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Work Session: V: Managing Critical New Public Health Concerns

Title: Pandemic Response and Emerging Laws

by

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BEFORE THE UNITED STATES SENATE
COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON HOMELAND SECURITY

REGARDING
BIODEFENSE AND PANDEMIC INFLUENZA PLANNING

May 23, 2006

Chairman Gregg, Senator Byrd, and Members of the Committee, it is an honor for me to testify before you today regarding my views on the state of biodefense and pandemic planning in the United States.

Just over one year ago, I had the honor to testify before you and this Committee on the state of implementation of the Project BioShield Act of 2004 and the need for liability protections to promote participation in the biodefense market, but also to stimulate development of influenza pandemic countermeasures. Since that time, significant progress has been made.

In the area of biodefense, the Department of Health and Human Services (HHS) has acquired 10 million doses of a safe and effective FDA licensed anthrax vaccine from BioPort Corporation to better prepare the Nation against another anthrax attack like the one suffered by this body in October 2001. In addition, HHS has announced that the long-awaited purchase of anthrax therapeutics for post-exposure treatment of anthrax victims will be completed very shortly.

From a policy standpoint, Deputy Secretary Alex Azar recently announced that he and Secretary Leavitt are about to complete a revised implementation strategy for Project BioShield to eliminate many of the delays that have been observed in the BioShield program. Given the substantial talents of Deputy Secretary Azar, his personal involvement in this effort is welcome and encouraging.

Of course, reintroduction of legislation by Senator Burr, with the Chairman's co-sponsorship, creating the Biomedical Advanced Research and Development Agency (BARDA), and the commitment by the President in his FY 2007 budget to fund such an effort with nearly $200 million, is a very positive development. Creation of BARDA will go a long way to address the "valley of death" in biodefense countermeasure development and merits the strong support of industry for passage this year.

In the area of research and development for pandemic vaccines, recent events have also been very positive. On May 3, 2006, Secretary Leavitt announced the award of almost $1 billion in advance development contracts for cell-culture influenza vaccines. These contracts are milestone driven, and support multiple companies pursuing diverse technologies. Given the recent challenges HHS has faced with its contractor, VaxGen, for an experimental anthrax vaccine being developed under BioShield, it is clear that HHS understands the need not put its eggs in one basket with influenza countermeasures.

We should also take heart in the size and diversity of the companies awarded the cell-culture contracts. From successfully engaging a large company like GlaxoSmithKline, to making awards to innovative biotechnology companies like

MedImmune - which has developed the first licensed innovation in flu vaccine technology in over 50 years with its FluMist vaccine - it is clear that HHS has made substantial progress over the last year. HHS is now moving forward with development of adjuvant technology to improve the disappointing effectiveness of the H5N1 vaccine purchased last year, as well as to continue development of exciting new vaccine technologies such as DNA-based vaccines and novel antivirals. At the same time, HHS has recognized the need to accelerate the development of critical rapid diagnostics, and has announced plans to move forward with an advance development program for such technology in the coming weeks.

But perhaps most importantly, under your leadership, Mr. Chairman, as well as the leadership of Majority Leader Frist and Senator Burr in the Senate, and Speaker Hastert, Congressman Lewis, and Congressman Issa in the House, on December 30, 2005, President George W. Bush signed into law the "Public Readiness and Emergency Preparedness Act" (PREP Act).

Through this legislation, the United States Congress has provided a key tool to protect the nation from infectious disease and other threats that could potentially cripple the U.S. and the global economy. As a result of the PREP Act, vaccine and countermeasure developers are now better protected from the mass of lawsuits that have basically eviscerated the U.S. vaccine and countermeasure manufacturing base, leaving it ill prepared for threats such as avian influenza. With the implementation of these strategic and valuable protections, the U.S. is now in a far better position to revitalize its domestic capability to produce the tools needed to secure the health and well-being of its citizens.

In short, the PREP Act offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Act creates a shield of immunity for claims arising out of, related to, or resulting from the administration or the use of a covered countermeasure (i.e., vaccines, countermeasures, devices and certain other products). This immunity covers a wide range of uses, including design, development, testing, manufacturing, distribution, administration, use and other activities so that the protections can be applied as broadly as possible.

This law dramatically improves the ability of the United States to develop the tools it needs to be prepared for a naturally occurring or terrorist-related public health emergency. However, it is absolutely critical for HHS take the necessary steps now to implement fully the PREP Act, as intended by Congress and the President, to prepare the Nation for a influenza pandemic. To that end, industry eagerly awaits the Secretary's declaration of a potential public health emergency for an influenza pandemic, thereby triggering the protections of the PREP Act for covered countermeasures. In addition, industry looks forward to the release of the

regulations required by the Act to provide further clarity on the scope of the Act and its protections.

