of fear that the

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Stafford Act would bar claims arising out of FEMA's non-performance. By avoiding this disincentive, our holding helps FEMA contract with other parties in the course of disaster relief assistance.

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United States v. Varig Airlines, 1984

467 U.S. 797 (1984), U.S. Supreme Court

UNITED STATES v. S.A. EMPRESA DE VIACAO AEREA RIO GRANDENSE (VARIG AIRLINES) ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT
No. 82-1349.

CHIEF JUSTICE BURGER delivered the opinion of the Court.

///.

The Federal Tort Claims Act, 28 U.S.C. 1346(b), authorizes suits against the United States for damages.

"for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission [467 U.S. 797, 808] of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred."

The Act further provides that the United States shall be liable with respect to tort claims "in the same manner and to the same extent as a private individual under like circumstances." 2674.

The Act did not waive the sovereign immunity of the United States in all respects, however; Congress was careful to except from the Act's broad waiver of immunity several important classes of tort claims. Of particular relevance here, 28 U.S.C. 2680(a) provides that the Act shall not apply to

"[a]ny claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." (Emphasis added.)

The discretionary function exception, embodied in the second clause of 2680(a), marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals.

Although the Court has previously analyzed the legislative history of 2680(a), see *Dalehite v. United States*, 346 U.S. 15, 26-30 (1953), we briefly review its highlights for a proper understanding of the application of the discretionary function exception to this case. During the years of debate and discussion [467 U.S. 797, 809] preceding the passage of the Act, Congress considered a number of tort claims bills including exceptions from the waiver of sovereign immunity for claims based upon the activities of specific federal agencies, notably the Federal Trade Commission and the Securities and Exchange Commission. See, e. g., H. R. 5373, 77th Cong., 2d Sess. (1942); H. R. 7236, 76th Cong., 1st Sess. (1940); S. 2690, 76th Cong., 1st Sess. (1939). 8 In 1942, however, the 77th Congress eliminated the references to these particular agencies and broadened the exception to cover all claims based upon the execution of a statute or regulation or the performance of a discretionary function. H. R. 6463, 77th Cong., 2d Sess. (1942); S. 2207, 77th Cong., 2d Sess. (1942). The language of the exception as drafted during the 77th Congress is identical to that of 2680(a) as ultimately adopted.

The legislative materials of the 77th Congress illustrate most clearly Congress' purpose in fashioning the discretionary function exception. A Government spokesman appearing before the House Committee on the Judiciary described the discretionary function exception as a "highly important exception:"

"[It is] designed to preclude application of the act to a claim based upon an alleged abuse of discretionary authority by a regulatory or licensing agency - for example, the Federal Trade Commission, the Securities and Exchange Commission, the Foreign Funds Control Office of the Treasury, or others. It is neither desirable nor intended that the constitutionality of legislation, the legality of regulations, or the propriety of a discretionary administrative act should be tested through the medium [467 U.S. 797, 810] of a damage suit for tort. The same holds true of other administrative action not of a regulatory nature, such as the expenditure of Federal funds, the execution of a Federal project, and the like.

"On the other hand, the common law torts of employees of regulatory agencies, as well as of all other Federal agencies, would be included within the scope of the bill." Hearings on H. R. 5373 and H. R. 6463 before the House Committee on the Judiciary, 77th Cong., 2d Sess., 28, 33 (1942) (statement of Assistant Attorney General Francis M. Shea). 9

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It was believed that claims of the kind embraced by the discretionary function exception would have been exempted from the waiver of sovereign immunity by judicial construction; nevertheless, the specific exception was added to make clear that the Act was not to be extended into the realm of the validity of legislation or discretionary administrative action. *Id.*, at 29; *id.*, at 37, Memorandum, with Appendixes, Federal Tort Claims Act (explanatory of Comm. Print of H. R. 5373, 1942). It was considered unnecessary to except by name such agencies as the Federal Trade Commission and the Securities and Exchange Commission, as had earlier bills, because the language of the discretionary function exception would "exemp[t] from the act claims against Federal agencies growing out of their regulatory activities." *Id.*, at 8 (emphasis added).

The nature and scope of 2680(a) were carefully examined in *Dalehite v. United States*, *supra*. *Dalehite* involved vast claims for damages against the United States arising out of a disastrous explosion of ammonium nitrate fertilizer, which had been produced and distributed under the direction of the United States for export to devastated areas occupied by the Allied Armed Forces after World War II. Numerous acts of [467 U.S. 797, 811] the Government were charged as negligent: the cabinet-level decision to institute the fertilizer export program, the failure to experiment with the fertilizer to determine the possibility of explosion, the drafting of the basic plan of manufacture, and the failure properly to police the storage and loading of the fertilizer.

The Court concluded that these allegedly negligent acts were governmental duties protected by the discretionary function exception and held the action barred by 2680(a). Describing the discretion protected by 2680(a) as "the discretion of the executive or the administrator to act according to one's judgment of the best course," *id.*, at 34, the Court stated:

"It is unnecessary to define, apart from this case, precisely where discretion ends. It is enough to hold, as we do, that the 'discretionary function or duty' that cannot form a basis for suit under the Tort Claims Act includes more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications or schedules of operations. Where there is room for policy judgment and decision there is discretion. It necessarily follows that acts of subordinates in carrying out the operations of government in accordance with official directions cannot be actionable." *Id.*, at 35-36 (footnotes omitted).

