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U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress

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Summary

There are many strains of avian influenza virus infecting poultry. Influenza A/H5N1 is a strain of influenza currently spreading throughout the world. Although it is a bird flu, it has infected a relatively small number of people and killed more than half of those infected. Some scientists are concerned that H5N1 may cause the next influenza pandemic. Since 1997, when the first human contracted H5N1 in Hong Kong, the virus has resurfaced and spread to nearly 50 countries in Asia, Europe, the Middle East, and Africa — infecting more than 200 people. In February 2006, the virus spread from Asia and central Europe to western Europe. By March 2006, health experts had confirmed new bird flu cases among more than 20 countries across Europe, Asia, and Africa. Most of the countries were experiencing their first H5N1 cases. The first human H5N1 fatalities outside of Asia occurred in 2006 when Turkey and Iraq announced their first human deaths related to H5N1 infection in January and February, followed by Azerbaijan and Egypt in March.

P.L.109-13, FY2005 emergency supplemental appropriations directed \$25 million to USAID for global avian flu efforts. The act also permitted the Secretary of State to transfer up to \$656 million for U.S. avian flu initiatives. Ultimately, \$6.3 million was transferred to USAID for those purposes, which enabled the United States to use \$31.3 million of FY2005 emergency appropriations on global avian flu activities. Emergency funds were directed to global avian flu efforts in FY2006 Defense Department appropriations, which provided \$3.8 billion for all U.S. avian flu initiatives. Although Congress did not specify a total amount that should be spent on all global initiatives, the U.S. State Department, responsible for coordinating the international response to avian flu, estimates that some \$280 million of the \$3.8 billion is being directed to global avian flu initiatives. U.S. agencies and departments have also used FY2005 and FY2006 non-emergency appropriations to fund global avian flu and pandemic preparedness efforts. The Senate version of H.R. 4939, FY2006 Emergency Supplemental Appropriations, provides \$3.2 billion to avian flu efforts. The House version does not include similar language. Relevant FY2007 U.S. department and agency justifications include some \$205 million for global H5N1 initiatives. As in previous fiscal years, additional resources might be directed to global avian flu efforts through complementary programs not categorized as avian flu, such as infectious disease programs and international influenza research.

This report provides an up-to-date account of global H5N1-related human infections and deaths, outlines U.S. government global avian flu programs, and presents some foreign policy issues for Congress. This report will be updated. For information on U.S. domestic preparedness efforts, agricultural issues, and anti-avian flu efforts of overseas governments, please see CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister; CRS Report RS21747, *Avian Influenza: Agricultural Issues*, by Jim Monke; and CRS Report RL33349, *International Efforts to Control the Spread of the Avian Influenza (H5N1) Virus: Affected Countries' Responses*, coordinated by Emma Chanlett-Avery.

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U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress

Background

There are many strains of avian influenza virus that can cause varying amounts of clinical illness in poultry. Bird (or avian) flu outbreaks have occurred at various times around the world.¹ Influenza A/H5N1 is a strain of bird flu currently spreading across the world. Although it is a bird flu, the virus has infected some people and killed more than half of those infected. Until 1997, there were no known human H5N1 cases. That year, 18 people in Hong Kong contracted the virus; of whom 6 died. To contain the virus, 1.5 million birds were killed. Since 2003, scientists have closely monitored resurgent H5N1 outbreaks, which have infected poultry in a growing number of countries.

According to the World Health Organization (WHO), the hallmarks of a pandemic are: 1) the emergence of a novel flu virus strain; 2) the strain causes human disease; and 3) person-to-person transmission is sustained. The pandemic steps usually occur in six phases. **Table 2** shows the phases of a flu pandemic, as described by WHO. The current global H5N1 outbreak is in pandemic alert phase three, which means a virus new to humans is causing infections, but not spreading easily from one person to another.

