

SHAPING A CULTURE OF
PUBLIC HEALTH PREPAREDNESS
AND MEDICAL EMERGENCY
RESPONSE; HOW THE
DEPARTMENT OF HEALTH AND
HUMAN SERVICES IS
TRANSFORMING TO MEET
TOMORROW'S HEALTH
THREATS

BY

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**SHAPING A CULTURE OF PUBLIC HEALTH PREPAREDNESS AND MEDICAL
EMERGENCY RESPONSE; HOW THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES IS TRANSFORMING TO MEET TOMORROW'S HEALTH THREATS**

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ABSTRACT

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In the aftermath of the terrorist events of September 11th 2001 fundamental questions were raised regarding our nation's ability to respond to a catastrophic incident requiring a coordinated medical response. As the initial legislative processes began to take shape, the 2002 Public Health Security and Bioterrorism Preparedness and Response Act established within the Department of Health and Human Services (HHS), The Office of Public Health Emergency Preparedness (OPHEP). OPHEP was established on June 12, 2002, and serves as the Secretary's principal advisory staff on matters related to bioterrorism and other public health emergencies. OPHEP also coordinates interagency activities between HHS, other Federal departments, agencies, offices and State and local officials responsible for public health preparedness and medical emergency response and the protection of the civilian population from acts of bioterrorism and other public health emergencies.

Over the past four years since OPHEP was established, the Department's responsibility for public health emergency preparedness and response has continued to grow and its role in homeland security has expanded. Recent legislation reorganized OPHEP as the Office of the Assistant Secretary for Preparedness and Response (ASPR). As ASPR matures to meet these new and expanded missions the *organizational culture* is evolving. Hurricane Katrina

highlighted the American expectation of a coordinated Governmental response at all levels, and the event exposed the significant shortfalls of the Federal, State, and Local governments. How will our Nation respond to the next disaster; whether man made or natural? Are we any better prepared to mitigate the loss of human life? Will the public health and a coordinated medical response be capable of responding to the task in a sufficient and timely manner? Are there strategic plans addressing these and other questions that have not been asked? Finally, how do you turn strategy into executable actions and measure progress? The Department of Health and Human Services must be able accountable to the American people that we are indeed moving forward in protecting the health of our citizens.

This project will outline a strategy for the Department of Health and Human Services in shaping the culture of public health preparedness and medical emergency response. Implementation of this strategy will focus on the Office of the Assistant Secretary for Preparedness and Response on its strategic mission, vision, and goals. Shaping a culture defined by operational values of service to the nation, teamwork, leadership, and integrity. The events and experiences of September 11th 2001 will forever live in our nation's soul. ASPR is charged with shaping just how our nation will respond to those we serve with a planned public health and medical emergency strategy in the future.

SHAPING A CULTURE OF PUBLIC HEALTH PREPAREDNESS AND MEDICAL EMERGENCY RESPONSE; HOW THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IS TRANSFORMING TO MEET TOMORROW'S HEALTH THREATS

"I am certainly not an advocate for frequent changes in laws and constitutions. But laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times. We might as well require a man to wear still the coat which fitted him when a boy as civilized society to remain ever under the regimen of their barbarous ancestors."¹

Thomas Jefferson; Taken from a letter to Samuel Kercheval, July 12, 1816.

As we move forward as a nation into the twenty first century, the words of our third president, Thomas Jefferson in the 19th century resonate even louder today than they did then. Our nation is dealing with a rapidly changing environment that threatens its very existence and our way of life. The attacks of September 11, 2001 were the largest attacks on American soil since the attack on Pearl Harbor on December 7, 1941. These single events of proportionate magnitude invoked the American will to enter World War II and engage in military Operations in Iraq and Afghanistan. The sequence of events leading to that tragic day have been and continue to be examined by all levels of government and society in an effort to prevent future attacks and better prepare to respond if one occurs. Since that time, the country has undergone unprecedented changes in the way we prepare for, and respond to, and even view domestic preparedness and response.

These threats we face are not solely manmade terrorist events, but also occur naturally with greater frequency. The 2005 hurricane season was record-setting in many ways. It was the most active season on record with 27 named storms, of which 15 were at least a category 3 on the Saffir-Simpson hurricane scale.^{2,3} Of the 27 named storms, 8 made landfall in the United States, including hurricanes Katrina and Rita.⁴ Additionally, the 2005 hurricane season will go

down in history as the costliest on record. The full expense of responding to these hurricanes will not be known for years, but already billions have been invested in the response, recovery and reconstruction efforts. Hurricane Katrina was a natural event that amplified our nation's inability to respond to the citizens of the nation in an appropriate and timely fashion. What went wrong during this event that now outlines a drastic need for change in how we conduct business? Our elected officials at all levels of government, local, state tribal and federal, must be able to adapt and meet these challenges that we face at a much greater pace than we did in the past. These diverse threats that have evolved over the past 25 years have become exceedingly more complex and demanding. How can we accelerate the rate of institutional change in government to cope with this new environment?

In the current environment, the Department of Health and Human Services (HHS) the institution primarily responsible for America's health; must act quickly and decisively with unprecedented integration of all the elements of federal capabilities, at the same time fostering cooperation among our governmental, non-governmental and private institutions in preparing for and responding to catastrophic public health emergencies. The current national health structure and intra-agency processes are rapidly adapting to meet the challenges of the future. These extraordinary efforts in the past ten years have made significant improvement in producing an effective and efficient emergency response system. Although there are several ongoing initiatives to improve the intra-agency process, much remains to be done to realize the full potential of HHS. To overcome resistance to change, agency biases, and cultural differences, we must resist the temptation to adopt minor evolutionary changes rather than the needed radical changes.

