

## **Appendix 3: Federal Government Agencies Involved in Immunization**

### **Department of Health and Human Services (HHS)**

#### **Secretary of Health and Human Services**

- Directs all HHS activities.

#### **Office of the Assistant Secretary for Health**

- Directs the National Vaccine Program.
- Advises Secretary on Public Health and Science as a part of directing HHS vaccination activities.
- Coordinates operations planning efforts of HHS agencies, operational divisions and offices.
- Assists with public communications and coordination with state and local public health partners.

#### **Office of the Assistant Secretary, Administration on Aging**

- Helps the elderly maintain dignity and independence through comprehensive, coordinated and cost-effective systems of long-term care and livable communities.
- Advances the concerns and interests of older people and their caregivers.
- Works with the Aging Services Network to promote the development of a comprehensive and coordinated system of home and community-based long term care, including vaccination services.

#### **Office of the Assistant Secretary, Administration for Children and Families**

- Communicates with and supports vaccine-preventable disease response activities of state, local, tribal, and nonprofit (including faith-based and community) human services organizations.
- Communicates information on child and family well-being, including the importance and availability of vaccinations.
- Encourages the participation of human services providers (e.g., Head Start centers, child care centers, family resource centers, community action agencies, runaway and homeless youth shelters, and shelters for unaccompanied alien children) in making vaccines available to vulnerable populations.

#### **Office of the Assistant Secretary for Legislation**

- Coordinates Congressional outreach and communications, including on vaccination issues.

#### **Office of the Assistant Secretary for Planning and Evaluation**

- Conducts research and evaluation studies on vaccine topics, develops policy analyses, and estimates the cost and benefits of policy alternatives under consideration by HHS or Congress.
- Advises the Secretary of HHS on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy.

- Leads special initiatives; coordinates HHS' evaluation, research and demonstration activities; and manages cross-HHS planning activities such as strategic planning, legislative planning, and review of regulations.
- Monitors effectiveness of response activities and modifies strategies, as needed.

#### **Office of Assistant Secretary for Preparedness and Response**

- Coordinates and communicates with other federal departments and agencies.
- Coordinates HHS pandemic and biodefense vaccine response activities.
- Provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.
- Manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield.

#### **Office of the Assistant Secretary for Public Affairs**

- Coordinates public information and communications, including all aspects of vaccination, vaccine supply, vaccine preventable diseases, and vaccine safety issues.

#### **Office of Intergovernmental Affairs**

- Advises and coordinates outreach and communications to state, local, and tribal officials and national intergovernmental organizations.

#### **Office of the Surgeon General**

- Oversees the operations of the 6,200 active duty officers of the Commissioned Corps of the U.S. Public Health Service (USPHS).
- Deploys commissioned officers to meet urgent public health needs and provide public health and medical services in response to natural and man-made disasters.
- Provides trusted and credible health and medical information to the public, improving health and reducing the risk of illness and injury.
- Assigns officers to HHS and non-HHS federal agencies to provide clinical, technical, regulatory, disease surveillance, program management, and research services.
- Coordinates nearly 800 local units of the Civilian Volunteer Medical Reserve Corps, representing over 170,000 health volunteers.
- Coordinates the USPHS Inactive Reserve Corps comprising over 1,000 health professionals in 11 professional categories who are federalized to respond to disasters or urgent public health need.

#### **Office of the General Counsel**

- Advises on legal issues and authorities related to key vaccination activities.

### **Office of Global Health Affairs**

- Coordinates interactions with health authorities in other governments and international organizations in coordination with the Department of State.

### **Office of the National Coordinator for Health Information Technology**

- Coordinates HHS' health information technology policies and programs internally and with other relevant executive branch agencies.
- Develops, maintains, and directs the implementation of HHS' strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors, to the extent permitted by law, including immunization information systems.
- Provides comments and advice at the request of the Office of Management and Budget regarding specific federal health information technology programs.

### **National Vaccine Program Office**

- Coordinates communication between vaccine manufacturers and HHS agencies.
- Coordinates National Vaccine Plan development and periodic review.
- Coordinates vaccine safety planning and public engagement.
- Coordinates and provides direction on vaccine research and development.
- Coordinates vaccine supply activities.
- Coordinates governmental and non-governmental vaccine activities.

### **Agency for Healthcare Research and Quality**

- Communicates with and supports federal, state, and local public health partners on vaccination and healthcare delivery plans.

### **Centers for Disease Control and Prevention (CDC)**

- Conducts and supports clinical and laboratory vaccine-preventable disease and microorganism surveillance, as well for diseases and microorganisms that may become vaccine-preventable.
- Coordinates vaccine-preventable disease response activities with state, local, and tribal public health agencies.
- Investigates the epidemiology of, environmental contributions to, and clinical characteristics of vaccine-preventable diseases.
- Leads in federal vaccination program implementation and supports state and health care provider immunization through vaccine purchase, distribution, guidance, evaluation, and quality control.
- Distributes public sector vaccines.
- Co-leads with the Food and Drug Administration in monitoring and investigating vaccine adverse events.
- Assesses vaccine effectiveness in population-based studies.
- Makes recommendations on diagnosis, management, and prevention of vaccine-preventable disease illness.
- Conducts and supports basic and applied research on vaccine-preventable diseases.
- Leads federal activities for surveillance, detection, and response to pandemic influenza.

