APPENDIX B

Glossary of Terms

For the purposes of the National Pandemic Influenza Implementation Plan (Plan):

Acronyms

AHPA Animal Health Protection Act

AIDS Acquired immunodeficiency syndrome

APEC Asia Pacific Economic Cooperation Forum

APHIS Animal and Plant Health Inspection Service

ASEAN Association of Southeast Asian Nations

ATF Bureau of Alcohol, Tobacco, Firearms, and Explosives

ATSA Aviation and Transportation Security Act

CBO Community-based organization

CBP Customs and Border Protection

CDC Centers for Disease Control and Prevention

CFR Code of Federal Regulations

CIP Critical infrastructure protection

CITES Convention on International Trade in Endangered Species of Wild Fauna and Flora

CONUS Continental United States
COOP Continuity of operations

DEA Drug Enforcement Administration
DHS Department of Homeland Security

DOC Department of Commerce

DOD Department of Defense
DOE Department of Energy

DOI Department of the Interior

DOJ Department of Justice
DOL Department of Labor

DOS Department of State

DOT Department of Transportation

DPA Defense Production Act

EIP Emerging Infections Program
EIS Epidemic Intelligence Service

EMAC Emergency Management Assistance Compact

EMS Emergency Medical Services

EMTALA Emergency Medical Treatment and Active Labor Act

EPA Environmental Protection Agency

ESA Endangered Species Act

ESAR-VHP Emergency System for the Advanced Registration of Volunteer Health Professionals

ESF Emergency Support Function

ESF #1 Emergency Support Function #1 - Transportation

ESF #8 Emergency Support Function #8 - Public Health and Medical Services
ESF #11 Emergency Support Function #11 - Agriculture and Natural Resources

ESF #13 Emergency Support Function #13 - Public Safety and Security

ESSENCE Electronic Surveillance System for Early Notification of Community-based Epidemics

FAA Federal Aviation Administration
FAMS Federal Air Marshal Service

FAO United Nations Food and Agriculture Organization

FBI Federal Bureau of Investigation

FBO Faith-based organization

FDA Food and Drug Administration

FEMA Federal Emergency Management Agency

FHWA Federal Highway Administration

FMCSA Federal Motor Carrier Safety Administration

FMS Federal medical station

FOAA Federal Operations, Export Financing, and Related Programs Appropriations Act

FPC Federal Preparedness Circular FRA Federal Railroad Administration

FWA Fish and Wildlife Act

G-8 Group of Eight (major industrialized nations) including the United States, France, Italy,

Germany, Japan, United Kingdom, Canada, Russia

GEIS Global Emerging Infections Surveillance and Response System

GHSAG Global Health Security Action Group

GOARN Global Outbreak Alert and Response Network

HAvBED National Hospital Available Beds for Emergencies and Disasters

HCA Humanitarian and Civic Assistance

HHS Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act

HPAI Highly pathogenic avian influenza

HSC Homeland Security Council

HSPD-5 Homeland Security Presidential Directive 5 HSPD-7 Homeland Security Presidential Directive 7 HSPD-8 Homeland Security Presidential Directive 8 **ICAO** International Civil Aviation Organization

ICLN Integrated Consortium of Laboratory Networks

ICU Intensive care unit

IFI International financial institution **IHR** International Health Regulations

IMO International Maritime Organization

IPAPI International Partnership on Avian and Pandemic Influenza

LBMS Live bird marketing system LEA Local education agencies

LRN Laboratory Response Network

MARAD Maritime Administration **MBTA** Migratory Bird Treaty Act

MDB Multilateral development banks

MTF Medical treatment facility

NAHLN National Animal Health Laboratory Network

NAMRU Naval Medical Research Unit

NBIS National Biosurveillance Integration System

NDMS National Disaster Medical System

NEC National Economic Council

NGO Non-governmental organization

NHTSA National Highway Traffic Safety Administration

Nuclear Regulatory Commission

NIMS National Incident Management System **NPIP** National Poultry Improvement Program

NRP National Response Plan

NRC

NSC National Security Council

NVS National Veterinary Stockpile

NVSL National Veterinary Services Laboratories

NVSN New Vaccine Surveillance Network **NWHC** National Wildlife Health Center

OCONUS Outside the continental United States

OHDCA Overseas Humanitarian, Disaster, and Civic Aid OIE World Organization for Animal Health (formerly named the "Office International des

Epizooties")

OPM Office of Personnel Management

Partnership International Partnership on Avian and Pandemic Influenza

PHEO Public Health Emergency Officer

PHS U.S. Public Health Service PHSA Public Health Service Act

PHSBPR Public Health Security and Bioterrorism Preparedness and Response Act

PPE Personal protective equipment
PPIA Poultry Products Inspection Act
PSAP Public safety answering point

REDI Regional Emerging Disease Intervention Center in Singapore

RT-PCR Reverse transcriptase - polymerase chain reaction

SAFETEA-LU Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users

SARS Severe acute respiratory syndrome

SCHIP State Children's Health Insurance Program

SLEP Shelf Life Extension Program
SNS Strategic National Stockpile
SPN Sentinel Provider Network

SPP Security and Prosperity Partnership

STB Surface Transportation Board

TIGR The Institute for Genomic Research

Treasury Department of the Treasury

TSA Transportation Security Administration

UN United Nations

USACE U.S. Army Corps of Engineers

USAID U.S. Agency for International Development

USCG U.S. Coast Guard

USDA Department of Agriculture
USTR U.S. Trade Representative

VA Department of Veterans Affairs
VHA Veterans Health Administration

WHO World Health Organization

Definition of Terms

Adjuvants. Substances that can be added to a vaccine to increase the effectiveness of the vaccine.

Affected country. An at-risk country experiencing endemic (widespread and recurring) or epidemic (isolated) cases in humans or domestic animals of influenza with human pandemic potential.

Antiviral medications. Medications presumed to be effective against potential pandemic influenza virus strains. These antiviral medications include the neuraminidase inhibitors oseltamivir (Tamiflu®) and zanamivir (Relenza®).

Arrival screening. Medical screening upon arrival to detect individuals who have signs of illness or who are at high risk of developing illness.

Asymptomatic. Asymptomatic means without symptoms of influenza.

At-risk country. An unaffected country with insufficient medical, public health, or veterinary capacity to prevent, detect, or contain influenza with pandemic potential.

Colleges. Educational institutions post 12th grade (post high school).

Community-based organization. A private nonprofit organization, Indian tribe or tribally sanctioned organization, or other type of group that works within a community for the improvement of some aspect of that community. Community-based organizations include non-profit organizations (501 c(3)), faithbased organizations, tribes, and their subsidiaries.

Containment. Contain an outbreak to the affected region(s) and limit of spread of the pandemic through aggressive attempts to contain.

Continuity of operations. Refers to the capability to ensure the performance of essential functions during any emergency or situation that may disrupt normal operations.

Cough etiquette. Covering ones mouth and nose while coughing or sneezing; using tissues and disposing in no-touch receptacles; and washing your hands to avoid spreading an infection to others.

Countermeasures. Refers to pre-pandemic and pandemic influenza vaccine and antiviral medications.

Critical infrastructure. Systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. Specifically, it refers to the critical infrastructure sectors and key resources identified in Homeland Security Presidential Directive 7 (HSPD-7). As defined by HSPD-7, critical infrastructure includes the following sectors and key resources: agriculture and food; public health and health care; drinking water and water treatment systems; energy (including the production, refining, storage, and distribution of oil and gas, and electric power except for nuclear facilities); banking and finance; national monuments and icons; defense industrial base; information technology; telecommunications; chemical; transportation systems (including mass transit, aviation, maritime, ground/surface, and rail and pipeline systems); emergency services; postal and shipping; dams; government facilities; commercial facilities; and nuclear reactors, material, and waste. Critical infrastructure in this Plan is used to refer to the 17 critical infrastructure and key resources included in the National Infrastructure Protection Plan.

Delegation of authority. Identification, by position, the authorities for making policy determinations and decisions at headquarters, field levels, and other organizational locations, as appropriate. Generally, pre-determined delegations of authority will take effect when normal channels of direction are disrupted and terminate when these channels have resumed.

Departure screening. Medical screening prior to departure from a high-risk area to identify individuals who have signs of illness (influenza) or who are at high risk of developing illness.

Devolution. The capability to transfer and sustain authority and responsibility for essential functions from an organization's primary operating staff and facilities, to other employees and facilities.