Respondents here insist that the view of 2680(a) expressed in *Dalehite* has been eroded, if not overruled, by subsequent cases construing the Act, particularly *Indian Towing Co. v. United States*, 350 U.S. 61 (1955), and *Eastern Air Lines, Inc. v. Union Trust Co.*, 95 U.S. App. D.C. 189, 221 F.2d 62, summarily *aff'd sub nom. United States v. Union Trust Co.*, 350 U.S. 907 (1955). While the Court's reading of the Act admittedly has not followed a straight line, we do not accept the supposition that *Dalehite* no longer represents [467 U.S. 797, 812] a valid interpretation of the discretionary function exception.

Indian Towing Co. v. United States, *supra*, involved a claim under the Act for damages to cargo aboard a vessel that ran aground, allegedly owing to the failure of the light in a lighthouse operated by the Coast Guard. The plaintiffs contended that the Coast Guard had been negligent in inspecting, maintaining, and repairing the light. Significantly, the Government conceded that the discretionary function exception was not implicated in *Indian Towing*, arguing instead that the Act contained an implied exception from liability for "uniquely governmental functions." *Id.*, at 64. The Court rejected the Government's assertion, reasoning that it would "push the courts into the 'non-governmental'-'governmental' quagmire that has long plagued the law of municipal corporations." *Id.*, at 65.

In *Eastern Air Lines, Inc. v. Union Trust Co.*, *supra*, two aircraft collided in midair while both were attempting to land at Washington National Airport. The survivors of the crash victims sued the United States under the Act, asserting the negligence of air traffic controllers as the cause of the collision. The United States Court of Appeals for the District of Columbia Circuit permitted the suit against the Government. In its petition for certiorari, the Government urged the adoption of a "governmental function exclusion" from liability under the Act and pointed to 2680(a) as textual support for such an exclusion. *Pet. for Cert. in United States v. Union Trust Co.*, O. T. 1955, No. 296, p. 18. The Government stated further that 2680(a) was "but one aspect of the broader exclusion from the statute of claims based upon the performance of acts of a uniquely governmental nature." *Id.*, at 37. This Court summarily affirmed, citing *Indian Towing Co. v. United States*, *supra*. 350 U.S. 907 (1955). Given the thrust of the arguments presented in the petition for certiorari and the pointed citation to *Indian Towing*, the summary disposition in *Union Trust Co.* cannot be taken as a [467 U.S. 797, 813] wholesale repudiation of the view of 2680(a) set forth in *Dalehite*. 10

As in *Dalehite*, it is unnecessary - and indeed impossible - to define with precision every contour of the discretionary function exception. From the legislative and judicial materials, however, it is possible to isolate several factors useful in determining when the acts of a Government employee are protected from liability by 2680(a). First, it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case. As the Court pointed out in *Dalehite*, the exception covers "[n]ot only agencies of government . . . but all employees exercising discretion." 346 U.S., at 33. Thus, the basic inquiry concerning the application of the discretionary function exception is whether the challenged acts of a Government employee - whatever his or her rank - are of the nature and quality that Congress intended to shield from tort liability.

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Second, whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator [467 U.S. 797, 814] of the conduct of private individuals. 11 Time and again the legislative history refers to the acts of regulatory agencies as examples of those covered by the exception, and it is significant that the early tort claims bills considered by Congress specifically exempted two major regulatory agencies by name. See *supra*, at 808-810. This emphasis upon protection for regulatory activities suggests an underlying basis for the inclusion of an exception for discretionary functions in the Act: Congress wished to prevent judicial "second-guessing" of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort. By fashioning an exception for discretionary governmental functions, including regulatory activities, Congress took "steps to protect the Government from liability that would seriously handicap efficient government operations." *United States v. Muniz*, 374 U.S. 150, 163 (1963).

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United States v. Gaubert, 1991

499 U.S. 315 (1991), U.S. Supreme Court

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UNITED STATES v. GAUBERT
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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The liability of the United States under the FTCA is subject to the various exceptions contained in 2680, including the "discretionary function" exception at issue here. That exception provides that the Government is not liable for

"[a]ny claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. 2680(a).

The exception covers only acts that are discretionary in nature, acts that "involv[e] an element of judgment or choice," Berkovitz, *supra*, at 536; see also *Dalehite v. United States*, 346 U.S. 15, 34 (1953); and "it is the nature of the conduct, rather than the status of the actor," that governs whether the exception applies. *Varig Airlines*, *supra*, at 813. The requirement of judgment or choice is not satisfied if a "federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow," because "the employee has no rightful option but to adhere to the directive." Berkovitz, 486 U.S. at 536.

Furthermore, even "assuming the challenged conduct involves an element of judgment," it remains to be decided "whether that judgment is of the kind that the discretionary [499 U.S. 315, 323] function exception was designed to shield." *Ibid.* See *Varig Airlines*, 467 U.S., at 813. Because the purpose of the exception is to "prevent judicial "second-guessing" of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort," *id.*, at 814, when properly construed, the exception "protects only governmental actions and decisions based on considerations of public policy." Berkovitz, *supra*, at 537.

Where Congress has delegated the authority to an independent agency or to the executive branch to implement the general provisions of a regulatory statute and to issue regulations to that end, there is no doubt that planning-level decisions establishing programs are protected by the discretionary function exception, as is the promulgation of regulations by which the agencies are to carry out the programs. In addition, the actions of Government agents involving the necessary element of choice and grounded in the social, economic, or political goals of the statute and regulations are protected.