This strategic research paper will focus on the development and growth of the public health preparedness and medical emergency response **enterprise** (requiring extensive planning and work, as defined for this paper the "The public health preparedness and medical

emergency response enterprise, further defined on page 9) within the Department of Health and Human Services. The paper traces the evolution of the HHS through the Department of Health Education and Welfare, and then the Department of Education and Organization Act of 1979, providing for a separate Department of Education. The analysis shows how the efforts to improve the intra-agency cooperation during the 1990's are beginning to mature and take shape with proven capabilities. It will then highlight some current initiatives to improve the inter/intra agency process, identify problems with the current structure and make a recommendation to enact legislation that mandates intra-agency cooperation similar to the Goldwater Nicholas Act of 1986 (GNA), which mandated jointness among the various services in DoD. For the purpose of this paper I will focus on the Public Health Preparedness and Medical Emergency Response Enterprise as it relates to the Department of Health and Human Services. The term "Intra-Agency" defined for this paper is the Divisions within the Department of Health and Human Services; both Operational and Staff Divisions as outlined later; each with a different culture, a different planning process, and a different perspective on what is best for the Nation.⁵ The term "Interagency" is defined as United States Government agencies and departments.⁶

Many of the issues in the current ***Intra-agency process*** are similar to those experienced by the Department of Defense (DoD) prior to Congress passing the Goldwater – Nichols Department of Defense Reorganization Act of 1986 (GNA).⁷ Although the DOD has not fully realized the interdependent state of all the Services working harmoniously to one common mission, they are in the maturation process of moving towards that goal. One of the major differences between DOD and HHS is that the DOD as an institution has been built to react to the nation's defense needs, adaptable to meet contingency requirements. On the other hand, HHS has a long standing culture of protecting the health of the nation through research and safety as it pertains to the nation's public health.

The Department of Health and Human Services

The Department of Health and Human Service can trace its lineage dating back to The Public Health Service, created in 1798 as the Marine Hospital Service. Passage of an act for the relief of sick and disabled seamen, this act established a federal network of hospitals for the care of merchant seamen.⁸ As our fledgling democracy developed the need to insure that the public health of our nation also developed to meet the needs of the American people. In the late 1800's, the Public Health Service played a major role in the control of yellow fever, which later resulted in the passage of the National Quarantine Act of 1878. In 1918, the Public Health Service was called upon to control the Spanish influenza. The Public Health Service remained in the Federal Service Agency from 1939 until it was elevated to cabinet status and renamed the Department of Health, Education and Welfare (HEW) in 1953; it was re-designated in 1979 as the Department of Health and Human Services with the creation of the Department of Education; as the Department of Health and Human Services. The secretary of the Department is the primary advisor to the President on health and welfare matters.

The HHS mission is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.⁹

HHS is composed of eleven operating divisions, including eight agencies in the United States Public Health Service (USPHS) and three human service agencies that administer HHS's programs. Eighteen staff divisions within the Office of the Secretary (OS) provide leadership, direction, and policy and management guidance to the Department. (See Fig 1)

HHS accomplishes its mission through more than 300 programs and initiatives that cover a wide spectrum of activities, with a fiscal year 2007 budget of \$698 billion dollars. HHS represents almost a quarter of all federal expenditures and administers more grant dollars than

all other Federal agencies combined. HHS works closely with state and local tribal governments, and many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees. The Department has 67,444 employees.¹⁰

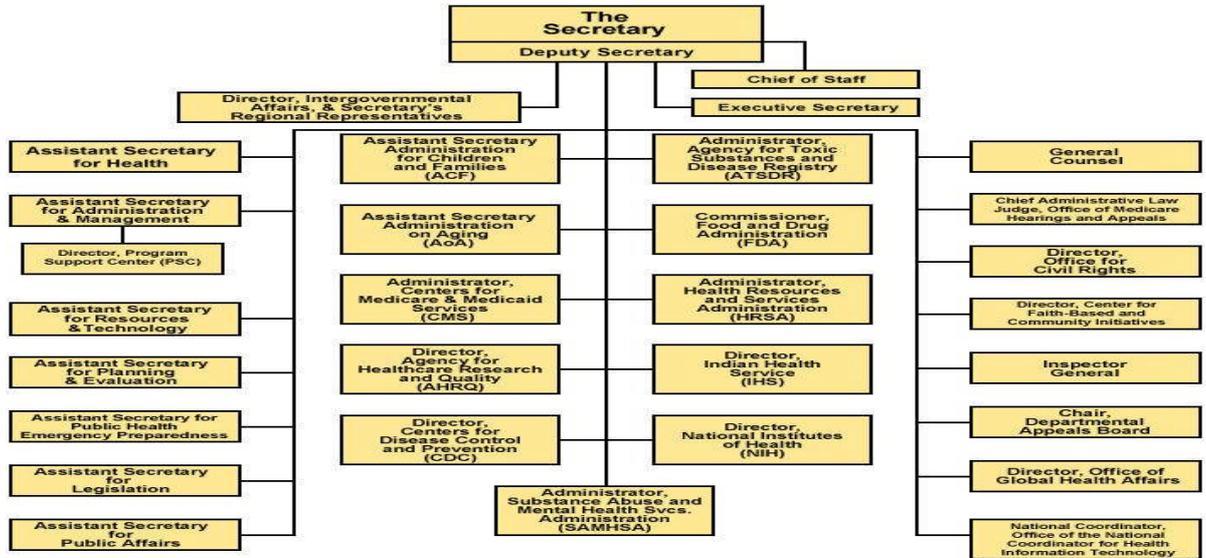


FIG 1 HHS Organizational Chart

To understand the complexity of the public health preparedness and medical emergency response enterprise within the intra-agency domain of HHS provided is a brief description of the key partners:

- **Assistant Secretary for Preparedness and Response** -- Serves as the Secretary's principal advisory staff on matters related to bioterrorism and other public health emergencies. ASPR directs the Department's emergency response activities and coordinates interagency activities related to emergency preparedness and the protection of the civilian population.
- **Centers for Disease Control and Prevention** -- Working with states and other partners, CDC provides a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. Provides for immunization services, workplace safety, and environmental disease prevention. CDC also guards against international disease transmission, with personnel stationed in more than 25 foreign

countries. The CDC director is also administrator of the **Agency for Toxic Substances and Disease Registry**, which helps prevent exposure to hazardous substances from waste sites on the U.S. Environmental Protection Agency's National Priorities List, and develops toxicological profiles of chemicals at these sites Established: 1946, as the Communicable Disease Center. Headquarters: Atlanta, Ga.