However, will all the outstanding progress the United States has made over the last year, both in the area of biodefense and pandemic planning, more can, and must, be done.

First, I would urge Congress to consider providing incentives to private entities to better prepare for a pandemic. A recent study by Mercer Human Resource Consulting has estimated that only 7% of U.S. companies have established budgets for pandemic preparedness, compared with 12% for European companies and 25% for Asian businesses. The private sector must take the lead in properly preparing for a pandemic threat, not only for their own businesses, but also, for the communities where they operate, and not rely upon government to prepare the Nation on its own.

Pandemic preparedness is first and foremost an issue of public health. But it is also an issue of ensuring American competitiveness in the global markets. If we are less prepared than the rest of the World, not only will our Nation's health suffer more, but so will our economy and our path to recovery from such an event. Companies must plan now for the possibility that 40% or more of their work force may not be able to show up to work during a pandemic, including, according to a recent study by the Johns Hopkins Bloomberg School of Public Health, up to 67% of back office health care workers providing technical support, payroll and payment processing, and other administrative functions. Public companies, of course, have an even greater obligation to implement internal controls to address such an event to assure that shareholder assets are protected and their business recovers as quickly as possible.

To that end, Congress should act now to consider changes in policy similar to those passed to prepare the Nation for the Y2K threat. This includes providing additional incentives, such as expanded liability protections, to those entities that make reasonable and prudent efforts to prepare for a pandemic. Congress should provide, at a minimum, the same level of protections provided by Congress on a bipartisan basis in the Y2K Act of 1998, signed by President Clinton.

Policy changes to improve telework and increase high-speed internet access should also be part of this effort. The Administration's pandemic plan recommends that employers keep employees three feet apart in a pandemic event. Given that more and more companies are enabling employees to work remotely, perhaps Congress should provide incentives now to ensure that telework options are widely available. With sufficient bandwidth and data security to operate with large numbers at the same time, workers could work safely from home, thereby stemming spread of the pandemic while reducing the economic impact.

To the greatest degree possible, we must also ensure that certain critical functions for maintaining the operations of our health care infrastructure can be automated or operated remotely in those circumstances. Thus, Congress should expedite passage of legislation promoting electronic medical records as soon as possible.

The Y2K legislation served as a national wake up call to Americas businesses and gave them the comfort of liability protection to identify and correct the problems with their IT infrastructure. Many businesses then (like many hospitals, health insurers, and other businesses critical to our nation's health care infrastructure today), were afraid to even explore their vulnerabilities for fear of creating a paper trail for eager trial lawyers to launch baseless lawsuits in the future. U.S. businesses, particularly those critical to our health care infrastructure, need a similar wakeup call - and equal liability protection - to upgrade, test, and retest our public health infrastructure to ensure pandemic readiness. Like with Y2K, even if a pandemic worst case scenario never happens, providing the legal certainty for businesses to upgrade their infrastructure and adequately prepare will improve our Nation's fragile health care system - leading to better patient care, lower costs, fewer medical mistakes, and better patient privacy. It is truly a win-win scenario.

Second, we must examine the supply chain for delivery of critical countermeasures that must be deployed during a pandemic, as well as the supply chain for delivery of good and services, as a whole, during a state of emergency caused by a pandemic. Most certainly, some - if not all borders - will close during a pandemic, thereby crippling food distribution and delivery of critical goods and component parts made outside of the United States. For critical countermeasures, Congress should deal now with policies to ensure protection from counterfeiting and theft of public health supplies. Congress should encourage the private sector to pursue implementation of workable, non-burdensome tracking mechanisms, while ensuring the protection of data and other information needed to allow the supply chain to function.

Because timing is essential, the federal government should rely on the expertise and experience of the private sector in developing and executing mission-critical functions like supply chain management and inventory control. We should ensure that policies encourage implementation of commercially tested systems – preferably those already in place in key parts of the health care infrastructure, that can be quickly and easily implemented. Effective supply chain management solutions for the strategic stockpiles must be proven and reliable, and be able to link thousands of stakeholders including pharmaceutical and medical supply companies, health care providers, distributors, shippers, security and customs organizations, and private and public local, state, federal and international health care agencies.

Effective supply chain management may also require considerable automation, since significant numbers of personnel throughout the supply chain may be sick or fail to show up for work. Information must also, to the greatest degree possible, be readily accessible, but yet secure, among multiple jurisdictions. In addition, the communication channels must be easily interoperable with multiple existing systems using different levels of technical standards and training of operating personnel.

