

## Protecting the Homeland: Fighting Pandemic Flu from the Front Lines

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Mr. Chairman, distinguished members of the committee, thank you for the opportunity to appear before you today to discuss the nation's preparedness to deal with a possible influenza pandemic.

My name is Tara O'Toole. I am the Director and CEO of the Center for Biosecurity of the University of Pittsburgh Medical Center and a professor of medicine at the University of Pittsburgh Medical School. The Center for Biosecurity is a non-profit, multidisciplinary organization which includes physicians, public health professionals and biological and social scientists located in Baltimore. The Center is dedicated to understanding the threat of large-scale lethal epidemics due to bioterrorism and to natural causes. My colleagues and I are committed to the development of policies and practices that would help prevent bioterrorist attacks or destabilizing natural epidemics, and, should prevention fail, to mitigating the destructive consequences of such events.

Last year, my colleagues and I had the privilege of participating in this committee's retreat at Wye River, where we held an interactive table-top based on Atlantic Storm, a ministerial exercise conducted in January 2005 which was designed to illuminate the kinds of issues that world leaders would confront in the wake of a bioterrorist attack using smallpox.

Over the past 18 months, the Center for Biosecurity has focused its attention on the threat of pandemic influenza and the capabilities needed to respond to such an event. I will focus my testimony on two aspects of pandemic response: containing the spread of influenza and the role of hospitals in pandemic preparedness and response. First, however, I will describe the current situation with respect to H5N1 and the potential impacts on hospitals were a flu pandemic to occur in the next year or two.

### **I. Background: The Likelihood and Implications of Pandemic Influenza**

#### **Current Situation**

The current situation in Asia and parts of Europe—namely, the infection of millions of wild, migratory birds and poultry with the H5N1 strain of influenza, and the infection of over 100 people—is unprecedented. H5N1 is an especially virulent type of flu against which no humans have immunity. More than half of all humans known to be infected have died. H5N1 is clearly endemic in wild birds, and cannot now be eradicated. Moreover, as the birds migrate to winter feeding grounds, they are spreading the virus into wild and domestic birds across Asia and into Europe. The World Health Organization (WHO) warned in 2005 that the evidence point towards the likelihood of an influenza pandemic, which could sicken one of four people on the planet, and kill millions.

Recently, bird flu has been found in domestic poultry in Turkey and in Kurdish Iraq. Peregrine falcons in Saudi Arabia have also been infected. Infection with avian flu continues in domestic flocks across wide expanses of Indonesia, and Southeast Asia. To date, 165 human cases of bird flu have been confirmed, with 88 deaths, although no human-to-human transmission has yet been observed.

### **Potential Impacts**

The WHO estimates that once the next human pandemic begins, it will be found on all continents (but not necessarily in every country) within three months and will spread across the world within 12 months. Recurrent outbreaks would be expected over subsequent winter and spring seasons. The specific pattern of spread is impossible to predict and will depend on the properties of the pandemic strain (how lethal, how contagious, how closely it could move around the planet).

The Congressional Budget Office (CBO) has estimated that in a 1918 scale pandemic, about 90 million people would become sick and 2 million would die in the US alone [Congressional Budget Office, “A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues”, Dec. 8, 2005]. The CBO estimates that a pandemic of this scale would lower real GDP by about 5% compared to the level it would have reached had there not been a pandemic. The CBO notes that “Improving the capacity of the health care system to care for many people in all parts of the country who are sick at the same time stands out as a priority . . .” [CBO, page 2].

There is no scientific way to predict whether an influenza pandemic will occur this year or next or several years from now or how severe it will be. That there will be an influenza pandemic in this century is certain; flu pandemics have occurred throughout history, about three times each century. The “good news” is that there is much that can be done to mitigate the death, suffering and economic and social disruption caused by epidemics -- if preparations are made in advance. Of course the preparations that could be put in place were a pandemic to occur in the next few months would differ considerably in scale and scope from what could be accomplished if we had 18 months or years to get ready. My colleagues and I are deeply concerned that the current pace and intensity of pandemic preparedness activities, including the search for effective vaccines, are still very inadequate given the possible consequences of this threat.