Thus, in *Dalehite*, the exception barred recovery for claims arising from a massive fertilizer explosion. The fertilizer had been manufactured, packaged, and prepared for export pursuant to detailed regulations as part of a comprehensive federal program aimed at increasing the food supply in occupied areas after World War II. 346 U.S., at 19 -21. Not only was the cabinet-level decision to institute the fertilizer program discretionary, but so were the decisions concerning the specific requirements for manufacturing the fertilizer. *Id.*, at 37-38. Nearly 30 years later, in *Varig Airlines*, the Federal Aviation Administration's actions in formulating and implementing a "spot-check" plan for airplane inspection were protected by the discretionary function exception because of the agency's authority to establish safety standards for airplanes. 467 U.S., at 815. Actions taken in furtherance of the program were likewise protected, even if those particular actions were negligent. *Id.*, at 820. Most recently, in *Berkovitz*, we examined a comprehensive regulatory [499 U.S. 315, 324] scheme governing the licensing of laboratories to produce polio vaccine and the release to the public of particular drugs. 486 U.S., at 533. We found that some of the claims fell outside the exception, because the agency employees had failed to follow the specific directions contained in the applicable regulations, *i.e.*, in those instances, there was no room for choice or judgment. *Id.* at 542-543. We then remanded the case for an analysis of the remaining claims in light of the applicable regulations. *Id.*, at 544.

Under the applicable precedents, therefore, if a regulation mandates particular conduct, and the employee obeys the direction, the Government will be protected, because the action will be deemed in furtherance of the policies which led to the promulgation of the regulation. See *Dalehite*, *supra*, at 36. If the employee violates the mandatory regulation, there will be no shelter from liability, because there is no room for choice, and the action will be contrary to policy. On the other hand, if a regulation allows the employee discretion, the very existence of the regulation creates a strong presumption that a discretionary act authorized by the regulation involves consideration of the same policies which led to the promulgation of the regulations.

Not all agencies issue comprehensive regulations, however. Some establish policy on a case-by-case basis, whether through

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adjudicatory proceedings or through administration of agency programs. Others promulgate regulations on some topics, but not on others. In addition, an agency may rely on internal guidelines, rather than on published regulations. In any event, it will most often be true that the general aims and policies of the controlling statute will be evident from its text.

When established governmental policy, as expressed or implied by statute, regulation, or agency guidelines, allows a Government agent to exercise discretion, it must be presumed that the agent's acts are grounded in policy when exercising that discretion. For a complaint to survive a motion to dismiss, it must allege facts which would support a finding [499 U.S. 315, 325] that the challenged actions are not the kind of conduct that can be said to be grounded in the policy of the regulatory regime. The focus of the inquiry is not on the agent's subjective intent in exercising the discretion conferred by statute or regulation, but on the nature of the actions taken and on whether they are susceptible to policy analysis. 7

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Bivens v. Six Unknown Fed. Narcotics Agents, 1971

403 U.S. 388 (1971), U.S. Supreme Court

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BIVENS v. SIX UNKNOWN FED. NARCOTICS AGENTS, 403 U.S. 388 (1971)
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Respondents do not argue that petitioner should be entirely without remedy for an unconstitutional invasion of his rights by federal agents. In respondents' view, however, the rights that petitioner asserts - primarily rights of privacy - are creations of state and not of federal law. Accordingly, they argue, petitioner may obtain money damages to redress invasion of these rights only by an action in tort, under state law, in the state courts. In this scheme the Fourth Amendment would serve merely to limit the extent to which the agents could defend [403 U.S. 388, 391] the state law tort suit by asserting that their actions were a valid exercise of federal power: if the agents were shown to have violated the Fourth Amendment, such a defense would be lost to them and they would stand before the state law merely as private individuals. Candidly admitting that it is the policy of the Department of Justice to remove all such suits from the state to the federal courts for decision, 4 respondents nevertheless urge that we uphold dismissal of petitioner's complaint in federal court, and remit him to filing an action in the state courts in order that the case may properly be removed to the federal court for decision on the basis of state law.

We think that respondents' thesis rests upon an unduly restrictive view of the Fourth Amendment's protection against unreasonable searches and seizures by federal agents, a view that has consistently been rejected by this Court. Respondents seek to treat the relationship between a citizen and a federal agent unconstitutionally exercising his authority as no different from the relationship [403 U.S. 388, 392] between two private citizens. In so doing, they ignore the fact that power, once granted, does not disappear like a magic gift when it is wrongfully used. An agent acting - albeit unconstitutionally - in the name of the United States possesses a far greater capacity for harm than an individual trespasser exercising no authority other than his own. Cf. *Amos v. United States*, 255 U.S. 313, 317 (1921); *United States v. Classic*, 313 U.S. 299, 326 (1941). Accordingly, as our cases make clear, the Fourth Amendment operates as a limitation upon the exercise of federal power regardless of whether the State in whose jurisdiction that power is exercised would prohibit or penalize the identical act if engaged in by a private citizen. It guarantees to citizens of the United States the absolute right to be free from unreasonable searches and seizures carried out by virtue of federal authority. And "where federally protected rights have been invaded, it has been the rule from the beginning that courts will be alert to adjust their remedies so as to grant the necessary relief." *Bell v. Hood*, 327 U.S., at 684 (footnote omitted); see *Bemis Bros. Bag Co. v. United States*, 289 U.S. 28, 36 (1933) (Cardozo, J.); *The Western Maid*, 257 U.S. 419, 433 (1922) (Holmes, J.).