Humans have no immunity against H5N1 since it is a bird flu and has not commonly infected people. Some predict that if H5N1 were to become transmissible among humans, an “influenza pandemic” (worldwide disease outbreak) could begin. Skeptics argue that such predictions are exaggerated, because if the virus were able to transform into a strain that is efficiently transmissible among people it would have already done so. Still some health experts stress that governments should prepare for some sort of pandemic. During the Spanish flu pandemic of 1918, it is estimated that between 20 and 50 million people died, and between 200 million and 1 billion were infected around the world. If a flu pandemic were to occur on the same scale as the

¹ For a list of past avian flu outbreaks see CRS Report RS21747, *Avian Influenza: Agricultural Issues*, by Jim Monke.

Spanish flu, some estimate that between 30 million and 384 million people could die around the world,² of which 1.9 million deaths could occur in the United States.³

Global Prevalence

Since 1997, when the first human contracted H5N1 in Hong Kong, the virus has resurfaced and spread to birds in nearly 50 countries.⁴ **Figure 1** in the Appendix maps H5N1 cases among animals and people. In 2004, nine Asian countries reported H5N1 poultry outbreaks. By August 2005, birds in Mongolia had become infected with the virus. Two months later, birds in Russia and Kazakhstan had contracted H5N1 reportedly through contact with wild birds at shared water sources. By late October 2005, H5N1 had spread westward, affecting six other regions in Russia and infecting birds in Romania, Croatia, and Turkey. In 2006, countries in western Europe, the Middle East, and Africa reported H5N1 infection among their poultry stocks. Also, Azerbaijan, Egypt, Iraq, and Turkey reported the first H5N1 human cases outside of Asia. Although Iraq has reported human H5N1 cases, no birds have been diagnosed with the virus. **Table 1** below shows the number of confirmed human H5N1 cases as reported by WHO as of April 27, 2006.⁵

² Osterholm, Michael, "Pandemic Influenza: A Harbinger of Things to Come." Presentation at the Woodrow Wilson International Center for Scholars, Sept. 19, 2005. [http://www.wilsoncenter.org/index.cfm?fuseaction=news.item&news_id=145329]

³ HHS Pandemic Influenza Plan. [<http://www.hhs.gov/pandemicflu/plan/>].

⁴ The World Organization for Animal Health (OIE) has confirmed H5N1 among birds in the following countries: Afghanistan, Albania, Austria, Azerbaijan, Bosnia and Herzegovina, Britain, Bulgaria, Burkina Faso, Burma, Cambodia, Cameroon, China, Croatia, Czech Republic, Denmark, Egypt, France, Georgia, Germany, Greece, Hungary, India, Indonesia, Iran, Israel, Italy, Japan, Jordan, Kazakhstan, Korea, Malaysia, Mongolia, Niger, Nigeria, Palestinian Autonomous Territories, Pakistan, Poland, Romania, Russia, Serbia and Montenegro, Slovakia, Slovenia, Sweden, Switzerland, Thailand, Turkey, Ukraine, and Vietnam.

⁵ WHO, *Cumulative Number of Confirmed Human Cases of Avian Influenza A/H5N1*, April 27, 2006. [http://www.who.int/csr/disease/avian_influenza/country/en/].

Table 1. Human Cases of Avian Influenza A/H5N1

COUNTRY	HUMAN CASES	DEATHS
Azerbaijan	8	5
Cambodia	6	6
China	18	12
Egypt	12	4
Indonesia	32	24
Iraq	2	2
Thailand	22	14
Turkey	12	4
Vietnam	93	42
Total	205	113

Source: WHO: Cumulative Number of Confirmed Human Cases of Avian Influenza A/H5N1.