- **Food and Drug Administration** -- FDA assures the safety of foods and cosmetics, and the safety and efficacy of pharmaceuticals, biological products, and medical devices -- products which represent almost 25 cents out of every dollar in U.S. consumer spending. Established: 1906, when the Pure Food and Drugs Act gave regulatory authority to the Bureau of Chemistry. Headquarters: Rockville, Md.
- **National Institutes of Health** -- NIH is the world's premier medical research organization, supporting over 38,000 research projects nationwide in diseases including cancer, Alzheimer's, diabetes, arthritis, heart ailments and AIDS. Includes 27 separate health institutes and centers. Established: 1887, as the Hygienic Laboratory, Staten Island, N.Y. Headquarters: Bethesda, Md.
- **Substance Abuse and Mental Health Services Administration** -- SAMHSA works to improve the quality and availability of substance abuse prevention, addiction treatment and mental health services. Provides funding through block grants to states to support substance abuse and mental health services, including treatment for more than 650,000 Americans with serious substance abuse problems or mental health problems. Helps improve substance abuse prevention and treatment services through the identification and dissemination of best practices. Monitors prevalence and incidence of substance abuse. Established: 1992. (A predecessor agency, the Alcohol, Drug Abuse and Mental Health Administration, was established in 1974.) Headquarters: Rockville, Md.
- **Health Resources and Services Administration** -- HRSA provides access to essential health care services for people who are low-income, uninsured or who live in rural areas or urban neighborhoods where health care is scarce. HRSA-funded health centers will provide medical care to almost 14 million patients at more than 3,700 sites nationwide in FY 2005. The agency helps prepare the nation's health care system and providers to respond to bioterrorism and other public health emergencies maintains the National Health Service Corps and helps build the health care workforce through training and education programs. HRSA administers a variety of programs to improve the health of mothers and children and serves people living with HIV/AIDS through the Ryan White CARE Act programs. HRSA also oversees the nation's organ transplantation system. Established: 1982 Headquarters: Rockville, Md.
- **Assistant Secretary for Health** -- To provide senior professional leadership across HHS on cross-cutting, population based public health and clinical preventive services. The Office of Public Health and Science is under the direction of the ASH, who serves as the Secretary's primary advisor on matters involving the Nation's public health and oversees the Commissioned Corps of the United States Public Health Service through the Office of the Surgeon General.¹¹

LEGISLATIVE CHANGES FOSTERING THE DEVELOPMENT OF THE PUBLIC HEALTH PREPAREDNESS AND MEDICAL RESPONSE CAPABILITIES

Legislative actions do not just occur--there is typically a precipitous event that precedes the action itself. Legislative action helps foster change in our society and lays the foundation for creating a change process. The rate of change is in direct correlation to the perceived need to change. The size and magnitude of the event has a direct correlation to the rate our society will change.

Major transformational changes began to take shape in the early 1800s; formalized emergency assistance from the government can be traced to this time period. Between the early 1800s and the late 1900s, federal disaster assistance resulted from two causes: floods and fires. The Congressional Act of 1803 is an early illustration of this assistance.

“Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, that all persons who, being indebted to the United States, for duties on merchandise, have given bond therefore, with one or more sureties, payable to the collector for the district of Portsmouth, and who have suffered a loss of property by the late conflagration at the place, shall be, and they hereby are allowed to take up, or have cancelled, all bonds heretofore give for duties as aforesaid...”¹²

This Act passed following Portsmouth’s “Great Fire” of 1802, in which 132 buildings burned. The Act provides a good example of an instance where the federal government provided financial support or relief following an unforeseen event, in this case a fire.¹³

Throughout the 1800s, Congress focused its attention on protecting the country’s rivers and waterways. Recognized as a source of economic vitality, and important in the strategic defense of the nation, great emphasis was placed on attempting to control or reduce the impact from major floods on these waterways. However, in spite of these efforts, flooding along the rivers was not uncommon. Between 1858 and 1927, twelve “great floods” occurred along the Mississippi River.^{14,15} In 1927 alone, 26,000 square miles of land across the states of Arkansas, Louisiana, Mississippi and Missouri were flooded by the Mississippi River.¹⁶

Over the years, Congress took steps to both prevent future floods and respond to the consequences of “great floods.” An example of this is the Flood Control Act of 1917¹⁷, which was enacted “to provide for the control of the floods of the Mississippi River and of the Sacramento River, California...”¹⁸ Unlike the Congressional Act of 1803, this Act provided specific statements regarding the responsibility of local interests to “contribute for such construction and repair a sum which the commission shall determine to be just and equitable...”¹⁹

While the federal government was taking a more proactive stance in supporting the disaster recovery effort, it was clear that communities affected by the disaster would also bear a burden for rebuilding. Funds donated to the American Red Cross, at the request of the federal government, were often the backbone of the reconstruction efforts.

With the invention of the atomic bomb, federal preparedness efforts shifted away from floods and fires, focusing more on the continuity of essential functions and continuity of government in the event of a nuclear attack. At that time, preparedness and response functions were coordinated through the Office of Emergency Preparedness within the Executive Office of the President. Over a period of approximately twenty years, the Office of Emergency Preparedness developed plans for emergency preparedness, administered disaster relief and oversaw the activities of the other Executive branch agencies. Legislative and Executive actions between 1973 and 1979 would lead to the closure of the Office of Emergency Preparedness and dramatically impact the manner in which the government organized to respond to disasters and emergencies. Through these incremental changes, each meant to “streamline” specific aspects of the Executive branch, Presidents Nixon, Ford and Carter collectively contributed to development of a unified national emergency management agency.

President Nixon would take the first of these actions in 1973. Seeking to “concentrate less responsibility in the President’s immediate staff and more in the hands of the departments

and agencies,²⁰ President Nixon closed the Office of Emergency Preparedness within the Executive Office of the President. Transferring the major functions of the office to the Departments of Housing and Urban Development (HUD), Treasury and the General Services Administration (GSA), the President identified “that the line Departments and agencies which have in the past shared the performance of the various preparedness functions now possess the capabilities to assume full responsibility for those functions.”²¹ The responsibilities “reserved to the President” would remain in the Executive Office, with an Assistant to the President in charge of executive management providing interagency coordination. In some ways, this role could be viewed as a precursor to the present day Homeland Security Advisor. Currently serving as the chair of the Homeland Security Council, the Homeland Security Advisor works to;

“...insure coordination of all homeland security-related activities among executive departments and agencies and promote the effective development and implementation of all homeland security policies.”²²

With the passage of the Disaster Relief Act of 1974, the Congress sought to achieve the following:

- Encourage development of comprehensive disaster preparedness and assistance plans, programs, capabilities, and organizations by the states and by local governments;
- Achieve greater coordination and responsiveness of disaster preparedness and relief programs; and
- Provide federal assistance programs for both public and private losses sustained in disasters.²³

A key component of the legislation, which remains relatively unchanged even today, was the manner in which the terms “emergency” and “major disaster” were defined. Both then and today, these terms shape the nature and type of federal support that can be provided to affected states, tribes and Territories.