First. Our cases have long since rejected the notion that the Fourth Amendment proscribes only such conduct as would, if engaged in by private persons, be condemned by state law. Thus in *Gambino v. United States*, 275 U.S. 310 (1927), petitioners were convicted of conspiracy to violate the National Prohibition Act on the basis of evidence seized by state police officers incident to petitioners' arrest by those officers solely for the purpose of enforcing federal law. *Id.*, at 314. Notwithstanding the lack of probable cause for the arrest, *id.*, at 313, it would have been permissible under state law if effected [403 U.S. 388, 393] by private individuals. 5 It appears, moreover, that the officers were under direction from the Governor to aid in the enforcement of federal law. *Id.*, at 315-317. Accordingly, if the Fourth Amendment reached only to conduct impermissible under the law of the State, the Amendment would have had no application to the case. Yet this Court held the Fourth Amendment applicable and reversed petitioners' convictions as having been based upon evidence obtained through an unconstitutional search and seizure. Similarly, in *Byars v. United States*, 273 U.S. 28 (1927), the petitioner was convicted on the basis of evidence seized under a warrant issued, without probable cause under the Fourth Amendment, by a state court judge for a state law offense. At the invitation of state law enforcement officers, a federal prohibition agent participated in the search. This Court explicitly refused to inquire whether the warrant was "good under the state law . . . since in no event could it constitute the basis for a federal search and seizure." *Id.*, at 29 (emphasis added). 6 And our recent decisions regarding electronic surveillance have made it clear beyond peradventure that the Fourth Amendment is not tied to the [403 U.S. 388, 394] niceties of local trespass laws. *Katz v. United States*, 389 U.S. 347 (1967); *Berger v. New York*, 388 U.S. 41 (1967); *Silverman v. United States*, 365 U.S. 505, 511 (1961). In light of these cases, respondents' argument that the Fourth Amendment serves only as a limitation on federal defenses to a state law claim, and not as an independent limitation upon the exercise of federal power, must be rejected.

Second. The interests protected by state laws regulating trespass and the invasion of privacy, and those protected by the Fourth Amendment's guarantee against unreasonable searches and seizures, may be inconsistent or even hostile. Thus, we may bar the door against an unwelcome private intruder, or call the police if he persists in seeking entrance. The availability of such alternative means for the protection of privacy may lead the State to restrict imposition of liability for any consequent trespass. A private citizen, asserting no

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Bivens v. Six Unknown Fed. Narcotics Agents, 1971

authority other than his own, will not normally be liable in trespass if he demands, and is granted, admission to another's house. See *W. Prosser, The Law of Torts* 18, pp. 109-110 (3d ed. 1964); 1 *F. Harper & F. James, The Law of Torts* 1.11 (1956). But one who demands admission under a claim of federal authority stands in a far different position. Cf. *Amos v. United States*, 255 U.S. 313, 317 (1921). The mere invocation of federal power by a federal law enforcement official will normally render futile any attempt to resist an unlawful entry or arrest by resort to the local police; and a claim of authority to enter is likely to unlock the door as well. See *Weeks v. United States*, 232 U.S. 383, 386 (1914); *Amos v. United States*, supra. 7 "In such cases there is no safety for the citizen, [403 U.S. 388, 395] except in the protection of the judicial tribunals, for rights which have been invaded by the officers of the government, professing to act in its name. There remains to him but the alternative of resistance, which may amount to crime." *United States v. Lee*, 106 U.S. 196, 219 (1882), 8 Nor is it adequate to answer that state law may take into account the different status of one clothed with the authority of the Federal Government. For just as state law may not authorize federal agents to violate the Fourth Amendment, *Byars v. United States*, supra; *Weeks v. United States*, supra; *In re Ayers*, 123 U.S. 443, 507 (1887), neither may state law undertake to limit the extent to which federal authority can be exercised. *In re Neagle*, 135 U.S. 1 (1890). The inevitable consequence of this dual limitation on state power is that the federal question becomes not merely a possible defense to the state law action, but an independent claim both necessary and sufficient to make out the plaintiff's cause of action. Cf. *Boilermakers v. Hardeman*, 401 U.S. 233, 241 (1971).

Third. That damages may be obtained for injuries consequent upon a violation of the Fourth Amendment by federal officials should hardly seem a surprising proposition. Historically, damages have been regarded as the ordinary remedy for an invasion of personal interests in liberty. See *Nixon v. Condon*, 286 U.S. 73 (1932); [403 U.S. 388, 396] *Nixon v. Herndon*, 273 U.S. 536, 540 (1927); *Swafford v. Templeton*, 185 U.S. 487 (1902); *Wiley v. Sinkler*, 179 U.S. 58 (1900); *J. Landynski, Search and Seizure and the Supreme Court* 28 et seq. (1966); *N. Lasson, History and Development of the Fourth Amendment to the United States Constitution* 43 et seq. (1937); *Katz, The Jurisprudence of Remedies: Constitutional Legality and the Law of Torts in Bell v. Hood*, 117 U. Pa. L. Rev. 1, 8-33 (1968); cf. *West v. Cabell*, 153 U.S. 78 (1894); *Lammon v. Feusier*, 111 U.S. 17 (1884). Of course, the Fourth Amendment does not in so many words provide for its enforcement by an award of money damages for the consequences of its violation. But "it is . . . well settled that where legal rights have been invaded, and a federal statute provides for a general right to sue for such invasion, federal courts may use any available remedy to make good the wrong done." *Bell v. Hood*, 327 U.S., at 684 (footnote omitted). The present case involves no special factors counseling hesitation in the absence of affirmative action by Congress. We are not dealing with a question of "federal fiscal policy," as in *United States v. Standard Oil Co.*, 332 U.S. 301, 311 (1947). In that case we refused to infer from the Government-soldier relationship that the United States could recover damages from one who negligently injured a soldier and thereby caused the Government to pay his medical expenses and lose his services during the course of his hospitalization. Noting that Congress was normally quite solicitous where the federal purse was involved, we pointed out that "the United States [was] the party plaintiff to the suit. And the United States has power at any time to create the liability." *Id.*, at 316; see *United States v. Gilman*, 347 U.S. 507 (1954). Nor are we asked in this case to impose liability upon a congressional employee for actions contrary to no constitutional [403 U.S. 388, 397] prohibition, but merely said to be in excess of the authority delegated to him by the Congress. *Wheeldin v. Wheeler*, 373 U.S. 647 (1963). Finally, we cannot accept respondents' formulation of the question as whether the availability of money damages is necessary to enforce the Fourth Amendment. For we have here no explicit congressional declaration that persons injured by a federal officer's violation of the Fourth Amendment may not recover money damages from the agents, but must instead be remitted to another remedy, equally effective in the view of Congress. The question is merely whether petitioner, if he can demonstrate an injury consequent upon the violation by federal agents of his Fourth Amendment rights, is entitled to redress his injury through a particular remedial mechanism normally available in the federal courts. Cf. *J. I. Case Co. v. Borak*, 377 U.S. 426, 433 (1964); *Jacobs v. United States*, 290 U.S. 13, 16 (1933). "The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury." *Marbury v. Madison*, 1 Cranch 137, 163 (1803). Having concluded that petitioner's complaint states a cause of action under the Fourth Amendment, supra, at 390-395, we hold that petitioner is entitled to recover money damages for any injuries he has suffered as a result of the agents' violation of the Amendment.