Transmission Among Birds

There is some debate over how H5N1 is spread. Some experts contend that migratory virus-carrying wild bird species, notably water fowl, are a key H5N1 vector, or medium of transmission. H5N1 has been detected in migratory birds in multiple countries, and in some instances, its spread has been temporally correlated with seasonal migrations of certain wild species. In some countries, wild birds comprise the sole known H5N1-positive animal population. Some wild species may also be passive carriers of H5N1, harboring but not exhibiting disease symptoms or ill effects from the virus.⁶

Other experts, however, maintain that cross-border trade in infected poultry and poor agricultural practices, including the use of infected bird feces in fertilizer and animal feed, may comprise equally or more important vectors. Indications that may support such assertions include the initial detection of H5N1 on commercial farms in caged poultry that are unable to mingle with wild fowl, and the detection of H5N1 on farms located far from wetlands where migratory birds seasonally dwell, or in regions where H5N1-linked wild fowl die-offs have not been reported. In some countries, such as in Nigeria, there are some indications that wild fowl may not be implicated in the transmission of H5N1.⁷

⁶ See FAO, *Wild birds and Avian Influenza*, Sept. 2005, among other sources.

⁷ See Ellen Paul [Exec. Dir., Ornithological Council], "What We Don't Know About Bird Flu," *Washington Post*, Dec. 27, 2005; BirdLife Int., "Are High Risk Farming Practices Spreading Avian Flu?," Jan. 18, 2006; and BirdLife Int., "Autumn Waterbird Migration (continued...)"

There has also been some debate about the role of cats in transmission of the virus, particularly since the virus has been detected among cats in a number of countries, including Germany. On April 14, 2006, the World Organization for Animal Health (OIE) and the United Nations Food and Agricultural Organization (FAO) confirmed that domestic and wild birds were essentially the animal species transmitting and spreading the H5N1 virus. Furthermore, the two organizations found that while some 50 non-domestic bird species have proved susceptible to infection with the virus, aquatic birds seemed to play a major role in the international spread of the virus. Concurrently, OIE and FAO confirmed the statement issued by the World Health Organization (WHO) in February 2006 that “there is no present evidence that domestic cats can play a role in the transmission cycle of H5N1 viruses.” Nonetheless, the OIE advised that domestic cats be kept indoors in infected zones and surveillance zones due to their susceptibility to the virus.⁸

Congressional Response

Congress provided \$31.3 million to support ongoing U.S. efforts to prevent and contain the global spread of H5N1 through P.L. 109-13, FY2005 Emergency Supplemental Appropriations. The act, which passed in May 2005, also provided funds for domestic pandemic preparedness.⁹ Congress directed \$25 million to the U.S. Agency for International Development (USAID). Pursuant to the statute, USAID transferred \$15 million of the \$25 million appropriation to CDC. The act also permitted the Secretary of State to transfer part of the tsunami relief funds to federal agencies for avian flu activities. Ultimately, an additional \$6.3 million was transferred to USAID for international avian influenza activities,¹⁰ bringing the total for FY2005 emergency supplemental spending on international avian influenza activities to \$31.3 million.

In FY2006, the President submitted a \$7.1 billion emergency supplemental request for avian flu and pandemic influenza preparedness. Appropriators attached \$3.8 billion in emergency supplemental funds for avian flu initiatives (reserving a portion for international efforts) to P.L. 109-148, FY2006 Defense Appropriations.¹¹

⁷ (...continued)

Ends Without Spread of H5N1 Bird Flu,” Aug. 12, 2005; David Brown, “Poultry, Not Wild Birds, Most Often Carries Deadly Avian Flu to Africa,” *Washington Post*, Feb. 16, 2006; and AFP, “Bird flu outbreak in Nigeria stirs fresh row over migrant birds,” Feb. 8, 2006.

⁸ OIE, “Susceptibility of animal species to the H5N1 Asian strain.” April 14, 2006. [http://www.oie.int/eng/press/en_060413.htm]

⁹ For more information on the domestic response to H5N1, see CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister, and CRS Report RS21747, *Avian Influenza: Agricultural Issues*, by Jim Monke.

¹⁰ FY2007 State Department Function 150 Budget Request. Of the \$6.3 million, \$1.8 million went to Asia and the Near East region, \$3.0 million to Europe and Eurasia, and \$1.5 million to sub-Saharan Africa.

¹¹ The conference report for P.L.109-148, FY2006 Defense Appropriations, H.Rept. 109- (continued...)