Disaggregation of disease transmission networks. The disruption of activities and social interactions that facilitate transmission of influenza (e.g., closure of schools, canceling public meetings or large social gatherings, keeping schoolchildren home, and restriction of travel).

Domestic animals. Livestock, including poultry, and other farmed birds or mammals; does not include companion animals such as dogs, cats, or pet birds.

Dose sparing strategies. Strategies to increase influenza vaccine immunogenicity and minimize the dose of vaccine necessary to confer immunity.

En route screening. Surveillance (typically by non-medical personnel) to detect individuals who develop signs of illness (influenza) while en route.

Epidemic. A pronounced clustering of cases of disease within a short period of time; more generally, a disease whose frequency of occurrence is in excess of the expected frequency in a population during a given time interval.

ESAR-VHP. Emergency System for Advance Registration of Volunteer Health Professionals.

Essential functions. Functions that are absolutely necessary to keep a business operating during an influenza pandemic, and critical to survival and recovery.

Face mask. Disposable surgical or procedure face mask (see definitions of both below).

Faith-based organization. Any organization that has a faith-inspired interest.

Geographic quarantine (cordon sanitaire). The isolation, by force if necessary, of localities with documented disease transmission from localities still free of infection.

Hand hygiene. Hand washing with either plain soap or antimicrobial soap and water and use of alcoholbased products (gels, rinses, foams) containing an emollient that do not require the use of water.

High-throughput rapid diagnostic kit. Medical technology to accurately and rapidly detect influenza strains. The technology is currently being used to rapidly detect avian influenza employing nucleic acid diagnostic primers (short strands of DNA/RNA).

High-risk country. An at-risk country that is located in proximity to an affected country, or in which a wildlife case of influenza with pandemic potential has been detected.

Highly pathogenic avian influenza (HPAI). An infection of poultry caused by any influenza A virus that meets the World Organization for Animal Health (OIE) definition for high pathogenicity based on the mortality rate of chickens exposed to the virus intravenously or on the amino acid sequence of the cleavage site of the virus' hemagglutinin molecule.

Installations. Refers to military posts, installation, bases, stations, and activities.

International financial institution. Usually refers to intergovernmental organizations dealing with financial issues, most often the International Monetary Fund and/or the World Bank.

International Partnership for Avian and Pandemic Influenza (the Partnership; IPAPI). Partnership announced by President Bush at the UN General Assembly on September 14, 2005. Over 80 countries and 8 international organizations are working in the Partnership to fight pandemic influenza nationally and globally.

Isolation. Separation of infected individuals from those who are not infected.

Key assets. Subset of key resources that are "individual targets whose destruction could cause large scale injury, death, or destruction of property, and/or profoundly damage our national prestige or confidence."

Key resources. Publicly or privately controlled resources essential to the minimal operations of the economy and government. This refers to the four key resources identified in HSPD-7 and the National Infrastructure Protection Plan. These four key resources include: dams; government facilities; commercial facilities; and nuclear reactors, material, and waste.

Laboratory Response Network. National network of local, State, and Federal public health, food testing, veterinary diagnostic, and environmental testing laboratories supported by CDC that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism, and other public health emergencies.

Layered protective measures. Rather than focusing on a single measure for mitigation, a layered approach uses an array of measures deployed in tandem, to reduce overall risk. A layered, system-wide, integrated approach to risk reduction includes redundant measures and is designed to avoid a single point of failure. Examples include, implementing pre-departure, en route, and arrival screening measures for international travel.

Live bird marketing system (LBMS). Live poultry markets in the United States and the poultry distributors and poultry production premises that supply those markets.

Local education agencies (LEAs). Local (State, county, city, district) school boards.

Localities. Refers to local (county, city, municipal) governments and agencies.

Multilateral development banks. Multilateral development banks are institutions that provide financial support and professional advice for economic and social development activities in developing countries.

National Animal Health Laboratory Network (NAHLN). Refers to a cooperative effort among the American Association of Veterinary Laboratory Diagnosticians, the USDA Animal and Plant Health Inspection Service, and the USDA Cooperative State Research, Education and Extension Service to coordinate the capabilities of Federal, State, and university veterinary diagnostic laboratories to enhance the response to animal health events.

National Poultry Improvement Plan (NPIP). Cooperative industry-State-Federal program that establishes standards for the evaluation of poultry with respect to freedom from certain diseases.

National veterinary services. The national veterinary administration, all the veterinary authorities, and all persons authorized, registered, or licensed by the veterinary statutory body of a country to prevent and/or control animal diseases.

National Veterinary Stockpile (NVS). Refers to the supply of materiel, including vaccine, that is appropriate for a response to a damaging animal disease and capable of deployment within 24 hours of an outbreak; the stockpile is maintained by USDA's Animal and Plant Health Inspection Service.

Orders of succession. Refers to the sequential order or ranking of individuals who would assume authority and responsibility if the leadership is incapacitated or unavailable.

Outbreak. An epidemic limited to localized increase in the incidence of disease, e.g., in a village, town, or closed institution; a cluster of cases of an infectious disease.

Outbreak containment. Disruption of epidemic amplification through the use of medical countermeasures and infection control techniques; "containment" also refers more generally to delaying the geospatial spread of an epidemic.

Pandemic. A worldwide epidemic when a new or novel strain of influenza virus emerges in which humans have little or no immunity, and develops the ability to infect and be passed between humans.

Pandemic vaccine. Vaccine for specific influenza virus strain that has evolved the capacity for sustained and efficient human-to-human transmission. This vaccine can only be developed once the pandemic strain emerges.

Pathogenicity. Refers to the condition or quality of being pathogenic, or the ability to cause disease.

Plan. Refers to the Implementation Plan for the National Strategy for Pandemic Influenza.

Post-exposure prophylaxis. The use of antiviral medications in individuals exposed to others with influenza to prevent disease transmission.

Pre-pandemic vaccine. Vaccine against strains of influenza virus in animals that have caused isolated infections in humans of pandemic potential. This vaccine is prepared prior to the emergence of a pandemic strain and may be a good or poor match (and hence of greater or lesser protection) for the pandemic strain that ultimately emerges.

Priority country. A priority country is a high-risk or affected country that merits special attention because of the severity of the outbreak, its strategic importance, its regional role, or foreign policy priorities.

Procedure mask. Disposable face mask that is either flat or pleated and is affixed to the head with ear loops.

Prophylaxis. Prevention of disease or of a process that can lead to disease. With respect to pandemic influenza this specifically refers to the administration of antiviral medications to healthy individuals for the prevention of influenza.

Quarantine. Separation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection.

Rapid diagnostic test. Medical test for rapidly confirming the presence of infection with a specific influenza strain.

Reconstitution. Refers to the process by which an organization resumes normal operations.

Respirator. Refers to a particulate respirator, commonly known as N-95 respirator, often used in hospitals to protect against infectious agents. Particulate respirators are "air-purifying respirators" because they clean particles out of the air as one breathes.

 $\mathbf{R_0}$. Represents the basic reproductive rate of a pathogen, i.e., the average number of secondary infections caused by an infected individual within a given social context. An $\mathbf{R_0} = 2$ means that infected individuals, on average, transmit infection to two other people, so that every generation of disease transmission doubles the number of people infected. $\mathbf{R_0}$ will change during an epidemic as public health interventions are applied, the behavior of individuals changes, and as the pool of persons susceptible to the disease is depleted.

Schools (**K-12**). Refers to schools, both public and private, spanning the grades kindergarten through 12th grade (elementary through high school).

Sector. Part or division of the national economy.

Sector-Specific Agency. Federal departments and agencies identified under HSPD-7 as responsible for infrastructure protection activities in a designated critical infrastructure sector or key resources category.

Situational awareness. Situational awareness is the ability to identify, process, and comprehend the critical elements of information about what is happening during an evolving influenza pandemic.

Snow days. Refers to days which the authorities recommend that individuals and families limit social contacts by remaining within their households to reduce community disease transmission of infection.

Social distancing. Infection control strategies that reduce the duration and/or intimacy of social contacts and thereby limit the transmission of influenza. There are two basic categories of intervention: transmission interventions, such as the use of facemasks, may reduce the likelihood of casual social contacts resulting in disease transmission; contact interventions, such as closing schools or canceling large gatherings, eliminate or reduce the likelihood of contact with infected individuals.

Standard of care. The level of care that is reasonably expected under the extant circumstances.

States. Refers to State governments and State agencies.

Strategy. Refers to the National Strategy for Pandemic Influenza.