### **Importance of Vaccine**

Having adequate amounts of an effective vaccine changes everything. Global supplies of a pandemic vaccine and the ability to distribute it could transform these grim scenarios decisively. Today, there are more than 20 projects to develop a vaccine against H5 type influenza viruses underway, pursued by private sector biopharma companies and the NIH but results to date have been disappointing. The recent Congressional appropriation for flu vaccine research and development is welcome and necessary, but still falls far short of what is warranted by the nature of this threat. The scientific basis of the effort is sound, but there is, as yet, no national strategy to pool America’s prodigious scientific and pharmaceutical industry capacity in the context of an overall strategic plan. I realize this issue is beyond the usual scope of this committee, but the matter is of such overriding importance that all of Congress should be aware of the situation.

## **II. Caring for the Sick During a Flu Pandemic or Mass Casualty Bioattack**

### **U.S. Health Sector is Unprepared to Meet Surging Pandemic Health Care Needs**

In the event of a 1918-scale flu pandemic, most Americans would be unable to access the health care sector because demand will exceed supply by large factors that cannot be bridged by incremental, marginal increases in health care capacity.

Hospitals would be flooded with desperately ill people seeking care. Most hospitals routinely operate at or near full capacity however, and have limited ability to rapidly increase services. During an epidemic, the health care workforce would be greatly reduced. Health care workers would face a high risk of infection because of contact with infected patients; many would need to stay home to care for sick relatives, and in the absence of vaccine, others might fear coming to work lest

they bring a lethal infection home to their families. The provision of critical, non-flu medical services would be adversely impacted in most communities.

In addition, because hospitals have adopted just-in-time supply chains, there would be an almost immediate shortage of critical supplies such as ventilators, masks and gowns, antibiotics, etc. The shortages of supplies and staff would likely worsen over time as critical components of supply chains are lost due to attrition and absenteeism in the US and overseas. (During the 2003 SARS outbreak, a single Ontario teaching hospital used 18,000 N95 masks per day).

All three TOPOFF exercises convincingly demonstrated that hospitals are among the most fragile components of mass casualty response. Hospitals have little money of their own to spend on stockpiling supplies or planning for catastrophes. The US health care delivery sector is financially pressured, and highly competitive. One third of US hospitals do not meet operating costs; among non-profit hospitals which are in the black, operating margins average only 3%. In a pandemic, hospitals would be forced to close clinics, cancel surgery and defer most money making services to care for the volume of flu victims. Many hospitals may be forced to close down due to lack of staff and/or lack of revenue.

Hospitals do not have the funds to pay for pandemic preparedness planning or to purchase stockpiles of equipment or train staff. Federal funds for hospital preparedness began only in FY 2002 and have remained at low levels. The federal appropriation for FY 2006 was only enough to cover the salary of a single nurse at each of the country's approximately 5000 hospitals for one year.

Within the medical community, there are widespread expectations that the military would quickly provide significant resources (personnel, mobile hospitals, equipment) during a mass casualty event. The military maintains that its medical resources are limited and that force support needs would be the priority.

### **CDC Flu Surge Projections: Pandemic Demands Would Overwhelm Most Hospitals**

It is important to have a clear picture of the health care pressures that would accompany pandemic flu. CDC has created "Flu Surge", a software program that allows one to project the patient demands that would be levied on hospitals of different types and sizes if the pandemic attack rates and severity of illness mimicked those of 1918.

For example, in a 1918 type pandemic, the Atlanta metro region would require: 300% of its current (pre-epidemic) hospital bed capacity to care for flu patients (and the necessary clinical staff to care for this increase in patients); 700% of Atlanta's pre-epidemic Intensive Care Unit capacity; and nearly four times as many ventilators as are usually available to care just for the flu patients. These demands do not take into account the resources that would be required to meet normal ongoing critical medical needs (care of heart attack victims, etc.).