Finally, Congress must act now to implement policies that will bolster our fragile public health infrastructure, and especially, our hospital system. Should a pandemic strike the Nation, the surge on the hospitals, nationwide, both from patients who are actually sick with influenza or another illness, as well as the "worried well," will cripple our Nation's healthcare system unless we are fully prepared. Addressing a *U.S. News & World Report* meeting on health and preparedness, Secretary of Homeland Security Michael Chertoff noted that hospitals, nursing homes, and other health facilities "have a *legal and moral obligation* to develop evacuation plans and other emergency plans to ensure that people with special needs whose care has been entrusted to these caregivers will, in fact, be taken care of and will get the appropriate care in an emergency." We must give these entities the tools they need to meet this legal and moral obligation.

Under the best of circumstances, emergency response workers may receive a vaccine that provides some level of immunity prior to a pandemic, and thus, will have some small degree of protection. However, the hospital administrators, claims processors, and support personnel are unlikely to receive any vaccine in time. With hospital support staff either at home to avoid illness, or already sick, while the hospitals are being pummeled by acute care patients, no claims will be processed to insurers. Thus, hospitals will be under significant financial strain, potentially unable to recover, and likely will be taken over by the Federal government, as has already occurred in some of the areas impacted by Katrina.

In addition, painfully hard triage decisions on who will receive care, and when they receive it, are certain to lead to baseless lawsuits unless some protections from liability are provided to health care providers. Trial lawyers are already lying in wait, planning their litigation strategies around the occurrence of such an event. The last thing the Nation will need during a flood of illness is a flood of lawsuits - Congress should act now to stem the tide of such an event.

In terms of other policy changes that would benefit overall preparedness for a pandemic, the United States has the opportunity to build the infrastructure today to support improved access to influenza vaccine and better immunization for annual influenza - which kills over 30,000 American each year. Expanded immunization recommendations for influenza vaccine, particularly among the young who drive disease transmission, should be strongly considered. Congress

should also challenge healthcare providers and the public health system to not squander the opportunity to begin building and testing the influenza vaccine infrastructure within the framework of current immunization recommendations. Policymakers should act quickly to accelerate those recommendations, including universal pediatric vaccination up to 18 years of age, in order to build as much vaccine infrastructure capacity as possible to better prepare the Nation for a pandemic without the expenditure of any additional Federal dollars. The bottom line is that we should build out the vaccine infrastructure with a seasonal flu approach, which will, in turn, not only protect the population today for the annual flu strain, but also allow us to look for any leaks that might sink the ship under the wave of a pandemic flu crisis.

Turning briefly to the implementation of Project BioShield, while implementation has been improved, and according to HHS, additional improvements are under way, more can be done. When I last testified before you in April 2005, I noted that the regulations mandated under Project BioShield had yet to be promulgated. Unfortunately, that is still the case today. I also noted that the material threat assessment (MTA) process conducted by the Department of Homeland Security under BioShield provided neither the speed nor the clarity necessary to allow the full promise of BioShield to "build a market" to materialize. While some improvements have been announced in the MTA process, industry has seen little evidence that this problem has been adequately addressed. For example, when I testified last year, I noted that the market for badly needed countermeasures for cyanide – a well known and clearly established threat – was uncertain due to implementation issues with BioShield. Again, unfortunately, that remains the case today.

Finally, HHS must learn from the set back in the VaxGen anthrax contract and not allow itself, or industry, to be deterred from this apparent failure by a single contractor. It is clear from the recent statements by Secretary Leavitt that HHS appears to be doing just that, and that is very encouraging. However, additional clarity and greater speed in implementing BioShield, along with the fast passage and implementation of BARDA, will provide industry with greater confidence in the long-term viability of the overall effort.

I close by noting that the proposals I have suggested have one thing in common - they do not require the appropriation of any additional dollars other than those that have already been passed or are proposed in the President's budget. While that may not appeal to you, Mr. Chairman, in your role as an Appropriations Cardinal, I suspect it may appeal to your views as Chairman of the Budget Committee. Thus, through changes in policy alone, we can make substantial progress in improving the Nation's preparedness for a pandemic or bioterrorist attack, as well as enhancing and protecting public health as a whole.

I very much appreciate the opportunity to offer testimony on this very important public health and anti-terrorism issue. Again, I applaud your efforts, and the efforts of President Bush and his Administration, and look forward to continuing our work with Congress and the Administration in this critical area.