Source: <http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=fed&navby=case&no=995043>

MSEHPA, 2001
Model State Emergency Health Powers Act
<i>This document is included in its entirety on the Deskbook CD-ROM.</i>
Purpose: Model Act outlining comprehensive response plan, data collection, response and reporting procedures, and treatment plans.
Source: http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf
UPDATE: None

63 Oklahoma Statutes §682.1, May 27, 2003
Definitions - Vaccination Program For First Responders - Exemptions
<i>This document is included in its entirety on the Deskbook CD-ROM</i>
<p>A. As used in this section:</p> <ol style="list-style-type: none">1. "Department" means the State Department of Health, Bioterrorism Division;2. "Director" means the Commissioner of Health;3. "Bioterrorism" means the intentional use of any microorganism, virus, infectious substance or biological product that may be engineered as a result of biotechnology or any naturally occurring or bioengineered component of any microorganism, virus, infectious substance or biological product, to cause or attempt to cause death, disease or other biological malfunction in any living organism;4. "Disaster locations" means any geographical location where a bioterrorism attack, terrorist attack, catastrophic or natural disaster or emergency occurs; and5. "First responders" means state and local law enforcement personnel, fire department personnel and emergency medical personnel who will be deployed to bioterrorism attacks, terrorist attacks, catastrophic or natural disasters and emergencies. <p>B. The Department shall offer a vaccination program for first responders who may be exposed to infectious diseases when deployed to disaster locations. The vaccinations shall include, but are not limited to, hepatitis B vaccination, diphtheria-tetanus vaccination, influenza vaccination, and other vaccinations when recommended by the United States Public Health Service and in accordance with Federal Emergency Management Directors Policy. Immune globulin will be made available when necessary.</p> <p>C. Participation in the vaccination program will be voluntary by the first responders, except for first responders who are classified as having "occupational exposure" to blood borne pathogens as defined by the Occupational Safety and Health Administration Standard contained at 29 CFR 1910.1030. First responders who are classified as having "occupational exposure" to blood borne pathogens shall be required to take the designated vaccinations.</p> <p>D. A first responder shall be exempt from vaccinations when a written statement from a licensed physician is presented indicating that a vaccine is medically contraindicated for that person or the first responder signs a written statement that the administration of a vaccination conflicts with their religious tenets.</p> <p>E. In the event of a vaccine shortage, the Director, in consultation with the Governor and the Centers for Disease Control and Prevention, shall give priority for vaccination to first responders.</p> <p>F. The Department shall notify first responders of the availability of the vaccination program and shall provide educational materials on ways to prevent exposure to infectious diseases.</p> <p>G. The Department may contract with county and local health departments, not-for-profit home health care agencies, hospitals and physicians to administer a vaccination program for first responders.</p> <p>H. This section shall be effective upon receipt of federal funding and/or federal grants for administering a first responders vaccination program. Upon receipt of such funding, the Department shall make available the vaccines to first responders as provided in this section. If federal funds for these vaccines cease, the state shall not be liable for the continuation or cost of vaccines.</p>
UPDATE: None

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NC Session Law 2003-227, June 11, 2003

An Act To Establish A Vaccination Program For First Responders To Terrorist Incidents, Catastrophic Or Natural Disasters, Or Emergencies.

This document is included in its entirety on the Deskbook CD-ROM

AN ACT TO ESTABLISH A VACCINATION PROGRAM FOR FIRST RESPONDERS TO TERRORIST INCIDENTS, CATASTROPHIC OR NATURAL DISASTERS, OR EMERGENCIES.

The General Assembly of North Carolina enacts:

SECTION 1. Article 22 of Chapter 130A of the General Statutes is amended by adding the following new section to read:

"§ 130A-485. Vaccination program established; definitions.

(a) The Department and local health departments shall offer a vaccination program for first responders who may be exposed to infectious diseases when deployed to disaster locations. The vaccinations shall include, but are not limited to, hepatitis A vaccination, hepatitis B vaccination, diphtheria-tetanus vaccination, influenza vaccination, pneumococcal vaccination, and other vaccinations when recommended by the United States Public Health Service and in accordance with Federal Emergency Management Directors Policy. Immune globulin will be made available when necessary, as determined by the State Health Director.