### **III. The U.S. Lacks a National Strategy for Providing Healthcare Surge Capacity in Mass Casualty Emergencies**

The NDMS, DMAT teams and uniformed public health service would be of little practical use in such an emergency. These organizations lack the necessary operational scale and skill sets and will be needed in their home communities. In a large-scale flu pandemic or bioterror attack, the National Disaster Medical System (NDMS) and the Disaster Medical Response Teams (DMATs) would be of little practical use. An analysis of the Department of Homeland Security's readiness to respond to national medical emergencies commissioned by former Secretary Ridge (January 2005) stated:

"A National healthcare system-wide strategy for providing surge capacity does not exist. Numerous Federal programs (e.g. NDMS, Commissioned Corp Readiness Force, and the Medical Reserve Corps program) exist to enhance surge ca-

capacity, but they are fragmented and not incorporated into the national response effort.” [Lowell, J. “Medical Readiness Responsibilities and Capabilities: A Strategy for Realigning and Strengthening the Federal Medical Response”, Jan. 3, 2005; accessed at <http://wid.ap.org/documents/dhsmedical.pdf>, 2/3/06.]

NDMS was designed to identify empty hospital beds beyond the area affected by an emergency to which casualties could be sent. However, in a pandemic, all areas of the country would be affected more or less simultaneously, or to fear that they will be hit next. Moreover, the crucial need is not for hospital beds, but for medical staff. The central premise of NDMS—that empty hospital beds imply the capacity to care for patients—is outdated. Similarly, the deployment of Disaster Medical Support Teams (DMATs), which consist of volunteers from around the country, would be impractical in contexts in which team members are needed in their home communities.

Following 9/11, the Medical Reserve Corp (MRC) was founded. This component of the Citizen Corps is located within the office of the Surgeon General in HHS. Still considered a pilot program, the MRC currently has 55,000 volunteers in 330 local MRC units who are intended to supplement local medical resources in times of need. MRCs have no uniform structure and volunteers are not necessarily medical professionals.

The U.S. healthcare sector is highly fragmented, competitive and largely private. In most locales, there is no “Organizing Authority” with the capacity to establish a regional pandemic plan that would obligate hospitals to collaborate in a manner designed to optimize health care delivery during a pandemic. Aside from a handful of cities such as New York, Minneapolis and Seattle, there are no well defined or practiced plans for mobilizing hospitals, HMOs and other sources of patient care during a mass casualty emergency. Public health agencies typically have not taken on this task, nor do most public health agencies have the personnel, funds or legal power to direct, manage or coordinate hospitals in crises.

The ability to identify and contact health care professionals and support staff is essential to hospitals’ capability to respond to emergencies. There is an urgent need to create regional data bases of health care workers that would allow rapid identification of and contact with professionals with certain credentials and skill sets. Further, provisions to credential clinicians at multiple hospitals in a region (ahead of an emergency), and to ensure that professionals and the institutions in which they work have adequate liability protection are essential. Some states have established Mutual Aid pacts or other provisions with neighboring jurisdictions to address such concerns. Yet few regions have successfully built the data bases needed, or solved all the legal problems necessary to ensure that qualified health care professionals can practice across state and institutional lines in times of emergency.

Collaboration among hospitals and other patient care institutions will require near-real time “situational awareness”. Yet most hospitals do not have electronic connections with other hospitals in their region or links to their local or state public health agencies. This will make it difficult for decision-makers to understand which hospitals are able to receive patients, where vital equipment is located or needed, what supplies are running low or where the public should be told to take those who are desperately ill.

The Federal government has failed to propose a coherent strategy for pandemic hospital response; has failed to adequately fund even minimal hospital preparedness activities. Responsibility and accountability for hospital preparedness within DHS and HHS are diffuse, confused and grossly under funded and understaffed. The HHS Pandemic Flu Plan contains a lengthy list of items associated with hospital preparedness. However, the FY06 appropriation for pandemic preparedness contains no funds for hospitals. Accordingly, it would not be possible for any hospital to implement everything suggested by the HHS list, partly because of cost and partly because individual hospitals lack the authority to accomplish much of what is recommended.

It is unclear who in the federal government—or indeed which agency—is in charge of medical response in a mass casualty emergency. The HHS missions and skill base more closely match the need than do the assets currently found in DHS. The

National Disaster Medical System (NDMS), transferred to DHS upon its creation, had its management personnel reduced from 144 to 57, leaving the NDMS without a staff physician, medical planner or logistician [Lowell, *ibid.* p. 6].