I am happy to respond to any questions you may have.

FY 2006 Pandemic Influenza State and Local Funding

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Phase I ($100M) and Phase II ($225M) Distribution Chart (total $325 million)

This chart reflects a revised allocation of funds as of 7/13/2006 (PDF) (23.1KB).

State/Jurisdiction	Phase I Allocations	Phase II Allocations
Alabama	$1,595,205	$3,480,727
Alaska	$657,647	$934,023
Arizona	$1,856,742	$4,384,193
Arkansas	$1,163,333	$2,317,518
California (exc. LA County)	$6,723,207	$17,632,167
LA County	$2,900,529	$6,997,627
Colorado	$1,605,882	$3,550,944
Connecticut	$1,347,950	$2,795,673
Delaware	$698,960	$1,051,650
District of Columbia	$635,601	$860,031
Florida	$4,633,819	$12,134,261
Georgia	$2,609,920	$6,433,307
Hawaii	$803,669	$1,333,955
Idaho	$832,432	$1,434,604
Illinois (exc. Chicago)	$2,878,268	$6,975,164
Chicago	$1,197,706	$2,371,858
Indiana	$2,007,596	$4,601,761
Iowa	$1,215,422	$2,439,931
Kansas	$1,162,607	$2,294,977
Kentucky	$1,501,451	$3,229,334
Louisiana	$1,592,758	$3,458,374
Maine	$818,369	$1,364,241
Maryland	$1,840,470	$4,162,556
Massachusetts	$2,061,287	$4,684,666
Michigan	$2,951,805	$7,118,866
Minnesota	$1,731,493	$3,856,761
Mississippi	$1,200,982	$2,410,341
Missouri	$1,890,782	$4,293,302
Montana	$723,275	$1,111,912
Nebraska	$922,515	$1,650,216
Nevada	$1,045,254	$2,079,242
New Hampshire	$813,384	$1,356,678
New Jersey	$2,601,641	$6,201,371
New Mexico	$956,824	$1,761,130
New York (exc. New York City)	$3,205,759	$7,792,266
New York City	$2,466,271	$5,799,926

North Carolina	$2,547,844	$6,178,689
North Dakota	$654,029	$916,376
Ohio	$3,281,387	$7,997,284
Oklahoma	$1,352,695	$2,820,254
Oregon	$1,366,765	$2,881,187
Pennsylvania	$3,508,291	$8,628,752
Rhode Island	$761,679	$1,203,809
South Carolina	$1,508,881	$3,282,750
South Dakota	$686,008	$1,007,447
Tennessee	$1,921,423	$4,399,671
Texas	$5,875,044	$15,450,021
Utah	$1,071,983	$2,115,066
Vermont	$650,610	$907,464
Virginia	$2,291,072	$5,448,990
Washington	$1,990,994	$4,612,085
West Virginia	$940,502	$1,688,192
Wisconsin	$1,831,224	$4,120,579
Wyoming	$622,102	$833,069
Commonwealth		
Puerto Rico	$1,443,014	$3,058,415
Territory		
American Samoa	$114,066	$137,853
Guam	$139,782	$210,238
Northern Marianas Islands	$118,513	$152,555
Virgin Islands (US)	$126,461	$171,093
Fed States of Micronesia	$126,298	$170,699
Marshall Islands	$113,722	$138,631
Palau	$104,795	$113,278
Grand Total	**$100,000,000**	**$225,000,000**

State and Local Pandemic Influenza Planning Checklist

Planning for pandemic influenza is critical. To assist you in your efforts, the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) have developed the following checklist. It identifies important, specific activities you can do now to prepare. Many are specific to pandemic influenza, but a number also pertain to any public health emergency.

This checklist is based on the HHS Pandemic Influenza Plan, Public Health Guidance for State and Local Partners, but is not intended to set forth mandatory requirements. Each state and local jurisdiction should determine for itself whether it is adequately prepared for disease outbreaks in accordance with its own laws and procedures.

Community Preparedness Leadership and Networking [Preparedness Goal 1—Increase the use and development of interventions known to prevent human illness from chemical, biological, radiological agents, and naturally occurring health threats.]

