The Lipman Report®

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**Exclusively for Management**

**November 15, 2005**

# Pandemic Influenza

## The time for urgency is now

*From November 7-9, policy makers, animal and human health experts, and industry representatives gathered in Geneva, Switzerland to work toward a global consensus to control the avian influenza virus (H5N1) in domestic animals and to prepare for a potential human influenza pandemic. The meeting, organized by the World Health Organization (WHO), the Food and Agriculture Organisation (FAO), the World Organisation for Animal Health (OIE) and the World Bank, is the culmination of a series of meetings held during the prior ten weeks to develop a plan to deal with a potential human pandemic.*

*With avian flu spreading rapidly among migratory birds and domestic poultry, experts believe it is only a matter of time before the H5N1 strain of avian flu acquires the ability to be transmitted from human to human sparking the outbreak of a human influenza pandemic. Estimates of the number of individuals who would die in a new pandemic have varied widely, but the WHO reports that a reasonable estimate would be 7.4 million worldwide and the Centers for Disease Control and Prevention reports that a "medium level epidemic" could result in the deaths of up to 207,000 Americans.*

*Despite the ominous signs, there is still a window of opportunity to substantially reduce the risk of a human pandemic evolving from H5N1by containing the virus in its animal source and limiting its spread. Nations need to develop and test national plans, and the global community needs to strengthen disease surveillance systems to rapidly detect and respond to avian flu threats. At the same time, longer-term efforts need to continue to develop antiviral medications and potential vaccines. With sustained focus and international cooperation, the effects of a potential pandemic can be mitigated. If ignored, the consequences could be catastrophic.*

### Recent developments

Currently, the number of confirmed human cases of H5N1 avian influenza is 125 with 64 cases resulting in fatality. All of the cases to date have occurred in Southeast Asia, but, recently, H5N1 has been identified in poultry and migratory birds in Russia, Kazakhstan, Mongolia, Turkey, Romania and Croatia. The spread of avian flu among birds, according to experts, gives the virus more opportunities to develop into a strain that can be transmitted from human to human.

Other troubling signs are present, but so far, fear of the disease has outpaced its physical effects, particularly in developed nations outside of Asia.

In Greece, recently, health authorities disinfected a farm on an isolated Aegean Sea island after bird flu was found in a lone turkey there. In China, the government has begun quarantine measures in a grasslands area of the country's north after the death of 2,600 birds was blamed on avian flu. China's Premier warned that the country faces a serious threat from avian flu, since the disease is still not under control despite massive nationwide efforts to stop the spread.

As the disease spreads among birds, health experts and leaders have begun to state that it is only a matter of time before an avian flu virus acquires the ability to be transmitted from human to human. In the face of this threat, it is imperative that plans are developed and precautions are taken to slow or halt the spread of a potential pandemic.

### The President's plan

On November 1, 2005, President George W. Bush outlined a proposed national strategy to deal with the potential danger of a pandemic influenza. The President requested $7.1 billion to fund his proposal, and his strategy is designed to meet three goals: Detecting human or animal outbreaks that occur anywhere in the world; protecting the American people by stockpiling vaccines and antiviral drugs while improving the capacity to produce new vaccines; and preparing to respond at the Federal, state, and local levels in the event of a pandemic.

### Detecting outbreaks

Detecting cases of H5N1 avian flu early is the first line of defense in limiting the spread of the virus. As part of this effort, President Bush announced the creation of the International Partnership on Avian and

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# Biological and Chemical Weapons

## Harbingers of a Perilous Future

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Pandemic Influenza at the United Nations General Assembly on September 14, 2005. Currently 88 countries and nine international organizations have joined the partnership and endorsed a set of principles focused on enhancing preparedness, prevention, response and containment activities.