The State Department, responsible for coordinating U.S. international avian flu efforts, estimates that some \$280 million of the \$3.8 billion is being directed to global avian flu initiatives. It is important to note that additional global avian flu efforts might be supported through other activities not specified in this report, such as avian flu related activities (e.g., infectious disease programs), ongoing influenza programs without “avian flu” requested funding, or international influenza research initiatives. Appropriators will be debating the appropriate level of funding for H.R. 4939, FY2006 Emergency Supplemental Appropriations. The Senate version includes \$3.2 billion for avian flu efforts, of which at least \$200 million is set aside for the Centers for Disease Control and Prevention (CDC) to implement global and domestic disease surveillance, laboratory capacity and research, risk communication, laboratory diagnostics, rapid response initiatives, and quarantine efforts. The House version does not specify additional funding for avian flu efforts.

The President requests about \$205 million specifically for international avian flu activities in FY2007. However, as in previous fiscal years, additional resources might be directed to global avian flu efforts through complementary programs or initiatives not specified as avian flu. The Senate Budget Committee passed S.Con.Res. 83 on March 16, 2006, which directs appropriators to provide up to \$2.3 billion in FY2007 appropriations for pandemic influenza preparedness. S.Con.Res. 83 also includes an additional \$352 million for pandemic influenza preparedness activities. The House version, H.Con.Res. 376, passed on March 31, 2006, exempts up to \$2.3 billion reserved for avian flu spending from budgetary controls. **Table 3** in the appendix outlines the amounts the Administration specifically requests for international avian flu initiatives in FY2007, and enacted spending for those activities through FY2005 and FY2006 emergency supplementals. Additional funds that an agency or department might have spent through regular FY2005 and FY2006 appropriations are not included in the table. Instead, reported figures are footnoted below the table.

Some Members have argued that the Administration had proposed allocating insufficient resources to the global fight against H5N1 and pandemic planning, particularly in Africa. For example, during the House Foreign Operations Subcommittee hearing on pandemic flu in March 2006, Chairman Jim Kolbe suggested that the \$55 million that USAID was requesting for FY2007 global avian flu initiatives might not be sufficient, and encouraged the agency to request additional funds if necessary. The Chairman also questioned why such a small proportion of the FY2007 requested funds were allocated to Africa (less than \$10 million). A number of Members have introduced legislation to increase U.S.

¹¹ (...continued)

359, contains \$3.8 billion for avian influenza initiatives. \$3.3 billion of the \$3.8 billion is directed to the Department of Health and Human Services (HHS) (of which \$267 million is reserved for international initiatives, disease surveillance, vaccine registries, research, and clinical trials). An additional \$500 million is reserved for international assistance, monitoring and tracking, and research and development, of which \$131.5 million is directed to USAID, \$130 million to the Department of Defense, \$91.4 million to the Department of Agriculture, \$47.3 million to the Department of Homeland Security, \$20 million to FDA, \$27 million to the Department of Veterans Affairs, \$31 million to the Department of State, and \$11.6 million to the Department of the Interior.

resources allocated to the global fight against avian flu. Some bills, such as H.R. 4062, *Pandemic Preparedness and Response Act* and its Senate companion, S. 1821, propose developing a “Pandemic Fund” to augment ongoing U.S. and international avian flu and pandemic preparedness initiatives. Other bills, such as H.R. 4476, *Global Network for Avian Influenza Surveillance Act*, and its Senate companion, S. 1912, advocate greater support for initiatives that prevent the spread of H5N1 among animals. A number of bills, such as H.R. 3369, *Attacking Viral Influenza Across Nations Act*, and its Senate companion, S. 969, suggest the U.S. strengthen surveillance capacity within affected countries. Bills, such as H.R. 813, *Flu Protection Act*, and its Senate companion, S. 375, aim to boost influenza vaccine supply. Additionally, other legislation, such as H.R. 4245, *Influenza Preparedness and Prevention Act* encourage greater international cooperation.