Completed	In Progress	Not Started	
☐	☐	☐	• Establish a Pandemic Preparedness Coordinating Committee that represents all relevant stakeholders in the jurisdiction (including governmental, public health, healthcare, emergency response, agriculture, education, business, communication, community-based, and faith-based sectors, as well as private citizens) and that is accountable for articulating strategic priorities and overseeing the development and execution of the jurisdiction's operational pandemic plan.
☐	☐	☐	• Delineate accountability and responsibility, capabilities, and resources for key stakeholders engaged in planning and executing specific components of the operational plan. Assure that the plan includes timelines, deliverables, and performance measures.
☐	☐	☐	• Within every state, clarify which activities will be performed at a state, local, or coordinated level, and indicate what role the state will have in providing guidance and assistance.
☐	☐	☐	• Assure that the operational plan for pandemic influenza response is an integral element of the overall state and local emergency response plan established under Federal Emergency Support Function 8 (ESF8): Health and medical service and compliant with National Incident Management System.
☐	☐	☐	• Address integration of state, local, tribal, territorial, and regional plans across jurisdictional boundaries in the plan.
☐	☐	☐	• Formalize agreements with neighboring jurisdictions and address communication, mutual aid, and other cross-jurisdictional needs.
☐	☐	☐	• Ensure existence of a demographic profile of the community (including special needs populations and language minorities) and ensure that the needs of these populations are addressed in the operation plan.
☐	☐	☐	• Address provision of psychosocial support services for the community, including patients and their families, and those affected by community containment procedures in the plan (see Supplement 11).

continued

Completed	In Progress	Not Started	
☐	☐	☐	• Test the communication operational plan that addresses the needs of targeted public, private sector, governmental, public health, medical, and emergency response audiences; identifies priority channels of communication; delineates the network of communication personnel, including lead spokespersons and persons trained in emergency risk communication; and links to other communication networks (see Supplement 10).
☐	☐	☐	• Identify for all stakeholders the legal authorities responsible for executing the operational plan, especially those authorities responsible for case identification, isolation, quarantine, movement restriction, healthcare services, emergency care, and mutual aid.
☐	☐	☐	• Make clear to all stakeholders the process for requesting, coordinating, and approving requests for resources to state and federal agencies.
☐	☐	☐	• Create an Incident Command System for the pandemic plan based on the National Incident Management System and exercise this system along with other operational elements of the plan.
☐	☐	☐	• Assist in establishing and promoting community-based task forces that support healthcare institutions on a local or regional basis.
☐	☐	☐	• Identify the authority responsible for declaring a public health emergency at the state and local levels and for officially activating the pandemic influenza response plan.
☐	☐	☐	• Identify the state and local law enforcement personnel who will maintain public order and help implement control measures. Determine in advance what will constitute a "law enforcement" emergency and educate law enforcement officials so that they can pre-plan for their families to sustain themselves during the emergency.
☐	☐	☐	• Ensure that the plans are scalable, to the magnitude and severity of the pandemic and available resources. Revise as necessary.

Surveillance [HHS Supplement 1. Preparedness Goal 3—Decrease the time needed to detect and report chemical, biological, or radiological agents in tissue, food, or environmental agents that cause threats to the public's health. Preparedness Goal 5—Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Conduct year-round traditional surveillance for seasonal influenza (e.g., virologic, outpatient visits, hospitalization, and mortality data), including electronic reporting.
☐	☐	☐	• Improve capacity for rapid identification of unusual influenza strains by working with federal partners to enhance laboratory-based monitoring of seasonal influenza subtypes, as described in Supplement 1 (Surveillance).
☐	☐	☐	• Develop and be prepared to implement enhanced surveillance once a pandemic is detected to ensure recognition of the first cases of pandemic virus infection in time to initiate appropriate containment protocols, and exercise regularly.
☐	☐	☐	• Link and routinely share influenza data from animal and human health surveillance systems.
☐	☐	☐	• Obtain and track information daily during a pandemic (coordinating with epidemiologic and medical personnel) on the numbers and location of newly hospitalized cases, newly quarantined persons, and hospitals with pandemic influenza cases. Use these reports to determine priorities among community outreach and education efforts.

Public Health and Clinical Laboratories [HHS Supplement 2. Preparedness Goal 3—Decrease the time needed to detect and report chemical, biological, and radiological agents in tissue, food, or environmental agents that cause threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Institute surveillance for influenza-like illnesses (ILI) among laboratory personnel working with novel influenza viruses.
☐	☐	☐	• Develop and test a plan for surge capacity of public health and clinical laboratories to meet the needs of the jurisdiction during a pandemic.
☐	☐	☐	• Assess regularly the influenza diagnostic testing proficiency and adherence to biosafety containment and biomonitoring protocols.
☐	☐	☐	• Inform frontline clinicians and laboratory personnel of protocols for safe specimen collection and testing, how and to whom a potential case of novel influenza should be reported, and the indications and mechanism for submitting specimens to referral laboratories (see Supplements 3, 4, 5).