At the time, and consistent with the present day process, the President's decision to declare an “emergency” or “major disaster” required the Governor of the affected state(s) to not only establish that “the disaster is of such severity and magnitude that effective response is

beyond the capabilities of the state,” but also furnish a statement “on the extent and nature of state resources which have been or will be used to alleviate the conditions of the disaster...”²⁴

The legislation also clarified the cost burden that would be shared between the federal and state governments following a Presidential disaster declaration. In addition to other assistance programs described in the Act, the law allowed the federal government to make public grants up to “100 per centum of the net cost,” and individual or family grants “equal to 75 per centum of the actual costs.”²⁵

Just as the Disaster Relief Act of 1974 clarified the federal roles in emergencies and major disasters, Executive Order 11921 (1976) clarified the federal health services that could be requested and provided in a catastrophic disaster response. As defined in the order, “emergency health services” meant:

“...medical and dental care for the civilian population in all of the specialties and adjunct therapeutic fields, and the planning, provision, and operation of first aid stations, hospitals, and clinics; preventative health services, including detection, identification, and control of communicable diseases, their vectors, and other public health hazards, inspection and control of purity and safety of food, drugs, and biologicals...preventative and curative care related to human exposure to hazardous agents (nuclear, biological and chemical)...”²⁶

Additionally, and consistent with the Congressional intent to develop “comprehensive disaster preparedness and assistance plans,” the Order further defined the preparedness role of HEW. The order directed the Secretary of HEW to “prepare national emergency plans and develop preparedness programs covering health services, civilian health manpower, health resources, [and] welfare services...”²⁷ While the Order is significant for its proactive nature in engaging the civilian health community, neither this order nor the Disaster Relief Act recognize or encourage regional planning, either within or among states.

The culmination of this group of efforts came when President Carter issued Reorganization Plan No. 3 (1978) and Executive Order 12148 (1979), establishing the Federal Emergency Management Agency (FEMA). Just as the Reorganization Plans issued by

Presidents Roosevelt, and Nixon sought to streamline preparedness and response efforts, this order too sought to achieve that goal:

“By consolidating emergency preparedness, mitigation and response activities, it cuts duplicative administrative costs and strengthens our ability to deal effectively with emergencies.”²⁸

President Carter recognized that “for the first time, key emergency management and assistance functions would be unified and made directly accountable to the President and the Congress.”²⁹ The Reorganization Plan and the ensuing Executive Order establishing FEMA resulted in the consolidation of functions of five agencies including the:

- Defense Civil Preparedness Administration;
- National Fire Prevention and Control Administration;
- Federal Insurance Administration;
- Federal Preparedness Agency; and
- Federal Emergency Broadcast System.³⁰

Transferred from DOD, Department of Commerce, HUD, GSA and the Executive Office of the President respectively, the consolidated agency would exist virtually unchanged until the Establishment of the Department of Homeland Security (DHS) in 2002.

In 1984, HHS, DVA, and DOD (three federal partners) created the National Disaster Medical System (NDMS) as a cooperative, asset-sharing partnership to leverage federal and non-federal resources in the Continental United States (CONUS). This was an initiative that grew out of a recommendation from the Emergency Mobilization Preparedness Board that was established by President Regan in 1981. In 1997 FEMA would join as a federal partner to NDMS.³¹

NDMS, system has three components: direct medical care; patient evacuation; and definitive care. NDMS was created as a nationwide medical response system to: supplement state and local medical resources during disasters and emergencies; provide back-up medical support to the military and VA health care systems during an overseas conventional conflict;

and to promote development of community based disaster medical systems. The availability of beds in civilian hospitals is coordinated by the VA and DOD through a system of Federal Coordinating Centers. It wasn't until the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 that NDMS would receive statutory authority.³²

Following the establishment of FEMA, the most significant legislation affecting disaster preparedness and response came on November 23, 1988. On this date, President Reagan signed Public Law 100-707, the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). Amended multiple times since its signing in 1988, the Stafford Act continues to be the principal legislative document guiding federal support to states, tribes and Territories during national disasters and emergencies.³³

Then and now, the Stafford Act establishes:

- Disaster preparedness and mitigation assistance programs;
- The process to administer disaster assistance; and
- Disaster and emergency assistance programs;³⁴

Within the legislation, the term "major disaster" is defined:

"...any natural catastrophe (including any hurricane, tornado, storm, high water, wind driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought), or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under this Act to supplement the efforts and available resources of states, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby."³⁵

What is particularly interesting in the definition is not its broad nature, but rather the lack of any specific mention of public health emergencies. Given the very specific examples provided to illustrate "natural catastrophe," it is hard to presume that this type of declaration could be used to cover public health emergencies such as a pandemic influenza. In these cases, the Public Health Service Act would most likely be the mechanism of choice.

First established in 1943, the Public Health Service Act provides the Secretary of HHS mechanisms to declare a public health emergency as long as the following conditions are met:

- A disease or disorder presents a public health emergency; or
- A public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.³⁶

A declaration of a public health emergency provides the Secretary with the ability to “take such action as may be appropriate to respond to public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.”³⁷ However, the “emergency fund” associated with the Public Health Service Act requires supplemental appropriations at the time of an event to fund the emergency response. This Congressional action is not immediately required for emergency responses authorized under the Stafford Act.