U.S. Executive Branch Response

On November 1, 2005, the President released the National Strategy for Pandemic Influenza.¹² One day later, on November 2, 2005, the Administration released the U.S. Department of Health and Human Services (HHS) Influenza Plan. The HHS plan provided a detailed explanation of how the national strategy would be implemented. Some were disappointed by the relatively small proportion of funds reserved for international efforts. It has been argued that greater investment in pandemic influenza preparedness abroad could enhance domestic pandemic preparedness efforts.

The President requested \$7.1 billion to fund the National Strategy for Pandemic Influenza, some of which he suggested be set aside for international activities. The majority of the funds, \$6.7 billion, were requested for HHS. The President requested that the \$6.7 billion be funded as such: \$3.2 billion in FY2006, \$2.3 billion in FY2007, and \$1.2 billion in FY2008. The President requested that the rest of the funds be funded through FY2006 emergency appropriations.

Of the \$7.1 billion related to international activities, the President requested:

- \$200 million for HHS to undertake a number of activities, including international pandemic preparedness planning initiatives and pandemic influenza disease surveillance;
- \$18.3 million for the U.S. Department of Agriculture to undertake research and development initiatives and to implement international programs that provide avian influenza surveillance and prevention technical assistance;
- \$120 million for the Department of Defense (DoD) to increase worldwide surveillance and upgrade related equipment;
- \$10 million for DoD to assist military partner nations in procuring protective equipment, portable field assay testing equipment, and related laboratory equipment;

¹² For more information on U.S. government avian flu and pandemic preparedness see [<http://www.pandemicflu.gov>]

- \$17 million for the Department of State to implement public diplomacy, training, and international outreach activities related to avian influenza and pandemic preparedness;
- \$1.5 million for the Department of State International Visitors Program to provide 100 additional professional exchanges of doctors, health practitioners, and non-governmental organizations (NGOs);
- \$75.2 million for Child Survival and Health Programs (CSH) of USAID to implement behavior change and avian flu awareness campaigns, diagnostic support initiatives, and pandemic preparedness and planning activities; and
- \$56.3 million for International Disaster and Famine Assistance Funds of USAID to pre-position supplies and equipment, such as antiviral medication and protective equipment.¹³

As indicated in the previous section, Congress ultimately provided \$3.8 billion through FY2006 emergency appropriations to fund the first phase of the National Strategy for Pandemic Influenza.

Prior to 2005, U.S. agencies had been enhancing laboratory capabilities, training health care providers, strengthening surveillance systems, and developing influenza pandemic plans. Through the FY2005 emergency appropriations, Congress directed U.S. agencies to revisit international influenza initiatives and ensure that there was a coordinated response to the global spread of H5N1. USAID and HHS (including its relevant agencies) undertook country planning visits to Vietnam, Cambodia, and Laos. After the trip, the team outlined in a report¹⁴ a number of factors that have complicated efforts to contain the spread of H5N1 in those countries, which included:

- Between 70% and 80% of poultry in the three countries are raised in small backyard farms, hindering national governments' ability to ensure health standards.
- Between 50% and 80% of poultry die from other avian infections, complicating efforts to identify unusual die-offs, and limiting farmers' likelihood of reporting bird deaths to authorities.
- Although culling is an essential element of controlling the spread of H5N1, poorer countries can not afford to systematically compensate farmers for lost stock, which also increases reluctance to report signs of infection.
- Wild birds and domesticated ducks are H5N1 reservoirs.

¹³ FY2006 Emergency Request for Avian and Pandemic Influenza Preparedness. [http://www.whitehouse.gov/omb/budget/amendments/supplemental_11_01_05.pdf]

¹⁴ Report from Country Planning Visits, "U.S. Government Emergency Response to Avian Influenza: A Plan of Action for Vietnam, Laos, and Cambodia." July 11-24, 2005. This report was provided to CRS by USAID.