Surge capacity. Refers to the ability to expand provision of services beyond normal capacity to meet transient increases in demand. Surge capacity within a medical context denotes the ability of health care or laboratory facilities to provide care or services above their usual capacity, or to expand manufacturing capacity of essential medical materiel (e.g., vaccine) to meet increased demand.

Surgical mask. Refers to disposable face masks that comes in two basic types: one type is affixed to the head with two ties, conforms to the face with the aid of a flexible adjustment to the nose bridge, and may be flat/pleated or duck-billed in shape; the second type of surgical mask is pre-molded, adheres to the head with a single elastic and has a flexible adjustment for the nose bridge.

Symptomatic. Symptomatic means with symptoms of influenza.

Targeted passenger travel restrictions. Travel restrictions to the United States targeting travelers from a high-risk area or from areas unable to meet U.S. criteria for departure and en route screening.

Telecommuting. Working from home or an alternate site and avoiding coming to the workplace through telecommunication (computer access).

Telework. Refers to the activity of working away (home) from the workplace through telecommunication (computer access).

 T_{g^*} Generation time of a pathogen, or how long it takes for infected individuals to infect others. Epidemics caused by a pathogen with an $R_0 = 2$ and a $T_g = 2$ days will double in size about every 2 days, epidemics caused by a pathogen with an $R_0 = 3$ and a $T_g = 9$ days will triple in size about every 9 days,

Treatment course (antiviral medications). The course of antiviral medication prescribed as treatment (not prophylaxis) for a person infected with an agent susceptible to the antiviral medication. For oseltamivir, a treatment course for seasonal influenza is 10 capsules, administered twice daily for 5 days (a prophylaxis course is much greater, typically 42 capsules taken once daily for 42 days).

Treatment course (vaccine). The course of vaccine (typically two injections) required to induce protective immunity against the target of the vaccine.

TRICARE. Department of Defense's worldwide health care program for active duty and retired uniformed services members and their families.

Universities. Refers to educational institutions post 12th grade (post high school).

U.S. travelers from affected areas. U.S. citizens traveling to the United States from countries or region where an outbreak (influenza pandemic) has occurred.

Virulence. Virulence refers to the disease-evoking severity of influenza.

Wave. The period during which an outbreak or epidemic occurs either within a community or aggregated across a larger geographical area. The disease wave includes the time during which disease occurrence increases rapidly, peaks, and declines back toward baseline.

APPENDIX C

Authorities and References

Various Federal statutes, regulations, orders, directives, and plans authorize or otherwise enable Federal departments and agencies to engage in actions to support the three pillars of the *National Strategy for Pandemic Influenza (Strategy)*: Preparedness and Communication; Surveillance and Detection; and Response and Containment. The major statutes, regulations, directives, and plans discussed in this Implementation Plan (Plan) are those summarized below.²³

Chapter 2 - U.S. Government Planning for a Pandemic

Executive Order 12656, Assignment of Emergency Preparedness Responsibilities (November 18, 1988). This Executive Order assigns responsibilities to each Federal agency for national security and emergency preparedness.

Homeland Security Presidential Directive 5 (HSPD-5) Management of Domestic Incidents (February 28, 2003). This Presidential Directive is intended to enhance the ability of the United States to manage domestic incidents by establishing a single, comprehensive national incident management system. In HSPD-5 the President designates the Secretary of Homeland Security as the Principal Federal Official for Domestic Incident Management and empowers the Secretary to coordinate Federal resources used in response to or recovery from terrorist attacks, major disasters, or other emergencies in specific cases. The directive assigns specific responsibilities to the Attorney General, Secretary of Defense, Secretary of State, and the Assistants to the President for Homeland Security and National Security Affairs, and directs the heads of all Federal departments and agencies to provide their "full and prompt cooperation, resources, and support," as appropriate and consistent with their own responsibilities for protecting national security, to the Secretary of Homeland Security, Attorney General, Secretary of Defense, and Secretary of State in the exercise of leadership responsibilities and missions assigned under HSPD-5. The directive also notes that it does not alter, or impede the abilities of Federal departments and agencies to carry out their responsibilities under law.

National Response Plan (NRP). In HSPD-5, the President directed the development of a new NRP to align Federal coordination structures, capabilities, and resources into a unified, all-discipline, and all-hazards approach to domestic incident management. The NRP, released in December 2004 and fully implemented in April 2005, is such a plan. It provides the structure and mechanisms for the coordination of Federal support to State, local, and tribal incident managers and for exercising direct Federal authorities and responsibilities. The NRP assists in the important homeland security mission of preventing terrorist attacks within the United States; reducing the vulnerability to all natural and manmade hazards; and minimizing the damage and assisting in the recovery from any type of incident that occurs.

Chapter 3 - Federal Government Response to a Pandemic

The Economy Act, 31 U.S.C. §§ 1535-1536 (2002). The Economy Act authorizes Federal agencies to provide goods or services on a reimbursable basis to other Federal agencies when more specific statutory authority to do so does not exist.

²³ Some of the authorities and references described in this appendix are applicable to actions discussed in more than one chapter but may only be set forth in the section they are primarily applicable to.

Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974, codified as amended at 42 U.S.C. §§ 5121-5206, and scattered sections of 12 U.S.C., 16 U.S.C., 20 U.S.C., 26 U.S.C., 38 U.S.C. (2002). The Stafford Act establishes programs and processes for the Federal Government to provide disaster and emergency assistance to States, local governments, tribal nations, individuals, and qualified private nonprofit organizations. The provisions of the Stafford Act are broad and may cover many situations, including natural disasters and terrorist events. In a major disaster or emergency as defined in the Stafford Act, the President "may direct any Federal agency, with or without reimbursement, to utilize its authorities and the resources granted to it under Federal law (including personnel, equipment, supplies, facilities, and managerial, technical, and advisory services) in support of State and local assistance efforts."

Under the Act, the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security (DHS), is authorized to coordinate the activities of Federal agencies in response to a Presidential declaration of a major disaster or emergency, if warranted, with the Department of Health and Human Services (HHS) having the lead for health and medical services. The President could declare either an emergency or a major disaster with respect to an influenza pandemic.

The National Emergencies Act, 50 U.S.C. §§ 1601-1651 (2003), establishes procedures for Presidential declaration and termination of national emergencies. The act requires the President to identify the specific provision of law under which he or she will act in dealing with a declared national emergency and contains a sunset provision requiring the President to renew a declaration of national emergency to prevent its automatic expiration. The Presidential declaration of a national emergency under the act is a prerequisite to exercising any special or extraordinary powers authorized by statute for use in the event of national emergency.

The Defense Production Act (DPA) of 1950, codified as amended by the Defense Production Act Reauthorization of 2003 at 50 U.S.C. app.§§ 2061-2171 (2002), is the primary authority to ensure the timely availability of resources for national defense and civil emergency preparedness and response. Among other things, the DPA authorizes the President to demand that companies accept and give priority to government contracts that the President "deems necessary or appropriate to promote the national defense." The DPA defines "national defense" to include critical infrastructure protection and restoration, as well as activities authorized by the emergency preparedness sections of the Stafford Act. Consequently, DPA authorities are available for activities and measures undertaken in preparation for, during, or following a natural disaster or accidental or man-caused event. The President's authority has been delegated to various agencies, depending on the product, with the Department of Commerce (DOC) providing overall coordination of the Defense Priorities and Allocations System. The DOC has redelegated DPA authority under Executive Order 12919, National Defense Industrial Resource Preparedness (June 7, 1994), as amended, to the Secretary of Homeland Security to place and, upon application, to authorize State and local governments to place priority-rated contracts in support of Federal, State, and local emergency preparedness activities.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PHSBPR), Pub. L. No. 107-188, 116 Stat. 294 (2002) (codified in scattered sections of 7 U.S.C., 18 U.S.C., 21 U.S.C., 29 U.S.C., 38 U.S.C., 42 U.S.C., and 47 U.S.C. (2002)), is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Key provisions of the PHSBPR, 42 U.S.C. §§ 247d and 300hh among others, address the development of a national preparedness plan by HHS designed to provide effective assistance to State and local governments in the event of bioterrorism or other public health emergencies; operation of the National Disaster Medical

System (NDMS) to mobilize and address public health emergencies; grant programs for the education and training of public health professionals and improving State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies; streamlining and clarifying communicable disease quarantine provisions; enhancing controls on dangerous biological agents and toxins; and protecting the safety and security of food and drug supplies.