SHAPING A CULTURE OF PUBLIC HEALTH PREPAREDNESS AND MEDICAL EMERGENCY RESPONSE

Events predicate change, the magnitude of the events dictates the rate of change. A series of events during the early to mid 1990’s enabled our nation to begin to look at our world and the threats out there in a different light. The World Trade Center Bombings of February 1993; Arab terrorists first attempt to blow up the World Trade Centers, using a weapon of mass destruction (WMD) a 1500lb bomb and the release of sodium cyanide. This attack killed six and injured 1042. Americans still did not perceive terrorism as a high threat. The mind set then was terrorism does not happen on American soil. The individuals responsible for this event were captured and convicted, Al-Qaeda terrorist Ramzi Yousef. The rate of change for Americans’ awareness level rose slightly.³⁸ The sarin attack on the Tokyo subway system killed 12 and injured 50 severely, 984 had temporary vision problems. Americans reacted with little concern because it did not happen on American soil. Rate of change for America awareness rose slightly.³⁹ The Oklahoma City Bombings killed 168 and injured over 800. Recognition of this event rates high because of the high death rate and domestic terrorism on United States soil.

These attacks led to the U.S. Government to passing legislation designed to increase protection around federal buildings and to thwart future attacks.⁴⁰ The frequency of these events prompted the federal government, in 1997, to initiate the “Domestic Preparedness Program,” which provided a significant infusion of funds into the nation’s emergency preparedness infrastructure.⁴¹

The Domestic Preparedness Program benefited HHS as it began to emerge as a leader in national efforts to prepare for and respond to the public health and medical consequences of an All-Hazard Event. Initial efforts in this regard began in the mid-1990s under the auspices of the Office of Emergency Preparedness (OEP), Office of Public Health and Science (OPHS) and focused primarily on potential terrorist uses of conventional explosives and chemical agents.⁴² It continued with the development of the Federal Response Plan (FRP) which assigned HHS the primary responsibility for national-level medical response to natural, technological, and man-made emergencies, including weapons of mass destruction terrorism. Beginning in FY1999, HHS took on a broader role in anti-terrorism preparedness and response supported by Presidential and Congressional actions. This initially involved an expansion of OEP activities and new research and other related efforts at the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). In FY2000, the anti-terrorism activities of these three components expanded further, complemented by efforts at the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). Also in FY2000, the Secretary approved the HHS Operating Plan for the Anti Bioterrorism Initiative, which outlined a range of activities for building a stronger national base for bioterrorism preparedness and response. Relying heavily on cooperation with State and local health agencies, as well as local emergency medical response units the plan:

- Increased the number of Metropolitan Medical Response Systems (MMRS) across the nation
- Initiated the National Pharmaceutical Stockpile (NPS)
- Accelerated research into diseases, diagnostics, vaccines and treatments

- Expanded the development of public health networks for infectious disease surveillance
- Enhanced deterrence through the regulations of shipments of certain hazardous biological organisms and toxins⁴³

This Domestic Preparedness Program sought “to provide enhanced support to improve the capabilities of state and local emergency response agencies to prevent and respond to such incidents at both the national and the local level.”⁴⁴ In contrast to traditional funding practices, the program provided funds directly to the nation’s largest 120 cities.⁴⁵

Over the lifetime of the program, training and equipment programs were administered by DOD and later the Department of Justice (DOJ). HHS through the Office of Emergency Preparedness and the Centers for Disease Control and Prevention (CDC) initiated broader public health and medical efforts.

CDC spent \$120.8 million, \$173.1 million and \$193.9 million respectively in fiscal years 1999-2001.⁴⁶ The majority of these funds targeted research initiatives focused on developing vaccines for anthrax and smallpox. The other major program within HHS focused almost exclusively on preparedness planning and systems development. Known as the Metropolitan Medical Response System (MMRS) development program,⁴⁷ individual contracts were awarded non-competitively with the largest 120 cities in the nation to develop plans to respond to the consequences of weapons of mass destruction. Using a contract mechanism (versus grants or cooperative agreements), it was possible to require cities to develop multi-disciplinary planning groups to represent not only the public health and medical communities, but also public safety, emergency management and others. As noted by the National Academies of Science Institute of Medicine, in 2002,

“...the MMRS program provides proactive, pre-disaster assistance; it is not a federal response. It provides funds for the purchase of special [chemical, biological, radiological] agent-specific equipment, supplies, and pharmaceuticals for local law enforcement, fire department, and emergency medical personnel, while it demands substantial integrated planning by the local partners.”⁴⁸

However beneficial the Domestic Preparedness Program and the associated programs from HHS were to national preparedness, the urgency and focus provided to preparedness, particularly within the public health and medical community was only truly recognized after the events of September 11, 2001. The establishment of DHS and new funding mechanisms from both the CDC and the Health Resources and Services Administration (HRSA) dramatically changed the preparedness and response picture.

The most visible of these changes was of course the establishment of DHS. Widely described as the largest reorganization of the Executive Branch since the establishment of DOD, the rationales have striking similarities to those presented previously in the Reorganization Plans of 1939 and 1978.⁴⁹ President Bush stated the problem:

“The responsibility for protecting the homeland here in Washington, at least at the federal level, is spread out among more than 100 different organizations, and not one organization has the primary responsibility. Each agency operates separately, sometimes completely unaware of what others are doing. The result is duplication that we cannot afford, and inefficiencies which create problems.”⁵⁰

Recognizing the significant gaps that remained in public health and medical preparedness following the anthrax attacks of 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The legislation called upon HHS to perform the following:

- Provide effective assistance to state and local governments in the event of bioterrorism or other public health emergency.
- Ensure that state and local governments have appropriate capacity to detect and respond effectively to such emergencies.
- Develop and maintain medical countermeasures (such as drugs, vaccines and other biological products, medical devices, and other supplies) against biological agents and toxins that may be involved in such emergencies.
- Ensure coordination and minimizing duplication of federal, state, and local planning, preparedness, and response activities, including during the investigation of a suspicious disease outbreak or other potential public health emergency.
- Enhance the readiness of hospitals and other health care facilities to respond effectively to such emergencies.⁵¹

To meet these requirements, CDC and HRSA established preparedness programs targeting the public health and hospital communities. Initial funding provided \$918 million to CDC's Public Health Preparedness and Response for Bioterrorism Program and \$125 million to HRSA's National Bioterrorism Hospital Preparedness Program. Over the following two years, CDC and HRSA provided an additional \$870 and \$498 million respectively to these programs.⁵²

ONE DEPARTMENT ONE MISSION INITIATIVE TO IMPROVE THE INTRA-AGENCY PROCESS

The HHS had many of the same problems as mentioned previously by President Bush. A restated problem statement for HHS might read:

“The responsibility for protecting the health of our citizens at least at the federal level is spread out among many different organizations, and not one organization has the primary responsibility of coordinating a united response. Each agency operates separately, sometimes completely unaware of what others are doing. The result is duplication and poor lines of communication, the most important factor necessary when dealing with an emergency”

In an attempt to rectify this shortfall Secretary Thompson initiated a “One Department, One Mission” initiative. However, there was no strategy to execute this initiative that could be followed by a clear concise implementation process. Although the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provided the legislative authorization to integrate public health and medical emergency response, providing the strategy for this integration was lacking.