- Provides training and reagents for diagnosis of vaccine-preventable diseases.
- Conducts and supports research and development of diagnostic test and immunologic assays for vaccine-preventable diseases.
- Conducts human health risk assessment of new and emerging vaccine-preventable diseases in the U.S. and globally.
- Conducts laboratory and animal studies of emerging vaccine-preventable diseases to identify markers for virulence and transmission among humans.
- Communicates with state and local health departments and other public health partners.
- Communicates information on vaccine-preventable disease health impacts and vaccination in collaboration with the Assistant Secretary for Public Affairs and other partners.
- Maintains close communication with vaccine manufacturers.
- Provides reference strains for influenza vaccine manufacturing.
- Works with the World Health Organization (WHO) and other international organizations to promote global health through vaccination.
- Provides scientific leadership and support to global laboratory networks for vaccine preventable diseases, technical support to eradication and elimination efforts, and accelerating use of new and underutilized vaccines.

#### **Centers for Medicare and Medicaid Services**

- Provides streamlined payment mechanisms and works with prescription drug plans, Medicare managed care plans, and Medicare providers, as necessary, to ensure ready access to vaccines for Medicare's population.
- Communicates specific vaccine-preventable disease guidance to the nation's hospitals, home health agencies, skilled nursing facilities and other health care providers, suppliers and practitioners that participate in Medicare and Medicaid.
- Communicates vaccine-preventable disease related information through existing outreach networks to Medicare and Medicaid beneficiary populations.
- Supports tracking and surveillance of Medicare and Medicaid patients, including high-risk and vulnerable patients, who have received vaccines, including review of Medicare and Medicaid claims and quality data.

#### **Food and Drug Administration**

- Performs research to 1) facilitate vaccine development and evaluation, including through innovation in regulatory pathways, and 2) enhance manufacturing and product quality (including assays, biomarkers and models for product safety, quality and efficacy, and methods for statistical and epidemiological analysis).
- Regulates the vaccine manufacturing process and promotes enhancement of manufacturing quality and problem prevention.
- Prepares reference strains, assays, standards, and reagents appropriate for vaccine manufacturing.
- Evaluates and licenses vaccines.
- Monitors vaccine quality, releases vaccine lots for distribution, and performs testing of vaccine quality and potency.

- Facilitates the development, evaluation and clearance or approval of diagnostic tests and devices.
- Reviews vaccine supply issues.
- Evaluates and issues Emergency Use Authorizations when appropriate.
- With CDC, monitors vaccine adverse events.
- Maintains close communication with vaccine manufacturers.
- Makes necessary changes in prescribing and patient information, including dosing, target populations, and other direction for use, for vaccines based on research and adverse events.
- Monitors to protect against the distribution of counterfeit vaccines.
- Designated as a WHO Collaborating Center for Biological Standardization, which encompasses responsibilities of setting and providing standards needed to assure products are high quality, safe, and available, and supporting efforts to harmonize product development and regulation.

### **National Institutes of Health**

- Studies the evolution and emergence of microorganisms, including the identification of factors that affect their host-range and virulence.
- Determines the molecular basis of virulence in humans and animals.
- Supports laboratory-based surveillance studies of the distribution of microorganisms that are, or may be, vaccine-preventable.
- Develops sensitive, specific, and rapid diagnostic tests for vaccine-preventable diseases.
- Develops and clinically evaluates novel vaccines and vaccination strategies (e.g., adjuvants, delivery systems).
- Evaluates the immune response to infection and vaccination.
- Supports basic research, with the goal of identifying new therapeutic targets.
- Evaluates the molecular and/or environmental factors that influence the transmission of viruses, bacteria and other organisms, including drug-resistant strains.
- Communicates frequently with vaccine manufacturers.
- Prepares reference strains appropriate for vaccine manufacturing.

### **Health Resources and Services Administration**

- Provides national leadership, program resources, and services needed to improve access to cultural, competent (including linguistically appropriate and health literate), and quality health care.
- As the nation's access agency, focuses on uninsured, underserved, and special needs populations in its goals and program activities (including vaccine-preventable diseases and vaccine administration).
- Communicates with and provides technical assistance and training to support vaccine-preventable disease control activities of state primary care associations, health centers, and other community-based providers.
- Operates the National Vaccine Injury Compensation Program to ensure an adequate supply of vaccines, stabilize vaccine costs, establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to receive compensation.

### **Indian Health Service**

- Communicates with and supports state, local, and tribal vaccination and vaccine-preventable disease response activities at HHS, tribal, and urban Indian sites serving American Indian and Alaska Native populations.