Flood Control and Coastal Emergencies Act, 33 U.S.C § 701n (2002), authorizes the U.S. Army Corps of Engineers (USACE) to use an emergency fund for preparation for emergency response to natural disasters, flood fighting and rescue operations, rehabilitation of flood control and hurricane protection structures, temporary restoration of essential public facilities and services, advance protective measures, and provision of emergency supplies of water. The USACE receives funding for such activities under this authority from the Energy and Water Development Appropriation.

Volunteer Services. There are statutory exceptions to the general statutory prohibition against accepting voluntary services under 31 U.S.C. § 1342 (2002) that can be used to accept the assistance of volunteer workers. Such services may be accepted in "emergencies involving the safety of human life or the protection of property." Additionally, provisions of the Stafford Act, 42 U.S.C. §§ 5152(a), 5170a(2) (2002), authorize the President to, with their consent, use the personnel of private disaster relief organizations and to coordinate their activities. Under the Congressional Charter of 1905, 36 U.S.C. §§ 300101-300111 (2002), the American Red Cross and its chapters are a single national corporation. The Charter mandates that the American Red Cross maintain a system of domestic and international disaster relief. The American Red Cross qualifies as a nonprofit organization under section 501(c)(3) of the Internal Revenue Code.

Chapter 4 - International Efforts

Clearance of Proposed International Agreements. The Department of State (DOS) must ensure that all proposed international agreements of the United States are fully consistent with U.S. foreign policy objectives. The requirements for this coordination with and clearance from DOS are codified, in part, at sections 181.1-8 of Title 22 of the Code of Federal Regulations (CFR). The C-175 clearance requirements are specifically referenced in 22 C.F.R. § 181.4 (and Volume 11 of the Foreign Affairs Manual, Chapter 700).

Foreign Assistance. Relevant foreign assistance authorities for health and disasters authorize the provision of assistance "notwithstanding any other provision of law." These authorities would permit the provision of aid, such as medical goods and services, and even security details to ensure delivery of these items. Annual foreign operations appropriations acts reenact this special health authority annually, as follows:

Section 522 of the FY06 Foreign Operations, Export Financing, and Related Programs Appropriations Act (FOAA), Pub. L. No. 109-102, funds child survival and health activities and includes robust authority that would enable us to overcome any country-specific and other assistance limitations (e.g., North Korea, Iran, Burma, China). In cases of emergency to health and human welfare, there is an exceptional authority reenacted annually from the usual 15-day Congressional notification period (required for reprogramming notifications). Any assistance appropriated as economic assistance (i.e., not just funds appropriated for health) may be used pursuant to this authority to provide assistance for health.

The Foreign Assistance Act of 1961, as amended, provides relevant authorities for disaster assistance, with a full "notwithstanding" authority, and for health, with a more limited "notwithstanding" authority, as follows:

- FAA § 491 authorizes provision of assistance for natural and man-made disasters, "notwith-standing any other provision of law."
- FAA \$104(c) (22 U.S.C. \$ 2151b-4) authorizes "[a]ssistance for [h]ealth and [d]isease [p]revention." Such assistance "may be made available notwithstanding any other provision of law that restricts assistance to foreign countries." There are some limitations on the "notwithstanding" authority (e.g., the notwithstanding clause does not trump limitations on assistance to organizations that support or participate in a program of coercive abortion or involuntary sterilization), but we do not foresee such exceptions constraining our ability to respond to a pandemic influenza.
- Title IV of the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, Pub. L. No. 109-13, 119 Stat. 231 (2005), appropriates \$656 million for emergency relief, rehabilitation, and reconstruction aid to countries affected by the Asian tsunami and earthquakes of December 2004 and March 2005, and the avian influenza virus, to remain available until September 30, 2006. Additional funding is being sought as part of the President's \$7.1 billion pandemic influenza legislative request.

Foreign Assistance to Address Civil Unrest Abroad. If foreign assistance were required for police to address civil unrest abroad associated with an outbreak, such assistance could be provided for police forces under various authorities, most notably, under FAA § 481(a)(4). Assistance for military forces for such purposes could also be provided under certain authorities, e.g., section 551 of the FAA for peace-keeping and other programs in the national security interest of the United States and section 23 of the Arms Export Control Act codified in 22 U.S.C. § 2751 et seq. (2000) for military assistance.

Title 11, Emergency Supplemental Appropriation to address Pandemic Influenza of the Department of Defense Appropriations Act of 2006, Pub. L. No. 109-148 (2006). This Act provides \$10 million and additional authority for the Department of Defense (DOD) to assist military partner nations in pandemic influenza response preparedness.

The Public Health Service Act (PHSA), 42 U.S.C. § 201 note (2005). The PHSA authorizes HHS to engage in international biomedical research, health care technology, and specified health services research and statistical activities "to advance the status of the health sciences in the United States" and thereby the health of the American people (42 U.S.C. 242). HHS has interpreted this authority to support numerous international surveillance and research activities as well.

Military assistance. The major authorities that DOD may rely on to provide assistance outside the United States, include:

- 10 U.S.C. § 401 (Humanitarian and Civic Assistance (HCA). This section of the Code provides for HCA projects, approved in coordination with the Combatant Commanders and DOS that improve operational readiness skills of participating U.S. forces and are conducted in conjunction with military operations.
- 10 U.S.C. § 402 (Transportation). Subject to certain exceptions, DOD may transport supplies provided by non-governmental, U.S. sources without charge on a space-available basis.

- 10 U.S.C. §404 (Foreign Disaster Assistance). Under certain circumstances and subject to certain congressional notice requirements, the President may direct the Secretary of Defense to provide disaster assistance outside the United States in order to respond to manmade or natural disasters when necessary to prevent the loss of life.
- 10 U.S.C. § 2557 (Excess Nonlethal Supplies: Humanitarian Relief). This provision authorizes
 excess supplies to be made available to DOS for humanitarian relief. DOS will be responsible for
 distribution.
- 10 U.S.C. § 2561(Transportation and Other Humanitarian Support). DOD also may provide fully funded transportation (on an other-than space-available basis), if it pays such transportation costs with its operation and maintenance funds earmarked for Overseas Humanitarian, Disaster, and Civic Aid (OHDCA) purposes.

Chapter 5 - Transportation and Borders

Transportation Authorities

General Transportation Security Authorities. DHS has broad authority to protect transportation security, including authorities that could keep quarantinable diseases from reaching the United States. The Transportation Security Administration (TSA) is "responsible for security in all modes of transportation" (49 U.S.C. § 114). If the TSA Assistant Secretary "determines that a regulation or security directive must be issued immediately in order to protect transportation security the [Assistant Secretary] shall issue the regulation or security directive without providing notice or an opportunity for comment and without prior approval of the Secretary [of Homeland Security]" (49 U.S.C. § 114(l)(2)(A)). TSA interprets these provisions on transportation security to provide authority for TSA to keep a flight destined for the United States from landing in the United States if it is determined that a flight may be transporting persons with a quarantinable disease. These TSA authorities are also sufficiently broad to allow TSA to direct an air carrier to temporarily avoid deplaning its passengers until HHS or other medical authorities can screen the passengers. Finally, pursuant to 49 U.S.C. § 114(q), the Federal Air Marshal Service (FAMS) of TSA has the authority to exercise law enforcement powers in the transportation domain.

Emergency Transportation Security Authorities. In the case of a national emergency, the Aviation and Transportation Security Act (ATSA) provides DHS with additional authorities. ATSA confers four specific national emergency responsibilities upon DHS: "(A) To coordinate domestic transportation, including aviation, rail, and other surface transportation, and maritime transportation (including port security); (B) To coordinate and oversee the transportation-related responsibilities of other departments and agencies of the Federal Government other than the DOD and the military departments; (C) To coordinate and provide notice to other departments and agencies of the Federal Government, and appropriate agencies of State and local governments, including departments and agencies for transportation, law enforcement, and border control, about threats to transportation; (D) To carry out such other duties, and exercise such other powers, related to transportation during a national emergency as the Secretary shall prescribe" (49 U.S.C. § 114(g) (1) (A)-(D)). ATSA qualifies this authority by adding: "(2) AUTHORITY OF OTHER DEPARTMENTS AND AGENCIES. The authority of the [Secretary of Homeland Security] under this subsection shall not supersede the authority of any other department or agency of the Federal Government under law with respect to transportation or transportation-related matters, whether or not during a national emergency (49 U.S.C. § 114(g) (2)). ATSA also adds: "(3) CIRCUMSTANCES. The Secretary [of Homeland Security] shall prescribe the circumstances constituting a national emergency for purposes of this subsection" (49 U.S.C. § 114(g) (3)).