Healthcare and Public Health Partners [HHS Supplement 3. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Test the operational plan for the healthcare sector (as part of the overall plan) that addresses safe and effective 1) healthcare of persons with influenza during a pandemic, 2) the legal issues that can affect staffing and patient care, 3) continuity of services for other patients, 4) protection of the healthcare workforce, and 5) medical supply contingency plans.
☐	☐	☐	• Ensure all components of the healthcare delivery network (e.g., hospitals, long-term care, home care, emergency care) are included in the operational plan and that the special needs of vulnerable and hard-to-reach patients are addressed.
☐	☐	☐	• Ensure that plan provides for real-time situational awareness of patient visits, hospital bed and intensive care needs, medical supply needs, and medical staffing needs during a pandemic.
☐	☐	☐	• Test the operational plan for surge capacity of healthcare services, workforce, and supplies to meet the needs of the jurisdiction during a pandemic.
☐	☐	☐	• Test the plan provisions for mortuary services during a pandemic.
☐	☐	☐	• Maintain a current roster of all active and formerly active healthcare personnel available for emergency healthcare services.
☐	☐	☐	• Determine what constitutes a medical staffing emergency and exercise the operational plan to obtain appropriate credentials of volunteer healthcare personnel (including in-state, out-of-state, international, returning retired, and non-medical volunteers) to meet staffing needs during a pandemic.
☐	☐	☐	• Ensure healthcare facilities in the jurisdiction have tested a plan for isolating and cohorting patients with known or suspected influenza, for training clinicians, and for supporting the needs for personal protective equipment.
☐	☐	☐	• Ensure the healthcare facilities in the jurisdiction have tested an operational plan to initiate, support, and implement quarantine of potentially exposed healthcare personnel (see Supplements 4 and 5).

Infection Control and Clinical Guidelines [HHS Supplements 4 and 5. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Ensure the Health Alert Network in the jurisdiction reaches at least 80% of all practicing, licensed, frontline healthcare personnel and links via the communication network to other pandemic responders (see Supplements 3, 10).
☐	☐	☐	• Craft messages to help educate healthcare providers about novel and pandemic influenza, and infection control and clinical guidelines, and the public about personal preparedness methods.
☐	☐	☐	• Develop and test a plan (as part of the communication plan) to regularly update providers as the influenza pandemic unfolds.
☐	☐	☐	• Ensure appropriate local health authorities have access to EPI-X and are trained in its use.

Vaccine Distribution and Use [HHS Supplement 6. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Work with healthcare partners and other stakeholders to develop state-based plans for vaccine distribution, use, and monitoring; and for communication of vaccine status.
☐	☐	☐	• Exercise an operational plan that addresses the procurement, storage, security, distribution, and monitoring actions necessary (including vaccine safety) to ensure access to this product during a pandemic.
☐	☐	☐	• Ensure the operational plan delineates procedures for tracking the number and priority of vaccine recipients, where and by whom vaccinations will be given, a distribution plan for ensuring that vaccine and necessary equipment and supplies are available at all points of distribution in the community, the security and logistical support for the points of distribution, and the training requirements for involved personnel.
☐	☐	☐	• Address vaccine security issues, cold chain requirements, transport and storage issues, and biohazardous waste issues in the operational plan.
☐	☐	☐	• Address the needs of vulnerable and hard-to-reach populations in the operational plan.
☐	☐	☐	• Document with written agreements the commitments of participating personnel and organizations in the vaccination operational plan.
☐	☐	☐	• Inform citizens in advance about where they will be vaccinated.

Antiviral Drug Distribution and Use [HHS Supplement 7. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Develop state-based plans for distribution and use of antiviral drugs during a pandemic via the Strategic National Stockpile (SNS), as appropriate, to healthcare facilities that will administer them to priority groups. Establish methods for monitoring and investigating adverse events.
☐	☐	☐	• Test the operational plan that addresses the procurement, storage, security, distribution, and monitoring actions necessary to assure access to these treatments during a pandemic.
☐	☐	☐	• Ensure the jurisdiction has a contingency plan if unlicensed antiviral drugs administered under Investigational New Drug or Emergency Use Authorization provisions are needed.