(b) Participation in the vaccination program is voluntary by the first responders, except for first responders who are classified as having "occupational exposure" to blood borne pathogens as defined by the Occupational Safety and Health Administration Standard contained at 29 C.F.R. §1910.10300 who shall be required to take the designated vaccinations or otherwise required by law.

(c) Nothing in this section shall require first responders, except first responders for whom the vaccination program is not voluntary as set forth in subsection (b) of this section, who present a written statement from a licensed physician indicating that a vaccine is medically contraindicated for the first responder or who sign a written statement that the administration of a vaccination conflicts with the first responder's religious tenets, to receive a vaccine.

(d) In the event of a vaccine shortage, the State Public Health Director, in consultation with the Centers for Disease Control and Prevention, shall give priority for vaccination to first responders deployed to a disaster location.

(e) The Department shall notify first responders of the availability of the vaccination program and shall provide educational materials on ways to prevent exposure to infectious diseases.

(f) As used in this section, unless the context clearly requires otherwise, the term:

(1) 'Bioterrorism' means the intentional use of any microorganism, virus, infectious substance, biological product, or biological agent as defined in G.S. 130A-479 that may be engineered as a result of biotechnology or any naturally occurring or bioengineered component of any microorganism, virus, infectious substance, or biological product to cause or attempt to cause death, disease, or other biological malfunction in any living organism.

(2) 'Disaster location' means any geographical location where a bioterrorism attack, terrorist incident, catastrophic or natural disaster, or emergency occurs.

(3) 'First responders' means State and local law enforcement personnel, fire department personnel, and emergency medical personnel who will be deployed to bioterrorism attacks, terrorist attacks, catastrophic or natural disasters, or emergencies."

SECTION 2. Nothing in this act obligates the General Assembly to appropriate State funds for the implementation of this act. The Department of Health and Human Services shall work with local employers to access, when available, federal funds to implement a vaccination program for first responders as enacted in Section 1 of this act.

SECTION 3. This act is effective when it becomes law.

In the General Assembly read three times and ratified this the 11th day of June, 2003.

s/ Marc Basnight, President Pro Tempore of the Senate

s/ James B. Black, Speaker of the House of Representatives

s/ Michael F. Easley, Governor

Approved 12:49 p.m. this 19th day of June, 2003

Source: <http://uscode.house.gov/usc.htm>

UPDATE: None

NYS Exec. Law, Chapter 18, Article 2-B

State and Local Natural and Man-Made Disaster Preparedness

This document is included in its entirety in Appendix B on the Deskbook CD-ROM.

Section 20. Natural and man-made disasters; policy; definitions.

21. Disaster preparedness commission established; meetings; powers and duties.
22. State disaster preparedness plans.
23. Local disaster preparedness plans.
- 23-a. County registry of disabled persons; notice.
24. Local state of emergency; local emergency orders by chief executive.
25. Use of local government resources in a disaster.
26. Coordination of local disaster preparedness forces and local civil defense forces in disasters.
27. Continuity of local governments.
28. State declaration of disaster emergency.
- 28-a. Post disaster recovery planning.
29. Direction of state agency assistance in a disaster emergency.
- 29-a. Suspension of other laws.
- 29-b. Use of civil defense forces in disasters.
- 29-c. Radiological preparedness.
- 29-d. Reports.
- 29-e. New York state emergency assistance program.
- 29-g. Emergency management assistance compact.

...
S 29-g. Emergency management assistance compact. 1. The emergency management assistance compact is made and entered into by and between the participating member states which enact this compact, hereinafter called party states. For the purposes of this agreement, the term "states" is taken to mean the several states, the commonwealth of Puerto Rico, the District of Columbia, and all United States territorial possessions.

The purpose of this compact is to provide for mutual assistance between the states entering into this compact in managing any emergency or disaster that is duly declared by the governor of the affected state or states, whether arising from natural disaster, technological hazard, man-made disaster, civil emergency aspects of resource shortages, community disorders, insurgency or enemy attack.

This compact shall also provide for mutual cooperation in emergency-related exercises, testing or other training activities using equipment and personnel simulating performance of any aspect of the giving and receiving of aid by party states or subdivisions of party states during emergencies, such actions occurring outside actual declared emergency periods. Mutual assistance in this compact may include the use of the states' national guard forces, either in accordance with the national guard mutual assistance compact or by mutual agreement between states.

2. Each party state entering into this compact recognizes that many emergencies transcend political jurisdictional boundaries and that intergovernmental coordination is essential in managing these and other emergencies under this compact. Each state further recognizes that there will be emergencies which require immediate access and present procedures to apply outside resources to make a prompt and effective response to such an emergency. This is because few, if any, individual states have all the resources they may need in all types of emergencies or the capability of delivering resources to areas where emergencies exist.

The prompt, full and effective utilization of resources of the participating states, including any resources on hand or available from the federal government or any other source, that are essential to the safety, care and welfare of the people in the event of any emergency or disaster declared by a party state, shall be the underlying principle on which all provisions of this compact shall be understood.

On behalf of the governor of each state participating in the compact, the legally designated state official who is assigned responsibility for emergency management will be responsible for formulation of the appropriate interstate mutual aid plans and procedures necessary to implement this compact.