During a national emergency declared by the President, the Department of Transportation (DOT), through the Maritime Administration (MARAD), can enhance U.S. sealift capacity by taking control of vessels, containers, and chassis through requisitioning (46 App. U.S.C. § 1242; 50 U.S.C. §§ 196-198).

Aviation. The Federal Aviation Administration (FAA) is the lead agency for aviation safety regulation and oversight and is responsible for the operation and maintenance (to include personnel, physical, and cyber) of the Air Traffic Control System (Title 49 U.S.C., subtitle VII, Aviation Programs). Any movement in the navigable airspace of the United States can be stopped, redirected, or excluded by the FAA, regardless of the commodity involved (49 U.S.C. § 44701). Additionally, the FAA can order U.S.-flag air carriers not to enter designated airspace of a foreign country (e.g., to keep airspace clear for rescue operations). If the FAA determines that an emergency exists related to safety in air commerce that requires immediate action, the FAA may prescribe regulations and issue orders immediately to meet that emergency (49 U.S.C. § 46105(c)). FAA interprets these provisions on aviation security or safety to provide authority for FAA to close airspace to, or redirect, a flight if it is determined that a flight may be transporting persons with a quarantinable disease.

Subject to the direction and control of the Secretary of Homeland Security, the TSA has the authority to cancel a flight or series of flights if a decision is made that a particular security threat cannot be addressed in a way adequate to ensure, to the extent feasible, the safety of passengers and crew (49 U.S.C. § 44905(b)). TSA is required to work in conjunction with the FAA with respect to any actions or activities that may affect aviation safety or air carrier operations (49 U.S.C. § 114(f)(13); 6 U.S.C. § 233(a)). TSA interprets these provisions to authorize TSA to cancel flights in the case of a pandemic influenza.

Chicago Convention. The Chicago Convention, a multilateral treaty establishing the framework for the operation of international civil aviation, provides authority to deny entry to flights that do not comply with U.S. laws and regulations, including those relating to entry, clearance, customs, and quarantine. The Chicago Convention articles that may be relevant include 11, 13, 14, 16, 29, and 89.

Rail. Any movement in the United States by rail carrier (including commuter rail but excluding urban rapid transit not connected to the general system of rail transportation) may be stopped, redirected, or limited by the authority of the Surface Transportation Board (STB) or the Federal Railroad Administration (FRA), or both, irrespective of commodity involved. The FRA may issue an emergency order imposing any restrictions or prohibitions necessary to abate what the FRA determines is an emergency situation involving a hazard of death or personal injury caused by unsafe conditions or practices (49 U.S.C. § 20104). For a period of 270 days, the STB may direct the movement and prioritization of freight traffic necessary to alleviate an emergency situation involving the failure of traffic movement having substantial adverse impacts on shippers or on rail service in any region of the United States (49 U.S.C. § 11123), and may also order that preference be given to certain traffic, when the President so directs in time of war or threatened war (49 U.S.C. § 11124).

Mass Transit. In general, DOT is forbidden from regulating the operation, routes, schedules, rates, fares, tolls, rentals, or other charges of public transportation system grantees of the Federal Transit Administration. However, the Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy for Users, Pub. L. No. 109-59, 119 Stat. 1144 (2005) (SAFETEA_LU), amended section 5334 of title 49 of the United States Code to create an express exception to the above prohibition when needed for national defense or in the event of a national or regional emergency.

Highways. The Federal Highway Administration (FHWA) possesses no authority to operate the Nation's highway system during times of emergency. States, local governments, and other Federal agencies own,

control, and operate the Nation's roads and bridges. The Federal Motor Carrier Safety Administration (FMCSA) can order a vehicle to cease operation and relocate to a safe place if there is reason to believe it would constitute a security threat because it carries a hazardous material (49 U.S.C. § 521(b)(5); 49 U.S.C. § 5103(b), Section 1711, Homeland Security Act of 2002, Pub. L. 107-296).

Pipelines. The operation of any pipeline facility used to transport gas or hazardous liquid can be stopped by the Pipeline and Hazardous Materials Safety Administration if continued operation of the facility is or would become hazardous (49 U.S.C. § 60112).

Hazardous Materials. Any aspect of hazardous materials transportation that presents an "imminent hazard" may be halted by court order (49 U.S.C. § 5122(b)). An "imminent hazard" is a condition that presents a substantial likelihood that death, serious illness, severe personal injury, or a substantial endangerment to health, property, or the environment may occur before the reasonable foreseeable completion date of a formal proceeding begun to lessen the risk of that death, illness, injury, or endangerment (49 U.S.C. § 5102). DOT is also authorized to issue or impose emergency restrictions, prohibitions, recalls, or out-of-service orders, without notice or an opportunity for a hearing, but only to the extent necessary to abate an imminent hazard (49 U.S.C. §5121(d)).

Transportation Authorities Relating Specifically to Vessels. In the case of vessels, if there is evidence that a vessel is carrying a person or persons with a quarantinable disease that would present a public health threat to the port if the ship or the person were allowed to enter, the U.S. Coast Guard (USCG) has authority to prevent the vessel from entering a U.S. port or place until the infected person(s) can be dealt with by HHS/CDC personnel so as to prevent the spread of the disease in the United States (50 U.S.C. §§ 191–195; 33 U.S.C. §§ 1221–1232; 33 C.F.R. part 6; 33 C.F.R. § 160.111).

The Saint Lawrence Seaway Development Corporation may halt traffic through those portions of the Saint Lawrence Seaway subject to the jurisdiction of the United States, if required for safety or security of the seaway or for national security (e.g., deepwater vessels could be barred from entering or leaving the Seaway) (33 U.S.C. §§ 984, 1226).

Defense Production Act of 1950, 50 U.S.C. App. §§ 2061-2171 (2002). The DPA is the primary authority to ensure the timely availability of resources for national defense and civil emergency preparedness and response. Under the DPA, the Secretary of Transportation has been delegated the authority to marshal civil transportation in a defined area if national defense or domestic emergency conditions require civil transportation materials, services, or facilities that are not being provided by the marketplace. However, formal findings must be made by DOD, Department of Energy (DOE), or DHS, before DOT can exercise its DPA authority.

Border Authorities

General Border Authorities. DHS has broad authority to protect U.S. borders, including specific statutory provisions designating USCG and the United States Customs and Border Protection (CBP) to assist in the enforcement of State health laws and Federal quarantine regulations (42 U.S.C. §§ 97, 268). CBP has general authority pursuant to the customs and immigration laws (e.g., 19 U.S.C. §§ 482, 1461, 1496, 1589a, 1499, 1581, 1582, 1595a, and 8 U.S.C. §§ 1157, 1357) to examine merchandise, cargo, conveyances and persons upon their entry to, and exit from, the United States to ensure compliance with U.S. law, and to seize and forfeit conveyances, animals, or other things imported contrary to law or used in the unlawful importation, exportation, or subsequent transportation of articles imported contrary to U.S. law (18 U.S.C. § 545, 19 U.S.C. § 1595a). Section 421 of the Homeland Security Act transferred to the

Secretary of Homeland Security certain agricultural import and entry inspection functions originally assigned to the Secretary of Agriculture under the Animal Health Protection Act. This transfer included the authority to enforce prohibitions or restrictions on the entry of livestock diseases into the United States. Finally, the Secretary of Homeland Security and the Commissioner of CBP may temporarily close ports of entry "when necessary to respond to a national emergency or to [respond to] a specific threat to human life or national interests" (19 U.S.C. § 1318(b)). Such closings would effectively stop the legal entry of persons and conveyances and the legal importation and exportation of articles at those places.

Border Authorities Relating to Travelers. DHS has authority to find inadmissible any alien "who is determined (in accordance with the regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance" (8 U.S.C. § 1182(a)(1)). Under 8 U.S.C. § 1222(a), DHS could detain aliens for the purpose of determining whether they have a communicable disease listed in section 1182(a). The list of communicable diseases of public health significance as defined in HHS regulations is, however, limited, and does not generally include quarantinable diseases, including pandemic influenza, listed in Executive Order 13295.