On November 1, 2001 Secretary Thompson appointed Dr. D.A. Henderson as the Director of a newly created Office of Public Health Preparedness (OPHP). The office was assigned to the immediate office of the Secretary and reported directly to the Secretary. This was the first attempt to have a single lead within the HHS for preparedness and response activities relating to bioterrorism and other public health emergencies. In an internal memo

within the Department it stated the following: The Director served as the principal advisor on these matters.

The Director was to integrate the Department's emergency preparedness and response programs, including our overall anti-bioterrorism efforts into a more efficient "One Department" activity. OPHP will provide a single point of contact for senior-level coordination between the Department and other Departments and agencies. OPHP will direct the Department's efforts to prepare for, protect against, respond to, and recover from acts of bioterrorism and other public health emergencies and will serve as the focal point within the Department for these activities.

The Director was to conduct a review of the Department's activities related to bioterrorism and other public health emergencies. This review covered preparedness and response activities, management and operations, internal planning and coordination, representation with key partners.

The activities for the new Director of OPHP included:

- Provide centralized leadership for the Secretary and for the Department's program to address bioterrorism and other public health emergencies, including program development and implementation, to ensure a unified approach to preparedness activities
- Coordinate the Department's review and response to Presidential Directives, Executive orders, and other memoranda related to bioterrorism and public health emergencies
- Coordinate the Department's emergency preparedness and response activities with other Departments and agencies. OPHP will be the central point of contact on these issues for HHS.
- Review and advise the Secretary on emergency preparedness and response, intelligence matters, and related inter-departmental activities.
- Establish and maintain, in collaboration with OS/ES, a system for on-going coordination with OPDIVs and STAFFDIVs involved with this initiative, including identification of a high-level single coordination point of contact within each OPDIV and STAFFDIV.
- Evaluate and recommend revisions of current delegations of authority, Federal Register Notices, and other memoranda related to these issues.
- Direct HHS OPDIV and STAFFDIV implementation of a comprehensive Department strategy to protect the civilian population from acts of bioterrorism and other public health emergencies.
- Lead the Department's planning and response efforts for public health emergencies and National Security matters including acts of terrorism, and collaborate with OPDIVs and STAFFDIVs to establish priorities for ongoing activities related to these issues.⁵³

Since the appointment of Dr. Henderson in 2001, the office has had six Directors / Acting Assistant Secretaries and three name changes over the period of six years. The Directors/ Acting Assistant Secretaries in order of succession were; Dr Jerome Hauer, Dr. William Raub, Mr. Stewart Simonson, Dr. Gerald Parker, and RADM Craig Vanderwagen. The office name changes were from the Office of Public Health Preparedness (OPHP), to the Office of Public Health and Emergency Preparedness (OPHEP), and its current name of the Office of the Assistant Secretary for Preparedness and Response (ASPR). Subsequently the capabilities and responsibilities of this office have continued to grow both in scope and magnitude. The number of personnel assigned to this office grew at a rate of 750% during the same period;

- FY 2003 - 49 FTE
- FY 2004 - 68 FTE
- FY 2005 - 119 FTE
- FY 2006 - 138 FTE
- FY 2007 - 364 FTE
- FY 2008 - 540 FTE

At the same time the organization is growing at such a rapid pace, and the turnover of leadership at the most senior level it has had to contend with established organizations within the Department and continue to develop the capabilities of Public Health preparedness and emergency response. In addition, the Project BioShield Act of 2004 primarily focused at accelerating advanced research and development of drugs and vaccines to protect the United States from health emergencies such as bird flu. This office of Research and Development Coordination would later evolve to the office of Public Health and Emergency Countermeasure (OPHEMC) and most recently to the Biomedical Advanced Research and Development Authority (BARDA).

The most recent legislative action to impact public health and medical emergency response was passed by Congress and signed into law by the President in Dec 2006 the

Pandemic and All Hazards Preparedness Act (PAHPA), Public Law No. 109-417⁵⁴. This legislation reauthorizes the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) to protect the public more effectively and efficiently by responding to public health emergencies with a clear line of authority from local to state to federal officials. It also builds on the Project BioShield Act of 2004 (P.L. 108-276). The major focus of this Act provides the following:

- Identifies the Secretary of Health and Human Services as the lead federal official responsible for public health and medical response to emergencies.
- Establishes an Assistant Secretary for Preparedness and Response with the offices to support the Department as the lead for the Preparedness Response Enterprise.
- Biomedical Advanced Research and Development Authority (BARDA) and Countermeasure Development
- NDMS Review and Evaluation of Surge Capacity
- National Health Security Strategy
- Cooperative Agreements and Evidence-Based Performance Measures
- National Electronic Public Health Situational Awareness Capability
- Commissioned Corps Readiness
- Medical Reserve Corps
- Curricula and Training⁵⁵

This legislative action clearly has one Department as the lead for public health and medical emergencies, the Secretary of Health and Human Services. Within the Department there is a single Office to lead both the Intra and Inter Office development of this enterprise.

LEADING A STRATEGY FOCUSED ORGANGIZATION

Within the first month of being appointed as the Assistant Secretary for the Office of Public Health and Emergency Preparedness, RADM Vanderwagen directed the development and implementation of a Strategic Management System (SMS) within OPHEP. The SMS provided a methodology to align activities with the overall mission and vision of the organization. This was the first Assistant Secretary to define the mission and vision of the organization:

- Mission - Lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters⁵⁶.

- Vision - A Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters⁵⁷.