- Low levels of awareness exist among local farmers.
- There is little pandemic preparedness activity in the countries toured.
- The capacity to monitor and respond effectively to animal outbreaks is limited. Veterinary services are inadequate to deal with the scope, severity, and rapid spread of H5N1 epidemics, which has resulted in the disease becoming increasingly endemic among animal populations in the region. The lack of human resources for disease surveillance, diagnostics, and response also severely limits the capacity of human health systems, and continued human infections of avian influenza threaten to overburden already fragile public health infrastructures.

The report also included an action plan, which outlined the activities that each agency would implement. Since then the agency-specific strategies have been augmented and are briefly described below.

Department of State

The U.S. Department of State is responsible for coordinating the U.S. international response to the global spread of H5N1. Ambassador John Lange replaced Ambassador Nancy Powell as the Senior Coordinator for Avian Influenza and Infectious Diseases in March 2006. Ambassador Lange is responsible for overseeing the work of the technical implementing agencies: HHS (and its relevant agencies), USAID, the Department of Agriculture, and the Department of Defense.

On September 14, 2005, President Bush announced the International Partnership on Avian and Pandemic Influenza (IPAPI) at the U.N. General Assembly High-Level Plenary Session. Through IPAPI, the U.S. government seeks to enhance public health and surveillance capacity through diplomatic initiatives that promote transparency and encourage reporting and rapid sharing of samples. IPAPI seeks to generate and coordinate political momentum and action for addressing the threats of avian and pandemic influenza based on a set of core principles. The principles are focused on enhancing preparedness, prevention, response, and containment activities (see **Table 4**). The Partnership brings key nations and international organizations together to improve global readiness by:

- elevating the issue of avian and pandemic influenza preparedness to the national level;
- coordinating efforts among donor and affected nations;
- mobilizing and leveraging resources;
- increasing transparency in disease reporting and surveillance; and
- building capacity to identify, contain, and respond to pandemic influenza.

The State Department works closely with regional organizations, including the Association of Southeast Asian Nations (ASEAN) and the Asia Pacific Economic Cooperation (APEC) forum, to address avian influenza and the threat of an influenza pandemic. The work includes efforts to encourage comprehensive national pandemic

preparedness plans that address the multi-sectoral impacts of an influenza pandemic.¹⁵ The next IPAPI meeting is scheduled for June 2006.

In the FY2006 supplemental request, the President proposed that the State Department receive \$38.5 million in FY2006 for international response coordination; diplomatic outreach; exchanges of U.S. and foreign medical personnel; and for avian and pandemic influenza health support and protection of U.S. government employees and families at U.S. missions overseas. About \$20 million of those funds would be reserved for the potential evacuation of U.S. government personnel and dependents from overseas missions. OMB reports that in FY2006, \$6 million of the funds were allocated to diplomatic support and international response coordination and \$25 million were directed to health support for embassy and evacuation contingency for overseas missions. The Administration did not request additional funds in FY2007 for State Department international avian flu activities.

U.S. Agency for International Development (USAID)

USAID coordinates its global H5N1 and influenza response with other U.S. agencies. It also works closely with WHO, the Food and Agriculture Organization of the United Nations (FAO), and other international governments and organizations to support national influenza and H5N1 prevention efforts. USAID reports that it has allocated \$22.1 million to global avian flu prevention and containment during FY2005 (\$16.3 million of which was funded through the FY2005 emergency appropriations).¹⁶ USAID has received \$131.5 million from FY2006 emergency supplemental appropriations for global avian flu efforts. The FY2007 budget requests \$55 million to USAID for continued avian flu and pandemic preparedness initiatives abroad. Specifically, the agency has:

- strengthened disease surveillance, laboratory diagnosis, and rapid containment of animal outbreaks in Cambodia, China, Indonesia, Laos, and Vietnam;
- supported communication campaigns in Laos, Cambodia, Vietnam, and Indonesia aimed at reducing animal handling practices that place humans at risk;
- distributed more than 30,000 personal protective equipment (PPE) sets, which include manual sprayers to assist in decontaminating hospital rooms and equipment, Tyvek suits (protective coveralls

¹⁵ The State Department also implements influenza pandemic preparedness initiatives through the Office of International Health Affairs (OES/IHA), which works with agencies throughout the U.S. government to facilitate policy-making regarding bioterrorism and health security, environmental health, infectious diseases (e.g., SARS, Avian Influenza, Pandemic Influenza, Polio), health in post-conflict situations, and surveillance and response. [<http://www.state.gov/g/oes/c1874.htm>].