Community Disease Control and Prevention (including managing travel-related risk of disease transmission) [HHS Supplements 8 and 9. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Exercise the jurisdiction's operational plan to investigate and contain potential cases or local outbreaks of influenza potentially caused by a novel or pandemic strain.
☐	☐	☐	• Exercise the jurisdiction's containment operational plan that delineates procedures for isolation and quarantine, the procedures and legal authorities for implementing and enforcing these containment measures (such as school closures, canceling public transportation, and other movement restrictions within, to, and from the jurisdiction) and the methods that will be used to support, service, and monitor those affected by these containment measures in healthcare facilities, other residential facilities, homes, community facilities, and other settings.
☐	☐	☐	• Ensure the jurisdiction has exercised the operational plan to implement various levels of movement restrictions within, to, and from the jurisdiction.
☐	☐	☐	• Inform citizens in advance about what containment procedures may be used in the community.

Public Health Communications [HHS Supplement 10. Preparedness Goal 4—Improve the timeliness and accuracy of communications regarding threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Assess readiness to meet communications needs in preparation for an influenza pandemic, including regular review, exercise, and update of communications plans.
☐	☐	☐	• Plan and coordinate emergency communication activities with private industry, education, and non-profit partners (e.g., local Red Cross chapters).
☐	☐	☐	• Identify and train lead subject-specific spokespersons.
☐	☐	☐	• Provide public health communications staff with training on risk communications for use during an influenza pandemic.
☐	☐	☐	• Develop and maintain up-to-date communications contacts of key stakeholders and exercise the plan to provide regular updates as the influenza pandemic unfolds.
☐	☐	☐	• Implement and maintain, as appropriate, community resources, such as hotlines and Web site, to respond to local questions from the public and professional groups.
☐	☐	☐	• Ensure the provision of redundant communication systems/channels that allow for the expedited transmission and receipt of information.

Workforce Support: Psychosocial Considerations and Information Needs [HHS Supplement 11. Preparedness Goal 6—Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.]

Completed	In Progress	Not Started	
☐	☐	☐	• Develop a continuity of operations plan for essential health department services, including contingency planning for increasing the public health workforce in response to absenteeism among health department staff and stakeholder groups that have key responsibilities under a community's response plan.
☐	☐	☐	• Ensure availability of psychosocial support services (including educational and training materials) for employees who participate in or provide support for the response to public health emergencies such as influenza pandemics.

continued

Completed	In Progress	Not Started	
☐	☐	☐	• Develop workforce resilience programs and ensure readiness to deploy to maximize responders' performance and personal resilience during a public health emergency.
☐	☐	☐	• Assure the development of public health messages has included the expertise of behavioral health experts (see Supplement 10).

JOHN M. CLERICI

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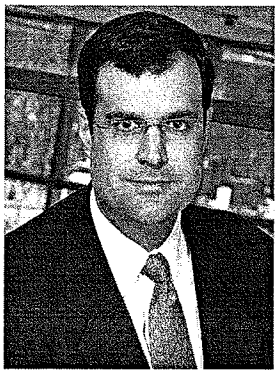
Attorneys at Law



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John Clerici is a Partner in the firm's government contracts practice and government affairs group. John's practice centers on working with new entrants to the government marketplace and existing government contractors to develop effective government affairs strategies for selling goods and services to the Federal, state and local governments. These strategies involve all aspects of government affairs, including providing targeted legislative and regulatory solutions, public relations strategies, and legal advice regarding appropriate contract vehicles and corporate structures to maximize business opportunities. In addition, John is a recognized expert on the topic of liability reform policy. John's practice focuses chiefly on Homeland Security, and in particular, the policy and legislative aspects of how the government procures anti-terrorism technology from the private sector.

John has extensive experience advising clients engaged in public/private partnerships with the Federal government, including representing one of the largest and most successful military housing privatization contractors in the nation. John has also represented a number of large pharmaceutical and biotechnology clients to impact significantly the legislation implementing Project BioShield, President Bush's initiative to promote and fund the development of biomedical countermeasures. He has negotiated several contracts for clients selling stockpiles of countermeasures to the Federal government, including several awards made under Project Bioshield.

PRACTICE AREAS

- Government Contracts
  - Biodefense
  - Canada-U.S. Practice
  - Commercial Products and Services
  - Homeland Security
- Public Policy and Regulatory Affairs
  - Government Affairs
    - Canada-U.S. Practice
    - Federal Government Affairs
    - International Government Affairs
    - Legislative Action
    - Public Policy and Crisis Management
  - Privatization

EDUCATION

- J.D., University of North Carolina School of Law, 1995
- B.A., The Catholic University of America, *summa cum laude*, 1992

BAR & COURT ADMISSIONS

- District of Columbia
- Georgia
- U.S. Court of Appeals for the Armed Forces

PROFESSIONAL AFFILIATIONS

- American Bar Association, Co-Chair, Legislative Coordinating Committee, Public Contract Law Section
- Member, U.S. Chamber of Commerce Homeland Security Task Force