In addition to the mission and vision the organization developed a strategy map and produced the ASPR Strategic plan. This ASPR Strategic Plan represents the culmination of a six-month strategic planning process. The goal of the Strategic Plan is to provide direction for the entire ASPR Organization over the next five years. Another important development in this process was the development of the ASPR values. These values as defined are:

- Service to the Nation - Our first responsibility is to serve the Nation; we are compassionate, selfless and respectful of the needs of those we serve.
- Teamwork - We act with a collective spirit and common commitment to collaboration that transcends individual concerns in order to achieve 'A Nation Prepared'
- Leadership - We lead by example and inspire others to action as we work together to serve the Nation; we drive innovation, provide direction, and coordinate delivery of a seamlessly integrated breadth of products and services; we are committed to individual and organizational excellence
- Integrity - We adhere to the highest professional and ethical standards, focusing on the best interests of those we serve

With the establishment of a strategic plan with stated goals, objectives, strategy map, and values the organization is beginning to shape its cultural identity within the HHS as the leader of the Public Health and Medical Emergency Preparedness and Response Enterprise.

CONCLUSIONS AND RECOMMENDATIONS

The Pandemic and All-Hazards Preparedness Act of 2006 codified the HHS Secretary's role as lead for the Federal public health and medical response to emergencies and incidents covered by the National Response plan (NRP), and authorizes HHS's operational control of Federal public health and medical response assets during these events⁵⁸. In addition, the development of the Homeland Security Council's National Strategy for Pandemic Influenza has stressed the importance of preparedness for natural and manmade disasters that have public health impact. Many of the strategies undertaken by HHS to achieve preparedness and response capability are done in concert with or in support of other Federal departments and agencies, State and local government, and private sector entities. This collaborative approach

is vital given that public health emergencies have the potential to affect nearly every sector of society.

The Office of the Assistant Secretary for Preparedness and Response is the single office responsible for preparedness and response activities within HHS. As the principal advisor to the Secretary on all matters related to public health and medical preparedness and response emergencies, ASPR leads and promotes a collaborative approach with many partners.

HHS is charged with the health of our nation both during day to day operations and during a crisis event. Providing a coordinated Federal response during an event is the expectation of the American people. Although the legislative process has enabled drastic improvement in preventing, preparing and responding to these events having one mission one voice is critical. Further development of both Intra / and Inter Agency processes are critical for the development and response of the Preparedness and Response enterprise.

With the passage of the PAHPA single leadership for developing this enterprise is with the Our national medical and public health resources must be configured to prepare, prevent and quickly respond to an event that threatens the health and well being of a large number of people. In the much the same way that ASPR is maturing and developing strategies and a strong performance measurement system the enterprise of public health preparedness and medical emergency must do the same. For both intra-agency and interagency the establishment of an Enterprise Governance Board (EGB) would enable the act of affecting decision making and oversight of a high-value program through the identification and appointment of a top team of talented, subject matter experts to provide dedicated, long term vision, strategy and direction for the program.

The HHS EGB would change the paradigm⁵⁹ of existing process within the department. The first order of business would be to direct a complete review of the enterprise, that would

include but not limited to areas such as; operations, logistics, policy, research, personnel, training and accountability. Establish a concept of operations for the public health and medical emergency enterprise. Conduct a gap analysis of the enterprise to determine the critical shortfalls and develop a prioritization of how an annual work plan can improve these shortfalls.

The EGB promotes success in decision making, especially an initiative as complex as a fundamental overhaul or transformation of a large organization, by providing a dedicated, second order process for guiding and updating all significant decisions (through a feedback loop) regarding the targeted initiative. The key to this process is accountability to the Secretary of the Department.

Duplication of this process at the interagency level would also yield dramatic results; again the key to this success is accountability of the process to the President of the United States. We are currently in an evolving period where relatively young Departments, DHS, HHS and reorganization of old Departments like DOD and State are just learning how to break down the silos of their agencies and are fostering an interdepartmental approach.

Legislation has been passed to enable this process; the leadership of our organizations must embrace this change in cultural behavior in order to preserve our way of life. Our laws and institutions must go hand in hand with the progress of the human mind.⁶⁰ Our world is changing at an exponential pace; we must be adaptive, flexible, and innovative to sustain our way of life.

Endnotes:

¹ Thomas Jefferson; Taken from a letter to Samuel Kercheval, July 12, 1816.

² National Oceanic and Atmospheric Administration. NOAA News. "NOAA Reviews Record-Setting 2005 Atlantic Hurricane Season." Available: <http://www.noaanews.noaa.gov/stories2005/s2540.htm> [21 March 2006].

³ Category 3 storms have winds 111-130 mph and a storm surge generally 9-12 feet above normal. Category 4 storms have winds 131-155 mph and storm surge generally 13-18

feet above normal. Category 5 storms have winds > 155 mph and storm surge generally >18 feet above normal.

⁴ Hurricanes Cindy, Dennis, Katrina, Ophelia, Rita and Wilma and tropical storms Arlene and Tammy all made landfall in the United States.

⁵ Defined by author.

⁶ Joint Publication 1-02, Department of Defense Dictionary of Military and Associated Terms.

⁷ (Footnote Organization Development of the Joint Chiefs of Staff 1942-1989 Page 4)

⁸ The National Archives. "Guide to Federal Records: Records of the Public Health Service, 1912-1968." Available: <http://www.archives.gov/research/guide-fed-records/groups/090.html> [4 April 2006].

⁹ HHS Strategic Plan, fiscal Years 2007-2012, Draft, dated 5/15/2007
http://www.hhs.gov/strategic_plan/strategicplanpdf.pdf

¹⁰ Current budget amounts and numbers of employees are available at <http://www.hhs.gov/about/whatwedo.html/>

¹¹ <http://www.hhs.gov/about/whatwedo.html>

¹² U.S. Congress. Seventh Congress, Session II, Chapter VI. "An Act for the relief of the sufferers by fire, in the town of Portsmouth." 19 February 1803.

¹³ City of Portsmouth, New Hampshire. Portsmouth Fire Department. "Portsmouth Fire History." Available: <http://www.cityofportsmouth.com/fires/history.htm> [10 February 2006].