3. (a) It shall be the responsibility of each party state to formulate procedural plans and programs for interstate cooperation in the performance of the responsibilities listed in this section. In formulating such plans, and in carrying them out, the party states, insofar as practical, shall:

(1) Review individual state hazard analysis and, to the extent reasonably possible, determine all those potential emergencies the party states might jointly suffer, whether due to natural disaster, technological hazard, man-made disaster, emergency aspects or resource shortages, civil disorders, insurgency or enemy attack.

(2) Review party states' individual emergency plans and develop a plan which will determine the mechanism for the interstate

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NYS Exec. Law, Chapter 18, Article 2-B

management and provision of assistance concerning any potential emergency.

(3) Develop interstate procedures to fill any identified gaps and to resolve any identified inconsistencies or overlaps in existing or developed plans.

(4) Assist in warning communities adjacent to or crossing the state boundaries.

(5) Protect and assure uninterrupted delivery of services, medicines, water, food, energy and fuel, search and rescue and critical lifeline equipment, services and resources, both human and material.

(6) Inventory and set procedures for the interstate loan and delivery of human material resources, together with procedures for reimbursement or forgiveness.

(7) Provide, to the extent authorized by law, for temporary suspension of any statutes or ordinances that restrict the implementation of the above responsibilities.

(b) The authorized representative of a party state may request assistance of another party state by contacting the authorized representative of that state. The provisions of this agreement shall only apply to requests for assistance made by and to authorized representatives. Requests may be verbal or in writing. If verbal, the request shall be confirmed in writing within thirty days of the verbal request. Requests shall provide the following information:

(1) A description of the emergency service function for which assistance is needed, such as, but not limited to, fire services, law enforcement, emergency medical, transportation, communications, public works and engineering, building inspection, planning and information assistance, mass care, resource support, health and medical services, and search and rescue.

(2) The amount and type of personnel, equipment, materials and supplies needed, and a reasonable estimate of the length of time that they will be needed.

(3) The specific place and time for staging of the assisting party's response and a point of contact at that location.

(c) There shall be frequent consultation between state officials who have assigned emergency management responsibilities and other appropriate representatives of the party states with affected jurisdictions and the United States government, with free exchange of information, plans and resource records relating to emergency capabilities.

4. Any party state requested to render mutual aid or conduct exercises and training for mutual aid shall take such action as is necessary to provide and make available the resources covered by this compact in accordance with the terms hereof provided, that it is understood that the state rendering aid may withhold resources to the extent necessary to provide reasonable protection for such state.

Each party state shall afford to the emergency forces of any party state, while operating within its state limits under the terms and conditions of this compact, the same powers (except that of arrest unless specifically authorized by the receiving state), duties, rights and privileges as are afforded forces of the state in which they are performing emergency services. Emergency forces will continue under the command and control of their regular leaders, but the organizational units will come under the operational control of the emergency services authorities of the state receiving assistance. These conditions may be activated, as needed, only subsequent to a declaration of a state of emergency or disaster by the governor of the party state that is to receive assistance or commencement of exercises or training for mutual aid and shall continue so long as the exercises or training for mutual aid are in progress, the state, or states, of emergency or disaster remains in effect or loaned resources remain in the receiving states, whichever is longer.

5. Whenever any person holds a license, certificate or other permit issued by any state party to the compact evidencing the meeting of qualifications for professional, mechanical or other skills, and when such assistance is requested by the receiving party state, such person shall be deemed licensed, certified, or permitted by the state requesting assistance to render aid involving such skill to meet a declared emergency or disaster, subject to such limitations and conditions as the governor of the requesting state may prescribe by executive order or otherwise.

6. Officers or employees of a party state rendering aid in another state pursuant to this compact shall be considered agents of the requesting state for tort liability and immunity purposes and no party state or its officers or employees rendering aid in another state pursuant to this compact shall be liable on account or any act or omission in good faith on the part of such forces while so engaged or on account of the maintenance or use of any equipment or supplies in connection therewith. Good faith shall not include willful misconduct, gross negligence or recklessness.

7. Inasmuch as it is probable that the pattern and detail of the machinery for mutual aid among two or more states may differ from that among the states that are parties hereto, this instrument contains elements of a broad base common to all states, and nothing contained herein shall preclude any state from entering into supplementary agreements with another state or affect any other agreements already in force between states. Supplementary agreements may comprehend, but shall not be limited to, provisions for evacuation and reception of injured and other persons and the exchange of medical, fire, police, public utility, reconnaissance, welfare, transportation and communications personnel, and equipment and supplies.

8. Each party state shall provide for the payment of compensation and death benefits to injured members of the emergency forces of that state and representatives of deceased members of such forces in case such members sustain injuries or are killed while

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rendering aid pursuant to this compact, in the same manner and on the same terms as if the injury or death were sustained within their own state.

9. Any party state rendering aid in another state pursuant to this compact shall be reimbursed by the party state receiving such aid for any loss or damage to or expense incurred in the operation of any equipment and the provision of any service in answering a request for aid and for the costs incurred in connection with such requests provided, that any aiding party state may assume, in whole or in part, such loss, damage, expense or other cost, or may loan such equipment or donate such services to the receiving party state without charge or cost provided, however, that any two or more party states may enter into supplementary agreements establishing a different allocation of costs among those states. Expenses under subdivision eight of this section shall not be reimbursable under this provision.