Domestically, the administration is launching the National Bio-Surveillance Initiative to help rapidly detect, quantify and respond to outbreaks of disease and deliver information quickly to local, state, national and international public health officials. In addition to the funding request, the President also announced the creation of a government website, *www.PandemicFlu.gov,* to provide a resource to inform Americans of the latest government preparations and to provide information for how individuals can reduce their own risk.

### Vaccines and Antiviral Drugs

Researchers at the National Institutes of Health (NIH) have developed a vaccine based on the current strain of avian flu. The vaccine is currently in clinical trials and the Administration is planning to stockpile enough doses to vaccinate 20 million people. The vaccine, while not a perfect match may offer some protection and save lives during the first months of an outbreak.

Antiviral drugs like Tamiflu® do not prevent people from contracting the flu, but they can reduce the severity of the illness when taken within 48 hours of getting sick. The approximately $1 billion the President is asking for would be to stockpile enough antiviral medications to treat the nation's first responders and populations most at risk during the first stages of a pandemic.

The NIH is also working with manufacturers to develop new cell-culture techniques that will bring a pandemic flu vaccine to the public faster in the event of an outbreak. Ideally, new technology would allow manufacturers to create capacity to produce enough vaccines for every American within six months of the start of a pandemic.

### Community response

State and local health officials must have emergency plans in place to deal with a potential outbreak. The Administration is working with public health officials and the medical community to develop effective pandemic emergency plans and is requesting funds so that states can complete and rehearse these plans before a pandemic strikes.

The federal government is also stockpiling critical medical equipment that will be in short supply in a pandemic.The Department of Health and Human Services is helping states to create rosters of medical personnel ready to respond, and every federal department involved in healthcare is ensuring their capabilities are ready to support local communities.

### Short term danger

While the planning of the WHO and the United States is encouraging, H5N1 avian flu still poses severe risks and challenges in the coming months, if not years. Although antiviral drugs can confer some measure of protection pending the availability of vaccines, these drugs should not perform the same public health function as vaccines. The mass administration of antiviral drugs to large numbers of healthy people for extended periods is not recommended, as this could accelerate the development of drug resistance.

Recently, the Swiss drugmaker Roche Holding AG announced that it would increase production of Tamiflu® to make 300 million treatments of the drug annually by 2007 to meet government orders from around the world. Roche has also been under pressure to ease its control of the manufacture of the drug and also said that it has begun negotiations with eight companies and a number of governments to expand worldwide supply.

Tamiflu®, though, has limits and cannot be looked

to as a panacea. According to Laurie Garrett, Senior Fellow for Global Health at the Council on Foreign Relations, "Tamiflu® can suppress H5N1 at the beginning of an infection, but it isn't a cure. It has also not been approved for prophylactic use in children. It must be taken at the right time or it's ineffective. And in some adults, it may only partly suppress the virus, leaving them ambulatory carriers of infection. On top of that, the latest scientific studies indicate that some H5N1 viruses may already be resistant to the drug."

Additionally, in Southeast Asia, where health officials say a human flu pandemic would most likely begin, national stockpiles of Tamiflu® are limited. The success of any strategy relying on antiviral drugs would also rely on several assumptions about the early behavior of a pandemic virus that cannot be known in advance. Success will also depend on excellent surveillance and logistics capacity in the initially affected areas.

Vaccines may offer hope for the long term but in the next few months are unlikely to provide relief in the face of a pandemic. A pandemic vaccine needs to be a close match to the actual virus, and commercial production cannot begin prior to emergence and characterization of the pandemic virus. As a result, at the beginning of a pandemic, and for many months after, no country will have adequate supplies of vaccine because large scale commercial production could not commence until approximately three to six months following the emergence of a pandemic virus.

Manufacturing capacity for influenza vaccines is overwhelmingly concentrated in Europe and North America and current production capacity is estimated at approximately 300 million doses per year – well below the demand that will arise during a pandemic. If a pandemic were to begin within the next few months, no company would be ready to move immediately into commercial production.