### **Substance Abuse & Mental Health Services Administration**

- Brings effective alcohol and drug treatment to every community.
- Provides national leadership to expand the availability of effective treatment and recovery services for alcohol and drug problems; to improve access, reduce barriers and promote high-quality effective treatment and medical care services (including vaccination services) for people with alcohol and drug problems, abuse, or addiction, as well as for their families and communities.

### **Department of Agriculture**

- Performs research on animal vaccines to prevent disease.
- Manages Women, Infant, and Children's Program for supplemental nutrition that also provides vaccination services.

### **Department of Defense (DoD)**

#### **Assistant Secretary of Defense for Health Affairs**

- Serves as the principal civilian advisor to the Deputy Secretary of Defense for health service support for pandemic influenza preparedness and response.
- Responsible for overall leadership of the Military Health System.
- Serves as the principal advisor to the Secretary of Defense for all Department of Defense health policies and programs.
- Oversees all DoD health resources.

#### **Defense Advanced Research Projects Agency**

- Maintains the technological superiority of the U.S. military and prevents technological surprise from harming national security.
- Funds researchers in industry, universities, government laboratories and elsewhere to conduct high-risk, high-reward research and development projects that will benefit U.S. national security.
- Develops technologies to accelerate the development and production of vaccines and other medical therapeutics from 12 years to 12 weeks.

#### **Defense Threat Reduction Agency (DTRA)**

- Provides capabilities to reduce, eliminate, and counter the threat of weapons of mass destruction (chemical, biological, radiological, nuclear, and high explosives), and mitigate its effects.
- Analyzes weapons of mass destruction threats, develops requirements forecasts and integrates the results into DTRA's future resource planning.

- Develops, provides, and maintains security, counterintelligence, and force protection products and services in support of the agency's global missions.

### **The Military Vaccine (Milvax) Agency**

- Synchronizes information among the military services and DoD staff elements.
- Delivers education for healthcare workers and the public (e.g., [Immunization University](#), [www.vaccines.mil](http://www.vaccines.mil), (877) GET-VACC, [Vaccines@amedd.army.mil](mailto:Vaccines@amedd.army.mil)).
- Promotes quality of immunization understanding and delivery.
- Coordinates and assesses U.S. military immunization programs worldwide.
- Assists senior DoD leaders with policy development, especially related to biodefense and pandemic issues.
- Safeguards shipping and handling of temperature-sensitive medical products.
- Enhances scientific understanding of the benefits and risks of vaccines.
- Fosters mutually beneficial relationships between DoD, other government agencies, and professional associations related to immunizations.
- Integrates electronic immunization tracking efforts of DoD and the military services.

### **United States Army Medical Institute for Infectious Diseases**

- Conducts basic and applied research on biological threats resulting in medical solutions to protect the warfighter.
- Plays a key role as the only laboratory in the DoD equipped to safely study highly hazardous infectious agents requiring maximum containment at biosafety level 4.
- Ensures that research is conducted in a safe and secure environment.
- Delivers competitive products to the advanced developer on schedule with the best value and quality.

### **United States Agency for International Development**

- Participates in the Global Alliance for Vaccines and Immunization and introduces new and under-utilized vaccines into developing countries.
- Provides technical and commodity assistance to more than 100 countries in support of routine child immunization programs, working closely with host-country Ministries of Health, non-governmental organizations, international organizations such as WHO and United Nations Children's Fund, foundations, and other international partners.
- Maintains a vaccine development program targeting malaria and HIV/AIDS in developing countries in coordination with DoD, HHS, and non-federal partners.
- Provides technical assistance and funding for the Global Polio Eradication Initiative.
- Supports global goals to eliminate and control other vaccine preventable diseases such as measles and neonatal tetanus.
- Raises awareness and helps generate greater resources, from both the public and private sectors, to help countries improve and sustain their capacity to deliver lifesaving vaccines and address diseases of international and domestic public health importance.

### **Department of State**

- Works with agencies throughout the U.S. government to facilitate policy-making regarding environmental health, infectious diseases, health in post-conflict situations, surveillance and response, and health security.

### **Department of Veterans Affairs (VA)**

- Mounts a system-wide annual seasonal influenza campaign for Veterans Health Administration (VHA) patients and health care providers.
- Actively monitors, on a national basis, receipt of influenza and pneumococcal vaccine among at-risk VHA patients.
- Monitors adverse events to vaccinations as part of a national pharmacovigilance program.
- Supports health services research in the area of improving vaccine delivery within VHA healthcare settings.
- Educates, communicates with, and provides technical assistance to VHA providers to support vaccine-preventable disease control activities in all VA health care facilities.
- Participates in clinical trials to determine efficacy of new/improved vaccines.
- Monitors national influenza vaccination rates of employees working in VHA health care facilities.
- Developing an occupational health record system for employees to track vaccination status.
- Contributes support and provides expertise to national bodies focused on vaccine and immunization programs.