10. Plans for the orderly evacuation and interstate reception of portions of the civilian population as the result of any emergency or disaster of sufficient proportions to so warrant, shall be worked out and maintained between the party states and the emergency management/services directors of the various jurisdictions where any type of incident requiring evacuations might occur. Such plans shall be put into effect by request of the state from which evacuees come and shall include the manner of transporting such evacuees, the number of evacuees to be received in different areas, the manner in which food, clothing, housing and medical care will be provided, the registration of the evacuees, the providing of facilities for the notification of relatives or friends, and the forwarding of such evacuees to other areas or the bringing in of additional materials, supplies and all other relevant actors. Such plans shall provide that the party state receiving evacuees and the party state from which the evacuees come shall mutually agree as to reimbursement of out-of-pocket expenses incurred in receiving and caring for such evacuees, for expenditures for transportation, food, clothing, medicines and medical care, and like items. Such expenditures shall be reimbursed as agreed by the party state from which the evacuees come. After the termination of the emergency or disaster, the party state from which the evacuees come shall assume the responsibility for the ultimate support of repatriation of such evacuees.

11. (a) This compact shall become operative immediately upon its enactment into law by any two states; thereafter, this compact shall become effective as to any other state upon its enactment by such state.

(b) Any party state may withdraw from this compact by enacting a statute repealing the same, but no such withdrawal shall take effect until thirty days after the governor of the withdrawing state has given notice in writing of such withdrawal to the governors of all other party states. Such action shall not relieve the withdrawing state from obligations assumed hereunder prior to the effective date of withdrawal.

(c) Duly authenticated copies of this compact and of such supplementary agreements as may be entered into shall, at the time of their approval be deposited with each of the party states and with the federal emergency management agency and other appropriate agencies of the United States government.

12. This compact shall be construed to effectuate the purposes stated in subdivision one of this section. If any provision of this compact is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of this compact and the applicability thereof to other persons and circumstances shall not be affected thereby.

13. Nothing in this compact shall authorize or permit the use of military forces by the National Guard of a state at any place outside the state in any emergency for which the president is authorized by law to call into federal service the militia, or for any purposes for which the use of the army or the air force would in the absence of express statutory authorization be prohibited under section 1385 of title 18, United States code.

14. The legally designated state official who is assigned responsibility for emergency management shall not offer resources to, or request resources from, another compact member state, without prior discussion with and concurrence from the state agency, department, office, division, board, bureau, commission or authority that may be asked to provide resources or that may utilize resources from another compact member state.

15. The director of the state emergency management office shall, on or before the first day of January, two thousand two, provide to the legislature and the governor copies of all mutual aid plans and procedures promulgated, developed or entered into after the effective date of this section. The director of the state emergency management office shall annually hereafter provide the legislature and governor with copies of all new or amended mutual aid plans and procedures on or before the first day of January of each year.

UPDATE: None

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Legal Deskbook**

VA Code Ann. §44-146.13, et seq. (2002)

Commonwealth of Virginia Emergency Services and Disaster Law of 2000

This document is included in its entirety on the Deskbook CD-ROM.

§ 44-146.23. Immunity from liability

(a) Neither the Commonwealth, nor any political subdivision thereof, nor federal agencies, nor other public or private agencies, nor, except in cases of willful misconduct, public or private employees, nor representatives of any of them, engaged in any emergency services activities, while complying with or attempting to comply with this chapter or any rule, regulation, or executive order promulgated pursuant to the provisions of this chapter, shall be liable for the death of, or any injury to, persons or damage to property as a result of such activities. The provisions of this section shall not affect the right of any person to receive benefits to which he would otherwise be entitled under this chapter, or under the Workers' Compensation Act (§ 65.2-100 et seq.), or under any pension law, nor the right of any such person to receive any benefits or compensation under any act of Congress.

(b) Any person owning or controlling real estate or other premises who voluntarily and without compensation grants a license or privilege, or otherwise permits the designation or use of the whole or any part or parts of such real estate or premises for the purpose of sheltering persons, of emergency access or of other uses relating to emergency services shall, together with his successors in interest, if any, not be liable for negligently causing the death of, or injury to any person on or about such real estate or premises or for loss of or damage to the property of any person on or about such real estate or premises during such actual or impending disaster.

(c) If any person holds a license, certificate, or other permit issued by any state, or political subdivision thereof, evidencing the meeting of qualifications for professional, mechanical, or other skills, the person may gratuitously render aid involving that skill in this Commonwealth during a disaster, and such person shall not be liable for negligently causing the death of, or injury to, any person or for the loss of, or damage to, the property of any person resulting from such gratuitous service.

(d) No person, firm or corporation which gratuitously services or repairs any electronic devices or equipment under the provisions of this section after having been approved for the purposes by the State Coordinator shall be liable for negligently causing the death of, or injury to, any person or for the loss of, or damage to, the property of any person resulting from any defect or imperfection in any such device or equipment so gratuitously serviced or repaired.

(e) Notwithstanding any law to the contrary, no individual, partnership, corporation, association, or other legal entity shall be liable in civil damages as a result of acts taken voluntarily and without compensation in the course of rendering care, assistance, or advice with respect to an incident creating a danger to person, property, or the environment as a result of an actual or threatened discharge of a hazardous substance, or in preventing, cleaning up, treating, or disposing of or attempting to prevent, clean up, treat, or dispose of any such discharge, provided that such acts are taken under the direction of state or local authorities responding to the incident. This section shall not preclude liability for civil damages as a result of gross negligence, recklessness or willful misconduct. The provisions of this section shall not affect the right of any person to receive benefits to which he would otherwise be entitled under this chapter, or under the Workers' Compensation Act (§ 65.2-100 et seq.), or under any pension law, nor the right of any such person to receive any benefits or compensation under any act of Congress. The immunity provided by the provisions of this paragraph shall be in addition to, not in lieu of, any immunities provided by § 8.01-225.

UPDATE: None