Aliens with pandemic influenza could be excluded pursuant to 8 U.S.C. § 1182(f), which provides that "[w]henever the President finds that the entry of any aliens or of any class of aliens into the United States would be detrimental to the interests of the United States, he may by proclamation, and for such period as he shall deem necessary, suspend the entry of all aliens or any class of aliens as immigrants or nonimmigrants, or impose on the entry of aliens any restrictions he may deem to be appropriate." The President may not delegate the authority to issue such a proclamation. Accordingly, if the President determined that the entry of any aliens or class of aliens was detrimental to the interests of the United States, for reasons that may include the threatened spread of a pandemic into the United States, he may issue a proclamation suspending such entry and directing enforcement by all Federal agencies.

Control of Communicable Diseases. The Public Health Service Act (PHSA), 42 U.S.C. § 264, authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. Under section 362 of the PHSA, 42 U.S.C. § 265, the Secretary of Health and Human Services may prohibit, in whole or in part, the introduction of persons and property from such countries or places as he/she shall designate for the purpose of averting a serious danger of the introduction of a communicable disease into the United States if he determines that such a prohibition is in the interest of the public health.

Vessels en route to the United States. Section 366 of the PHSA (42 U.S.C. § 269) requires vessels at foreign ports clearing or departing for the United States to obtain a bill of health from a U.S. consular officer, U.S. Public Health Service officer, or other U.S. medical officer, unless otherwise prescribed in regulations. Historically, a bill of health was a document required from ships in international traffic that set forth the sanitary history and condition of the vessel and, in some cases, the condition of the port during the time of departure. Foreign quarantine regulations in part 71 currently state that a bill of health is not required. Under the CDC's proposed rule, the CDC Director, to the extent permitted by law and in consultation with such other Federal agencies as the Director may deem necessary, would be authorized to require a foreign carrier clearing or departing for a U.S. port to obtain a bill of health from a U.S. consular officer or a medical officer designated for such purpose.

Animals, Poultry, and Wildlife

The Animal Health Protection Act (AHPA) of 2002, 7 U.S.C. 8301 et seq. The AHPA, described in detail

in Authorities Chapter 7, gives the Secretary of Agriculture a broad range of authorities to use in the event of an outbreak of avian influenza in the United States and to prevent the introduction of such a disease into the United States.

The Poultry Products Inspection Act, 21 U.S.C. 451 et seq. This Act requires the inspection of poultry products and provides for criminal penalties for adulteration and misbranding of poultry products.

Importation of wild bird species parts and products. The importation of these items must comply with conservation laws and treaties enforced by the Department of the Interior (DOI), including the Wild Bird Conservation Act, the Migratory Bird Treaty Act of 1918, 16 U.S.C. 703-712, the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531-1544, which implements the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), T.I.A.S. 8249; the Lacey Act Amendments of 1981, 16 U.S.C. 3371-3378; and the Bald Eagle Protection Act of 1940, 16 U.S.C.668-668d. The DOI has the authority to take measures to restrict trade in wild birds based on threats to wildlife populations. In the event of an outbreak of highly pathogenic avian influenza (HPAI) in domestic or wild exotic birds in the United States, DOI has the authority (under 50 C.F.R. Part 13) to suspend the issuance of export and reexport permits under CITES and the ESA if such action is deemed necessary after coordination with USDA.

Chapter 6 - Protecting Human Health

The Public Health Service Act (PHSA), 42 U.S.C. §§ 201 et seq. (1994). The Secretary of Health and Human Services is authorized to develop and take such action as may be necessary to implement a plan under which the personnel, equipment, medical supplies, and other resources of the Department may be effectively used to control epidemics of any disease or condition and to meet other health emergencies and problems, (see 42 U.S.C. § 243). During an emergency proclaimed by the President, the President has broad authority to direct the services of the Public Health Service, (42 U.S.C. § 217). Under that section, the President is authorized to "utilize the [Public Health] Service to such extent and in such manner as shall in his judgment promote the public interest."

- Research. Section 301 of the PHSA, 42 U.S.C. § 241, authorizes the Secretary to conduct and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental impairments of man. The Secretary is also authorized to collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities.
- Public Health Emergency. Section 319(a) of the PHSA, 42 U.S.C. 247d, authorizes the Secretary of Health and Human Services to declare a public health emergency and "take such action as may be appropriate to respond" to that emergency consistent with his authorities. Appropriate action may include making grants, entering into contracts, and conducting and supporting investigation into the cause, treatment, or prevention of the disease or disorder that presents the emergency. The Secretary's declaration also can be the first step in authorizing emergency use of unapproved products or approved products for unapproved uses under section 564 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), or waiving certain regulatory requirements of the Department, such as select agents requirements, or -- when the President also declares an emergency -- waiving certain Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) provisions.

- Vaccines and therapeutics. The PHSA provides additional authorities for core activities of HHS that will be needed to plan and implement an emergency response. For example, sections 301, 319F-1, 402, and 405 of the PHSA authorize the Secretary of Health and Human Services to conduct and support research and development of vaccines and therapeutics. Section 351 of the PHSA and provisions of the Federal Food, Drug, and Cosmetics Act authorize the Secretary and the Food and Drug Administration (FDA) to regulate vaccine development and production. Infrastructure support for preventive health services such as immunization activities, including vaccine purchase assistance, is provided under section 317 of the PHSA.
- Liability protection. Section 319F-3 of the PHSA provides immunity to manufacturers, distributors, program planners, "qualified persons," and their employees for claims for loss caused by, arising out of, relating to, or resulting from the administration or use of any "covered countermeasure" that is the subject of a declaration made by the Secretary. A covered countermeasure is a drug, device, or biological that is (1) subject to an emergency use authorization under section 564 of the Federal Food Drug and Cosmetic Act, (2) used against an epidemic or pandemic and either approved or subject to an IND, or (3) a security countermeasure as defined under the Project BioShield Act. Section 319F-4 allows the Secretary to, by declaration, establish an emergency fund in the Treasury which will be used to provide compensation for injuries directly caused by administration of a covered countermeasure.
- Strategic National Stockpile. Section 319F-2 of the PHSA authorizes the Secretary, in coordination with the Secretary of Homeland Security, to maintain the Strategic National Stockpile to provide for the emergency health security of the United States.
- Quarantine. Section 361 of the PHSA (42 U.S.C. § 264), authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one State or possession into any other State or possession. Implementing regulations are found at 42 C.F.R. Parts 70 and 71. The HHS Centers for Disease Control and Prevention (CDC) administers these regulations as they relate to quarantine of humans. Diseases for which individuals may be quarantined are specified by Executive Order; the most recent change to the list of quarantinable diseases was Executive Order 13375 of April 1, 2005, which amended Executive Order 13295 by adding "influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic" to the list. CDC issued a new proposed rule updating these regulations on November 30, 2005. 70 Fed. Reg. 71892 (www.cdc.gov/ncidod/dq/nprm/index.htm). Other provisions in Title III of the PHSA permit HHS to establish quarantine stations, provide care and treatment for persons under quarantine, and provide for quarantine enforcement by specified components of DHS and cooperating State and local entities.
- Vaccine Development. Further, HHS has broad authority to coordinate vaccine development, distribution, and use activities under section 2102 of the PHSA, describing the functions of the National Vaccine Program. The Secretary has authority for health information and promotion activities under title XVII and other sections of the PHSA. HHS can provide support to States and localities for emergency health planning under title III of the PHSA.
- National Goals. Under section 1701 of the PHSA, 42 U.S.C. § 300u, the Secretary is authorized to formulate national goals for health information, promotion, health services, and education

and to undertake activities, including training, support, planning, and technical assistance, to carry out those goals.

• Mobilizing the Commissioned Corps. Section 203 of the PHSA, 42 U.S.C. § 204, authorizes the Federal Government to mobilize officers of the United States Public Health Service Regular Commissioned Corps and the Reserve Commissioned Corps, including commissioned corps officers who are veterinarians, in times of emergencies.

Department of Veterans Affairs (VA) Authorities. The primary function of the Veterans Health Administration (VHA) is to provide a complete medical and hospital service for the medical care and treatment of veterans. Section 8111A of title 38 of the U.S. Code authorizes the Secretary to provide care to members of the Armed Forces during a time of war or national emergency. Section 1784 of title 38 authorizes the Secretary to furnish hospital care or medical services as a humanitarian service to non-VA beneficiaries in emergency cases. Section 1785 of title 38 authorizes the Secretary to provide hospital care and medical services to non-VA beneficiaries responding to, involved in, or otherwise affected by a disaster or emergency. This provision codifies VA's existing obligations under the Federal Response Plan (now National Response Plan). These include VA's obligations under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121, et seq., and during activation of the National Disaster Medical System (NDMS), 42 U.S.C. § 300hh-11.