## IV. Containing the Spread of Disease During a Flu Pandemic

### Not All Interventions to Prevent Disease Spread Are Worth the Costs.

Most disease containment interventions are logistically difficult to implement, of imperfect or uncertain effectiveness, and may have significant adverse economic and social consequences. It is important that decision-makers understand the “return on investment” of various interventions. When considering possible interventions to stop or slow the spread of influenza—or of any contagious disease—it is important to consider both the possible benefits of the intervention as well as the costs. The interventions that are likely to produce a reasonable “return on investment” are likely to differ, depending on the specific disease and the context. It is critical that elected officials understand how flu spreads and carefully consider the trade-offs involved in various disease containment measures. Some public health interventions will cause more harm than good.

Influenza is a highly contagious disease. In normal flu seasons, each infected victim passes the infection to at least two others. What makes flu so contagious however is the speed at which people are infected. One becomes contagious within 24 to 72 hours after being infected. Thus, flu can spread from one person to the next before symptoms occur. In normal flu seasons as many as half the cases may never show any symptoms but can still be contagious. Infectious but asymptomatic pandemic flu patients can be expected as well.

This means that screening interventions—for example, screening airline passengers for fever or for cough and other symptoms—will not be effective. This was apparent during the SARS outbreak of 2003. Both Canadian and Chinese authorities, in careful studies, concluded that such screening was of no value although requiring a great deal of time, effort and cost.

### Possible Interventions to Control the Spread of a Contagious Disease:

- **Vaccine:** Having sufficient supplies of an effective pandemic flu vaccine changes everything. An effective vaccine is by far the single most important component of pandemic preparedness. If available in time and in sufficient quantities vaccine would make a decisive difference.
- **Therapies which can be used in treatment:** Tamiflu is proposed for use although little information is yet available regarding its actual effectiveness. Given within 36 hours after symptoms begin, it would be expected to reduce growth of the virus and perhaps reduce the likelihood of a fatal outcome. However, virus resistance to this drug is expected and supplies of the drug are limited.
- **Therapies which may prevent spread:** Tamiflu decreases the amount (“load”) of virus in the patient’s throat and hence may prevent disease and, as well, diminish the likelihood of transmission. Prevention with this drug, however, would require daily administration of the drug throughout the course of an epidemic. The quantities of drug required and the cost, let alone complications of the drug itself, recommend against its general use.
- **Isolation of sick individuals:** This is an essential component of all influenza containment strategies. Especially in health care settings, isolation of infected patients is critically important to limiting disease spread. However, health care workers are at special risk of infection and thus appropriate isolation of infected patients and use of “barrier controls” (gowns, face masks, gloves) and hand-washing are essential. It would also be highly desirable to isolate individuals who are sick with flu but not so desperately ill that they need to be hospitalized. It is likely that many sick people will remain at home, though some communities are making provisions to equip sports arenas and other large spaces with beds to accommodate those who cannot be cared for at home. To the extent possible, patients should be encouraged to stay at home from the first signs of illness and to stay out of close contact with others until they are no longer contagious.



**The resources needed to enforce compulsory isolation or quarantine are enormous and the likelihood of failure is high. Cooperative rather than compulsory measures are to be preferred.** There are significant challenges associated with isolation of infected persons, whether they are restricted to their homes or isolated in some central facility. Arrangements must be made to provide people with food and medical services (including medicines for chronic illnesses). A recent Harvard survey found that people are more likely to voluntarily comply with isolation if they can remain in communication with other family members.

- **Quarantine:** Historically, quarantine referred to sequestration of large groups of people who are without symptoms—some of whom may have been infected with a disease, some not—until it was certain that all who might have been infected were past the point of being able to spread the illness. Large scale quarantine requires vast resources, most likely including the use of force. Experience shows that it has seldom proved to be effective and, in some cases, has led to suppression of reports of disease and of persons fleeing or escaping the restricted area. Rarely does it succeed in limiting spread of the disease.
- **Social Distancing:** This involves voluntary avoidance of close contact (3-6 feet) with others. Social distancing could include cancellation of schools or large public gatherings such as sports events or business conventions. It could also include asking employees to work from home, urging people to avoid coming within 3 feet of others, forgoing handshakes and other forms of direct contact.
- **Use of Personal Protective Equipment, such as Masks, Respirators, Gowns, Gloves:** These are of value for use of health care personnel in preventing their acquisition of infection. Masks are of uncertain value for public use.