John was instrumental in developing the legislative strategy and drafting key provisions of the SAFETY Act, a major component of the Homeland Security Act of 2002, and in developing the Act's implementing regulations. John has testified on behalf of the U.S. Chamber of Commerce before the U.S. House of Representatives on the SAFETY Act's implementation and has represented a number of entities that have successfully received SAFETY Act certification. In 2005, John played a substantial role in the drafting and passage of the Public Readiness and Emergency Preparedness Act (PREP Act), landmark legislation that provides substantial liability protections for makers and distributors of pandemic, epidemic, and bio-terrorism countermeasures. John testified as an expert in support of this legislation on four occasions before the United States Senate Appropriations Committee, HELP Committee, and Judiciary Committee. John's expertise in the area of biodefense has been recognized by leading news outlets such as the Wall Street Journal, Business Week, the Associated Press, the Boston Globe, and The Hill. He has also appeared live on the Fox News Channel as a bioterrorism expert.

John's political involvement spans more than a decade, having worked on campaigns for the United States Senate, House of Representatives, and state offices. In 2001, John was a candidate for the Virginia House of Delegates. John was elected as a member of the Virginia delegation to the 2004 Republican National Convention in New York City that re-nominated President George W. Bush.

Prior to joining the firm, John was a judge advocate with the U.S. Air Force where, among other assignments, he advised the Air Force Research Laboratory on the procurement of technology from research institutions throughout the United States, Europe and Asia. John has appeared as a military law analyst for the Fox News Channel and MSNBC before national audiences.

Articles

- "Meeting The Challenge Of Avian Flu – A Blueprint For Global Pandemics?" *Metropolitan Corporate Counsel*, July 2006 (Co-authored with Jennifer Hannesschlager)
- "From BioShield to the PREP Act and Beyond: Developing a Market for Infectious Disease and Bioterror Countermeasures," *Metropolitan Corporate Counsel*, March 2006 (Co-authored with Dana Perkins)
- "Congress Enacts Substantial Liability Protections for Public Health Emergencies," *Washington Legal Foundation Legal Opinion Letter*, February 10, 2006 (Co-authored with Doug Farry and Frank Rapoport)

ROSALIND RUBENS NEWELL

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Attorneys at Law



PRACTICE AREAS

- Public Finance
- Public Policy and Regulatory Affairs
- Government Affairs
- Economic Development

EDUCATION

- J.D., Emory University School of Law, 1986
- B.A., Emory University, 1981

BAR & COURT ADMISSIONS

- Georgia
- U.S. Supreme Court

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Rosalind Rubens Newell focuses her practice on governmental issues at the state and local level. She provides McKenna Long & Aldridge's clients with integral insight into affairs involving the exchange between government and private enterprise. Her proficiency in local government brings additional balance to the firm's governmental affairs team, which includes attorneys and advisors with a variety of backgrounds in legal and governmental/public policy issues.

Prior to joining McKenna Long & Aldridge, she practiced for almost 18 years in the City of Atlanta's Legal Department, most recently serving as Deputy City Attorney of the Commercial Transactions Practice Group. In this role, she was responsible for overseeing financial, land use, zoning and procurement matters, commercial transactions, public finance transactions and real estate. During her tenure, Ms. Newell also developed an expertise in Section 1983, Title VII and other constitutional law litigation. She also worked with the Mayor and City Council on a wide array of legal and policy matters.

From January 2002 - August 2002, Ms. Newell served as Interim City Attorney during Mayor Shirley Franklin's transition into office. She was also an Adjunct Professor in the School of Social Work at Clark Atlanta University from 1992 through 2002.

She earned a B.A. from Emory University in 1981 and a J.D. from Emory Law School in 1986. She became a member of the State Bar of Georgia in 1986 and is admitted to practice before all state and federal courts in Georgia, as well as the United States Supreme Court. She is a member of the American Bar Association, the Gate City Bar Association, the DeKalb Lawyers Association, the National Association of Bond Lawyers, and the Board of Trustees of the Carrie Steele-Pitts Home for Children in Atlanta. Ms. Newell has been a continuing legal education presenter for the ABA and ICLE in Georgia, and a continuing education presenter on law and ethics for social workers, professional counselors and licensed marriage and family therapists.

Community/Civic Involvement

American Bar Association Carrie Steele-Pitts Home for Children, Inc., Board of Trustees Caucus of Emory Black Alumni DeKalb Lawyers Association Gate City Bar Association Georgia Association of Black Women Attorneys National Association of Bond Lawyers