• The explicit language in section 8111A and the legislative history of section 1785 indicate that during declared major disasters and emergencies and activation of NDMS, the highest priority for receiving VA care and services goes to service-connected veterans, followed by members of the Armed Forces receiving care under section 8111A and then by individuals affected by a disaster or emergency described in section 1785 (i.e., individuals requiring care during a declared disaster or emergency, or during activation of the NDMS). As a practical matter, when faced with individuals who require emergency medical treatment (e.g., during a disaster or emergency situation), VHA practitioners must prioritize based on medical need. This may require deferring routine or elective care for veterans in order to treat medical emergencies. Life-threatening conditions are treated prior to less severe or routine conditions, regardless of priority. Such prioritization is not dictated by statute or regulation. Rather, it is derived from the general authority granted to the Secretary (and through delegation to the Under Secretary for Health and to health care providers) to provide "needed care" to veterans. Thus, during a disaster or an emergency, VA has flexibility and discretion in providing needed care.

Exemption of Certain International Persons from Quarantine or other Restrictions. There are certain legal bases pursuant to which Federal authorities could insist that certain people on an aircraft be released from quarantine (e.g., diplomats and their families are "inviolable" under the Vienna Convention on Diplomatic Relations; United Nations (UN) diplomats are "inviolable" under the UN General Convention on Privileges and Immunities and the HQ Agreement; diplomats attending UN conferences are "inviolable" under the General Convention; consular officers (not families) are potentially "inviolable" under Articles 40 and 41 of the Vienna Convention on Consular Relations; and heads of States are generally subject to immunity).

ENHANCE 911 Act of 2004. Pub. L. No. 108-494. This Act requires officials of the Department of Transportation and the Department of Commerce to establish a joint program to facilitate coordination and communication between Federal, State, and local communications systems, emergency personnel, public safety organizations, telecommunications carriers, and telecommunications equipment manufac-

turers and vendors. The Act also requires those agencies to create an E-911 Implementation Coordination Office to implement that program. The Office will be housed at the Department of Transportation, National Highway Traffic Safety Administration (NHTSA) and is required to: develop, collect, and disseminate information concerning practices, procedures, and technology used in the implementation of E-911 services.

Other Authorities

The Defense Production Act, 50 U.S.C. p. §§ 2601-2171 (2002). Under the DPA, agencies can: (1) issue rated orders to manufacturers to give Government orders priority over all other orders, (2) issue rated orders to non-influenza countermeasure manufacturing facilities to manufacture influenza vaccine or antiviral medications, or (3) pursuant to DHS/FEMA regulations, and in consultation with Department of Justice (DOJ) and the Federal Trade Commission, convene industry and execute voluntary agreements as to how industry might meet the Government's vaccine and antiviral requirements.

Chapter 7 - Protecting Animal Health

The Animal Health Protection Act (AHPA) of 2002, 7 U.S.C. 8301 et seq. The AHPA enables the Secretary of Agriculture to prevent, detect, control, and eradicate diseases and pests of animals, such as avian influenza, in order to protect animal health, the health and welfare of people, economic interests of livestock and related industries, the environment, and interstate and foreign commerce in animals and other articles. The AHPA provides a broad range of authorities to use in the event of an outbreak of avian influenza in the United States and to prevent the introduction of such a disease into the United States. The Secretary is specifically authorized to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock, which includes poultry, 7 U.S.C. 8308, and to promulgate regulations and issue orders to carry out the AHPA (see 7 U.S.C. 8315). The Secretary may also prohibit or restrict the importation, entry, or interstate movement of any animal, article, or means of conveyance to prevent the introduction into or dissemination within the United States of any pest or disease of livestock (7 U.S.C. 8303 8305). Section 421 of the Homeland Security Act, 6 U.S.C. 231, transferred to the Secretary of Homeland Security certain agricultural import and entry inspection functions under the AHPA, including the authority to enforce the prohibitions or restrictions imposed by USDA. Under certain specified circumstances, the Secretary of Agriculture may declare an extraordinary emergency to regulate intrastate activities or commerce (7 U.S.C. 8306). The Secretary also has authority to cooperate with other Federal agencies, States, or political subdivisions of States, national or local governments of foreign countries, domestic or international organizations or associations, Indian tribes, and other persons to prevent, detect, control, or eradicate avian influenza (7 U.S.C. 8310).

The Poultry Products Inspection Act (PPIA) of 1957, 21 U.S.C. 452. The PPIA provides for the inspection of poultry and poultry products and otherwise regulates the processing and distribution of such articles to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. All articles and poultry which are regulated under the PPIA are either in interstate or foreign commerce or substantially affect

such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers. USDA statutory authorities to inspect and condemn animal carcasses and parts that may become adulterated or otherwise unfit may be relied upon for government action in appropriate situations.

The Virus-Serum-Toxin Act, 21 U.S.C. 151 et seq. The Secretary of Agriculture is authorized under this act to regulate veterinary biological products. These products generally act through a specific immune process and are intended for use in the treatment, including prevention, diagnosis, or cure, of diseases in animals. They include, but are not limited to, vaccines, bacterins, sera, antisera, antitoxins, toxoids, allergens, diagnostic antigens prepared from, derived from, or prepared with microorganisms, animal tissues, animal fluids, or other substances of natural or synthetic origin.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, 116 Stat. 594 (2002). Title II of this act, "Enhancing Controls on Dangerous Biological Agents and Toxins" (sections 201-231), provides for the regulation of certain biological agents and toxins by HHS (subtitle A, sections 201-204) and USDA (subtitle B, sections 211-213, also known as the Agricultural Bioterrorism Protection Act of 2002). The Act also provides for interagency coordination between the two departments regarding certain agents and toxins that present a threat to both human and animal health. The regulations governing HHS's select agent program are found at part 73 of title 42 of the CFR; the regulations governing USDA's select agent program are found at part 331 of title 7 of the CFR (plants) and part 121 of title 9 of the CFR (animals). For HHS, the CDC is designated as the agency with primary responsibility for the select agent program. The Animal and Plant Health Inspection Service (APHIS) is the USDA agency fulfilling that role for the provisions applicable to animals and plants. These statutes and their implementing regulations require entities, such as private, State, and Federal research laboratories, universities, and vaccine companies, that possess, use, or transfer biological agents or toxins which are determined to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products register these agents with APHIS or CDC. USDA's select agent regulations may be applicable in the event of an outbreak of avian influenza, as HPAI is listed as select agent under USDA regulations. For example, the USDA regulations will govern the possession, use, or movement of an HPAI virus in connection with any research attendant to a response to the outbreak. At the same time, it should be noted that the Agricultural Bioterrorism Protection Act provides that the Secretary may grant exemptions from the applicability of provisions of the regulations, in the case of listed agents or toxins, if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products.

Animal Damage Control Act of 1931, 46 Stat. 1468, codified as amended at 7 U.S.C. §§ 426-426b (2000), and the Rural Development, Agriculture, and Related Agencies Appropriations Act of 1988, Pub. L. No. 100-202, 101 Stat. 1329-133 (codified at 7 U.S.C. § 426c (2000). Under these acts, USDA has authority to cooperate with other Federal agencies, States, local jurisdictions, individuals, public and private agencies, organizations, and institutions while conducting a program involving animal species that are injurious and/or a nuisance to, among other things, agriculture, horticulture, forestry, animal husbandry, wildlife, and human health and safety, as well as conducting a program involving mammal and bird species that are reservoirs for zoonotic diseases.

The Fish and Wildlife Act (FWA) of 1956, 16 U.S.C. § 742a et seq. The FWA establishes a comprehensive national fish and wildlife policy and authorizes the Secretary of the Interior to take steps required for the development, management, conservation, and protection of fish and wildlife resources through research,

land acquisition, facilities development, and other means. The FWA authorizes the Secretary to direct a program of continuing research, extension, and information services on fish and wildlife matters, both domestically and internationally.

The Migratory Bird Treaty Act (MBTA) of 1918, 16 U.S.C. §§ 703-712. The MBTA places with the Secretary of the Interior Federal responsibility for protection and management of migratory birds and implements four international treaties that affect migratory birds common to the United States, Canada, Mexico, Japan, and the former Soviet Union. The MBTA makes it unlawful to hunt, kill, capture, possess, or otherwise take migratory birds, including their feathers, other parts, nests, or eggs, except as allowed by the Secretary through permit or regulation.