## **V. Possible Congressional Actions to Improve U.S. Hospitals**

### **Response During a Pandemic or Mass Casualty Situation**

- The Secretary of HHS is the nation's leader on pandemic preparedness and Secretary Leavitt's commitment to this issue is evident and commendable. Given the breadth and urgency of pandemic preparedness activities, however, it seems essential that someone be appointed who can be fully devoted to overseeing flu preparedness strategy across all agencies. The federal government must clearly identify someone who is knowledgeable and has both authority and resources to assume direction of pandemic preparedness programs and to enlist appropriately trained staff to address the array of problems posed by a potentially catastrophic pandemic. Of special importance are the problems posed by the need to provide medical care to an unprecedented number of victims.
- In spite of the often heroic efforts of individual, highly expert federal employees, the federal agencies do not now include the full range and depth of talent and experience required to develop and implement a pandemic flu plan or a strategic defense against bioterrorist attacks. There is a pressing need to immediately acquire a staff of 50-100, including senior professionals and executives, who could assist in establishing pandemic response policies and programs.
- There should be a federal/state task force charged with designing a plan to deliver medical care during a pandemic or mass casualty event. This group should focus on options for dealing with surges in medical demand comparable to those predicted by Flu Surge models for a 1918 type pandemic. Every effort should be made to work directly with the hospital community as well as with governors and mayors to address these urgent problems. HHS should be directed to work with hospital and health care leaders as well as local officials on the state and local level and members of Congress to devise "organizing authorities" that could effectively coordinate medical services during mass casualty emergencies. Funds to institute such authorities should be appropriated
- HHS should distinguish which specific pandemic preparedness are the responsibility of individual hospitals, and for what functions states or the federal government are accountable and create mechanisms to fund and oversee these functions.

- The Congress should appropriate sufficient funds, on an ongoing basis, to allow hospitals to execute specific, clearly identified and measurable preparedness activities. It should charge HHS with responsibility for designing processes, possibly in collaboration with the Joint Commission on Accreditation of Health Care Organizations, for ensuring that these activities are implemented and adequate.
- It would be highly useful for the Administration and the Congress to orchestrate a public “call to service” to the medical care community, to clearly communicate the gravity of the threat of mass casualty events and the need for immediate action on the part of hospitals, health care organizations and providers.
- Federal financing to spur the development of hospital electronic medical records should be considered a national security priority. Federal funds should be contingent on hospitals linking health information systems to other hospitals in their region and to public health authorities.
- Congress should immediately consider the possibility of a large-scale pandemic and hold public hearings on the need to enforce “eminent domain” type authorities over health care assets should such a crisis arise as well as mechanisms to ensure that people who lack health insurance are not denied care or shunted to public or not-for-profit hospitals.
- Congress should establish legal provisions to ensure that hospitals who must forgo routine revenue flows to care for mass casualty victims will remain financially viable throughout the crisis.
- The single most important preparation in coping with a pandemic is education of the public. It will be critical that people understand what they can do to protect themselves and others during a pandemic. In particular, members of the public need to clearly understand that in a pandemic many people will find it difficult to access the health care system and should not expect to visit their doctors unless absolutely necessary.
- The Congress—and elected officials—should be educated on the basic facts about flu and participate in a nation-wide education campaign to prepare the public for a potential epidemic. In particular, leaders should acquaint themselves with the potential advantages and downsides of various interventions intended to contain the spread of flu and be prepared to explain why certain measures are necessary or unfounded. There will be great temptation to “do something” in the emergency. The probable benefits and longer term costs of such measures should be clearly articulated to the public and the cost-benefit of instituted measures should be carefully monitored.
- Employers should be encouraged and incentivized to plan for a major pandemic and in particular to prepare to enable employees to work from home and to avoid the workplace if they are ill. People should be encouraged to prepare to voluntarily remain at home—get themselves out of circulation—at the first sign of flu like symptoms or if they know they were in close contact with someone with flu.