Further, according to Laurie Garrett, even with additional production capacity making a vaccine available to Europe, North America, Japan and other wealthy countries, individuals in developing countries would still go unvaccinated. Infection rates in those countries could reach between 30 and 50 percent. The WHO states that, based on current trends, most developing countries will have no access to a vaccine during the first wave of a pandemic and perhaps throughout its duration.

**Consequences of a pandemic**

The human and economic impact of a pandemic could be catastrophic. The World Bank estimates that a two percent drop in global GDP during an influenza pandemic – such as that caused by SARS in East Asia during the second quarter of 2003 – would represent a loss of about $200 billion in output in one quarter or $800 billion over a year. The CDC estimates that direct medical costs alone in the United States could top $166 billion, not including costs of vaccination.

The human toll could be devastating as well. The WHO predicts that an H5N1 flu pandemic would affect about 25 percent of countries' populations. Given that H5N1 has had an unusually high fatality rate among humans so far (approximately half of the infected have died) the prospects for a pandemic are grim.

**Results of the global meeting**

More than 600 delegates from over 100 countries concluded a global meeting on pandemic influenza in Geneva, Switzerland on November 9, 2005 and agreed that there is an urgent need for financial and other resources for countries which have already been affected by avian influenza, as well as for those which are most at risk, and to identify and respond to a human pandemic the moment it emerges.

Experts and officials at the meeting set out key steps that must be taken in response to the threat of the H5N1 influenza virus that is currently cir-

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culating in animals in Asia and had been identified in parts of Europe. They recommended that the following actions be taken to combat this threat.

**The H5N1 virus must be controlled at its source in birds.** Veterinary services must be improved, emergency preparedness plans and control campaigns, including culling, vaccination and compensation must be implemented. Funding and assistance must be provided to countries to control avian influenza in animal populations.

**Global surveillance, early detection and rapid response systems for animal and human influenza must be strengthened by building and improving laboratory capacity.** Hospitals in affected countries need support in case detection and laboratory confirmation.

An infrastructure needs to be developed to complement national testing with rapid international verification in WHO certified laboratories, especially as each confirmed human case yields information essential to surveillance and risk assessment.

**Rapid containment plans need to be in place for when animal and human cases are discovered.** International stockpiles of antiviral drugs need to be built and there needs to be a mass delivery mechanism for antiviral drugs. Mechanisms for using an international stockpile need to be defined precisely in terms of triggers for deploying the stockpile and time frames for emergency delivery and administration.

Many characteristics of a pandemic that will guide the selection of response measures will become apparent only after the new virus has emerged and begun to cause large numbers of cases. Because of this, real-time monitoring of the outbreak is essential. This monitoring will give health officials answers to key questions about age groups at greatest risk, severity of the disease, risk to health care workers and mortality rates.

**National, state and local health organizations must have plans that are developed and integrated to provide the basis for coordinated and technical support, and communication systems are vital.** There must be rapid, factual and transparent communication to support all of the efforts to control and minimize a potential pandemic. As soon as a pandemic is declared, health authorities will need to start a continuous process of risk communication to the public. A communication strategy for a pandemic should include training in outbreak communication and the integration of communicators in senior management teams.

Once a pandemic has begun, political leaders will be under great pressure to protect their citizens. Countries with planned and rehearsed pandemic response plans will be in the best position to act quickly.

*In his conclusion to the historic global meeting on pandemic influenza, Dr. LEE Jong-wook, Director-General of the World Health Organization said "The world recognizes that this is a major public health challenge. WHO is ready to focus its resources to reduce the risk of a human pandemic. We have plans on paper, but we must now test them. Once a pandemic virus appears, it will be too late."*

*As Hurricane Katrina demonstrated, even when disasters come with warning they can create chaos and unanticipated consequences. Pandemic influenza has the potential to create that chaos not in one particular region but globally. Nations, non-governmental organizations, businesses and individuals must work together to plan, and to test those plans, so that the worst-case scenario does not happen.*

**The Lipman Report Editors**



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