The Fish and Wildlife Coordination Act of 1934, 16 U.S.C. 661-667e. This act authorizes the Secretary of the Interior to provide assistance to, and cooperate with, Federal, State, and public or private agencies and organizations in the conservation of wildlife and in controlling losses of wildlife from disease and other causes. It also authorizes the Secretary to make surveys and investigations of wildlife of the public domain, including lands and waters or interests therein acquired or controlled by any agency of the United States.

Commissioned Corps. Section 203 of the PHSA, 42 U.S.C. § 204, authorizes the Federal Government to mobilize officers of the United States Public Health Service Regular Commissioned Corps and the Reserve Commissioned Corps, including commissioned corps officers who are veterinarians, in times of emergencies. Under section 361 of the PHSA, 42 U.S.C. § 264, HHS may make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into States or possessions or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Secretary may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures as in his judgment may be necessary.

Chapter 8 - Law Enforcement, Public Safety, and Security

Protecting Federal Facilities and Property. DHS is charged with protecting the buildings, grounds, and property that are owned, occupied, or secured by the Federal Government (including any agency, instrumentality, or wholly-owned or mixed-ownership corporation thereof) and the persons on the property (40 U.S.C. 1315). DHS may designate employees of the Department of Homeland Security, including employees transferred to the Department from the Office of the Federal Protective Service of the General Services Administration pursuant to the Homeland Security Act of 2002, as officers and agents for duty in connection with the protection of property owned or occupied by the Federal Government and persons on the property, including duty in areas outside the property to the extent necessary to protect the property and persons on the property. While engaged in the performance of official duties, an officer or agent designated under this section may enforce Federal laws and regulations for the protection of persons and property, and carry out such other activities for the promotion of homeland security as the Secretary may prescribe.

Strategic National Stockpile. In accordance with Public Law 108-276 (Project BioShield Act of 2004) and Emergency Support Function #8 - Public Health and Medical Services (ESF #8), DHS will coordinate with HHS and DOJ in ensuring the adequate physical security of the stockpile. ESF #8 instructs DOJ to provide stockpile security and quarantine enforcement upon request of HHS.

Assistance to States in Maintaining Order

Emergency Federal Law Enforcement Assistance Act. Upon written request by a Governor, the Attorney General can coordinate and deploy emergency Federal law enforcement assistance to State and local law enforcement authorities (42 U.S.C. § 10501). Federal law enforcement agencies that are authorized to provide assistance to State and local government officials by enforcing State and local law should be duly deputized to do so under State and local statutes.

Robert T. Stafford Disaster Relief and Emergency Assistance Act. In disaster and emergency situations, this Act authorizes Federal agencies to assist in the provision of State and local public health measures, including by providing logistical or materials support to State and local law enforcement (42 U.S.C. §§ 5170, 5192-5193, 5195a). The Act also authorizes DHS/FEMA to "procure by condemnation or otherwise, construct, lease, transport, store, maintain, renovate, or distribute materials and facilities for emergency preparedness," (emphasis added). The term "materials" includes "raw materials, supplies, medicines, equipment, component parts, and technical information and processes necessary for emergency preparedness," (id. § 5195a(5)); the term "facilities" includes "buildings, shelters, utilities, and land," (id. § 5195(a)(6)). The term "emergency preparedness" includes measures to be undertaken in preparation for anticipated hazards, during a hazard, or following a hazard. An influenza pandemic would fit within the broad definition of "hazard" (see, id. § 5195a(a)(1), 5195a(a)(3)).

The Insurrection Act, 10 U.S.C. §§ 331-335. The President may, upon request of a State legislature, or the Governor when the legislature cannot be convened, send the Armed Forces as necessary to suppress an insurrection against State authority (*id.* at § 331). Ordinarily requests under this provision specify that the violence cannot be brought under control by State and local law enforcement agencies and the State National Guard troops. In addition, the President may use the Armed Forces or the federalized National Guard as he considers it necessary to suppress any insurrection, domestic violence, unlawful combination, or conspiracy if it (1) so hinders the execution of State and Federal law that people are deprived of their rights secured by the Constitution and laws, or (2) opposes or obstructs the execution of Federal law (*id.* at § 333). The President may also use the Armed Forces of the federalized National Guard to enforce Federal law (*id.* at 332). This statutory authority is an exception to the Posse Comitatus Act, 18 U.S.C. § 1385 (2002), authorizing the military to make arrests, conduct searches, and perform other traditional law enforcement functions.

Under the Insurrection Act, the President may use the National Guard (when called into Federal service), reserves (when called to active duty), and members of the Armed Forces to enforce Federal laws or to suppress the insurrection. DOD has an established protocol, the Commander, U.S. Joint Forces Command Civil Disturbance Plan ("Garden Plot"). Under this plan, the Attorney General is responsible for receiving and coordinating requests for military assistance. The military on-scene commander acts in coordination with the Senior Civilian Representative of the Attorney General, most likely the U.S. Attorney in the given area.

Military Support for Civilian Law Enforcement Agencies. The Secretary of Defense may, in accordance with other applicable law, make available any equipment (including associated supplies or spare parts), base facility, or research facility of the DOD to any Federal, State, or local civilian law enforcement official for law enforcement purposes (10 U.S.C. § 372(a)). Training and personnel to maintain and operate equipment may also be provided (10 U.S.C. §§ 373-4).

Enforcement of Quarantines

State and local Quarantines. State and local officials draw their authority to enforce State and local quarantines from State and local law. Under section 311 of the PHSA, 42 U.S.C. § 243(a), the Secretary of Health and Human Services is authorized to accept State and local authorities' assistance in the enforcement of Federal quarantine rules and regulations, and is required to assist State and local authorities in the enforcement of their quarantines and other health regulations.

The U.S. Coast Guard, and "military officers commanding in any fort or station upon the seacoast," as well as Customs officers, which may include Customs and Border Protection officers and Immigration and Customs Enforcement special agents, must, at the direction of the Secretary of Health and Human Services, aid in the execution of such State quarantines and other health laws "according to their respective powers and within their respective precincts" (42 U.S.C. § 97).

The President also could use the Insurrection Act (see above) and use the Armed Forces or federalized National Guard to help suppress violence arising out of a State quarantine, as for any other law enforcement activity permitted under the Insurrection Act, 10 U.S.C. §§ 331-335, provided the requirements for using the Act described above are met (e.g., if the President is asked by a State to assist and if the defiance to the State quarantine orders amounts to an insurrection against State authority that the State cannot handle (see 10 U.S.C. § 331), or there is widespread unlawful activity that has the effect of depriving people of rights secured by the Constitution and laws) (see 10 U.S.C. § 333).

Federal Quarantines. Customs officers, which may include Customs and Border Protection officers and Immigration and Customs Enforcement special agents, and the U.S. Coast Guard have specific authority and responsibility to assist with the enforcement of quarantines at ports of entry (42 U.S.C. § 268). With regard to other Federal law enforcement officers, the United States Marshals Service has the broadest of Federal law enforcement missions, 28 U.S.C. § 565; and, along with other Department of Justice agencies (FBI, DEA, ATF) can be directed by the Attorney General to enforce quarantines. The U.S. Marshals Service can also deputize other Federal law enforcement officers throughout the executive branch to give them law enforcement powers in circumstances that extend beyond those for which they are otherwise statutorily authorized to exercise them, as was done during Hurricane Katrina.

Under the Insurrection Act the President may direct the military to enforce quarantines, or conduct security functions such as guarding stockpiles and pharmaceuticals, when he finds it necessary to enforce Federal law (see 10 U.S.C. §§ 332-334), or other prerequisites for use of the Act described above are met.

Criminal Sanctions. The violation of Federal quarantine regulations is a crime punishable by a fine of not more \$1,000 or by imprisonment for not more than 1 year, or both (42 U.S.C. § 271). Additionally, individuals may be fined up to \$250,000 if a violation of the regulation results in death, or up to \$100,000 if a violation of the regulation does not result in death (18 U.S.C. §§ 3559, 3571(c)).

Chapter 9 - Institutions: Protecting Personnel and Ensuring Continuity of Operations

The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to promote the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; and establishing partnerships. The Occupational Safety and Health Administration has promulgated several standards to protect workers that would be particularly important in the event of a pandemic influenza outbreak. These standards include, but are not limited to: 29 CFR 1910.120 (Hazardous Waste Operations and Emergency Response), 29 CFR 1910.132 (Personal Protective Equipment), 29 CFR 1910.134 (Respiratory Protection), and 29 CFR 1910.1030 (Bloodborne Pathogens).