¹⁴ Daniel, Peter. "Deep'n As It Come: The 1927 Mississippi River Flood" New York: Oxford University Press (1977). pp. 4-5.

¹⁵ The Mississippi River flooded in 1858, 1862, 1867, 1882, 1884, 1890, 1897, 1903, 1912, 1913, 1922, and 1927.

¹⁶ Congressional Research Service. "Disaster Response and Appointment of a Recovery Czar: The Executive Branch's Response to the Flood of 1927." 25 October 2005.

¹⁷ 16 U.S.C. 460d; Public Law 78-534, December 22, 1944; 58 Stat. 887

¹⁸ Sixty-Fourth Congress, Session II, Chapter 144 – An Act to provide for the control of the floods of the Mississippi River and the Sacramento River, California, and for other purposes. (1917).

¹⁹ U.S. Congress. Public Law 64-367. "Flood Control Act of 1917." 1 March 1917.

²⁰ Reorganization Plan No. 1 (1973). Title 5 *U.S. Code* GPO Access. Available: http://www.access.gpo.gov/uscode/title5a/5a_4_96_.html [21 March 2006].

²¹ Ibid

²² Homeland Security Presidential Directive No. 1 (2001). Available <http://www.whitehouse.gov/news/releases/2001/10/20011030-1.html> [27 March 2006].

²³ U.S. Congress. Public Law 93-288. "Disaster Relief Act Amendments of 1974." 22 May 1974.

²⁴ Ibid

²⁵ Ibid

²⁶ Adjusting Emergency Preparedness Assignments to Organizational and Functional Changes in Federal Departments and Agencies. Executive Order 11921 (1976). Available: <http://www.fas.org/irp/offdocs/eo/eo-11921.htm> [27 March 2006].

²⁷ Ibid

²⁸ Reorganization Plan No. 3 (1978) Title 5 *U.S. Code* GPO Access. Available: http://www.access.gpo.gov/uscode/title5a/5a_4_100_.html [21 March 2006].

²⁹ Ibid

³⁰ Federal Emergency Management. Executive Order 12148 (1979). Available: <http://www.fema.gov/library/eo12148.shtm> [27 March 2006].

³¹ National Disaster Medical System Memorandum of Agreement among the Departments of Homeland Security, Health and Human Services, Veterans Affairs, and Defense", p. 1. Available online at: http://emilms.fema.gov/IS1900_NDMS/assets/NDMS_Partners_MOA_with_sig.pdf; accessed April 6, 2007

³² U.S. Congress. Public Law 107-188. "Public Health Security and Bioterrorism Response Act of 2002." 12 June 2002.

³³ Federal Emergency Management Agency. "About FEMA: Statutory Authority." Available: www.fema.gov [20 March 2006].

³⁴ U.S. Congress. Public Law 100-707. "Robert T. Stafford Disaster Relief and Emergency Assistance Act as Amended by Public Law 106-390." 30 October 2002. Available: <http://www.fema.gov/library/stafact.shtm#sec501> [4 April 2006].

³⁵ Ibid

³⁶ Public Health Emergencies. Title 42 *U.S. Code* GPO Access Available: <http://frwebgate.access.gpo.gov/cgi-bin/multidb.cgi> [27 March 2006].

³⁷ Ibid

³⁸ Wikipedia.org/wiki/World_Trade_Center_Bombing

³⁹ Wikipedia.org/wiki/sarin_Gas_Tokyo

⁴⁰ Wikipedia.org

⁴¹ U.S. Congress. Public Law 104-201. "National Defense Authorization Act for Fiscal Year 1997: Defense Against Weapons of Mass Destruction Act." 23 September 1996.

⁴² Capture footnote from Book in office over desk...

⁴³ Research and Development for Preparedness Get Book and page....

⁴⁴ Ibid

⁴⁵ Prior to this Act programs funded the states, who then made further allocations to cities, counties and townships. In fiscal year 2002, the approach shifted back to the states with more limited funding available directly to cities and other metropolitan areas.

⁴⁶ "Bioterrorism: Federal Research and Preparedness Activities." GAO (2001) Available: <http://www.gao.gov/new.items/d01915.pdf> [27 March 2006].

⁴⁷ The program began in 1995-1996 with the development of two prototype teams based in Washington DC and Atlanta, GA. Following the initial funding of the 27 cities the name was changed from Metropolitan Medical Strike Team to MMRS. The name change was made to reflect the focus on systems development.

⁴⁸ Preparing for Terrorism: Tools for Evaluating the Metropolitan Medical Response System Program. National Academy Press, Institute of Medicine. Washington D.C. 2002.

⁴⁹ The establishment of DHS consolidated functions from the following organizations: the Departments of Agriculture, Defense, Energy, Health and Human Services, Justice, Transportation, Treasury, the Federal Emergency Management Agency, the Federal Bureau of Investigations, and the General Services Administration.

⁵⁰ President Bush Pushes for Homeland Security Department. Remarks by the President at District of Columbia Metropolitan Police Operations Center District of Columbia Metropolitan Police Operations Center Washington, D.C. (2002) White House Website Available: <http://www.whitehouse.gov/news/releases/2002/11/20021112-1.html> [29 March 2006].

⁵¹ U.S. Congress. Public Law 107-188. "Public Health Security and Bioterrorism Response Act of 2002." 12 June 2002.

⁵² Heinrich, Janet. GAO. "HHS Bioterrorism Preparedness Programs: States Reported Progress but Fell Short of Program Goals for 2002." 10 February 2004.

⁵³ Memorandum from the Secretary of the HHS, dtd Jan 3, 2002

⁵⁴ U S Congress, Public Law No. 109-417, Pandemic and All Hazards Preparedness Act (PAHPA)

⁵⁵ Ibid

⁵⁶ ASPR Strategic Plan FY 2007-2012, dated July 2007

⁵⁷ Ibid

⁵⁸ An except into this authorization is those assets under the control of the Department of Defense

⁵⁹ Kenneth Arrow, *the Limits of Organization*, New York: Norton, 1974 "A paradigm is a set of rules and regulations (written or unwritten) that does two things: 1) it establishes or defines boundaries; and 2) it tells you how to behave inside the boundaries in order to be successful. "

⁶⁰ Thomas Jefferson; Taken from a letter to Samuel Kercheval, July 12, 1816.