¹⁶ USAID Avian Flu Update #29, February 9-March 13, 2006. [http://www.usaid.gov/our_work/global_health/home/News/news_items/actions.html].

used in hazardous situations), gloves, boots, masks, and eye protection in Asia, Europe, and Africa;

- deployed infectious disease and animal health experts to Iraq, Turkey, Ukraine, Romania, Armenia, Azerbaijan, Georgia, Moldova, and Nigeria to provide short-term technical assistance, assisted in the rapid collection of animal samples and helped implement procedures to strengthen surveillance and containment efforts in the countries;
- provided Ukraine PPE kits that two veterinary laboratories and cullers and first responders from the Ministry of Emergencies are using in their response and containment activities;
- granted WHO \$300,000 for international coordination efforts and for improving disease control and surveillance measures; and
- provided WHO an additional \$250,000 for PPE.¹⁷

U.S. Department of Health and Human Services (HHS)

CDC is the key agency at HHS responsible for implementing U.S. anti-influenza activities around the world. The Coordinating Center for Infectious Diseases and the Field Epidemiology Training Program — a CDC-sponsored activity — are also critical components of HHS global pandemic preparedness initiatives. Activities with foreign governments or populations include pandemic preparedness and planning; training in avian influenza surveillance; laboratory safety and skills instruction; epidemiology training; developing and training rapid response teams; stockpiling support; and deployment of expert disease control teams.

A significant part of H5N1 and pandemic influenza planning is funded through the Global Disease Detection (GDD) Initiative at CDC. GDD aims to recognize infectious disease outbreaks faster, improve the ability to control and prevent outbreaks, and detect emerging microbial threats. In FY2006, HHS enhanced its international pandemic research activities. Research activities included assisting in the development and testing of candidate vaccines and drugs produced by Vietnam and other countries with endemic avian influenza; expanding the clinical trials infrastructure and research in southeast Asia; conducting human-animal interface studies, including disease surveillance among animals in the region; and expanding other research to accelerate the development of pandemic influenza vaccines, drugs, and diagnostics.¹⁸

HHS budget officials estimate that CDC spent \$15 million on international avian flu initiatives through FY2005 emergency appropriations. OMB estimates that

¹⁷ USAID, Avian Influenza Updates 29 and 32, March 13, 2006 and April 14, 2006. [http://www.usaid.gov/our_work/global_health/home/News/news_items/actions.html]

¹⁸ HHS FY2007 budget request. [<http://www.hhs.gov/budget/07budget/2007BudgetInBrief.pdf>]

HHS will spend \$114 million on global avian flu initiatives through FY2006 emergency supplemental funds included in FY2006 DoD appropriations. However, these figures might be adjusted as the fiscal year progresses and additional funds might be provided through FY2006 Emergency Supplemental Appropriations. The Administration requests \$145 million for HHS global pandemic influenza and preparedness initiatives in FY2007.

Department of Agriculture (USDA)

U.S. Department of Agriculture (and its related agencies) works closely with other U.S. agencies on the ground, as well as other international organizations to help nations take steps to address and control the spread of avian influenza. Dr. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service (APHIS) of USDA stated that addressing avian flu at its source — in affected poultry abroad — and participating in international eradication efforts provide the best opportunity to reduce or eliminate the risk of an H5N1 pandemic.¹⁹ In that view, USDA and other analysts consider the department's efforts a critical element in the global fight against the spread of H5N1.

USDA works closely with OIE, FAO, and WHO to assist HPAI-affected countries and other neighboring countries, including Europe, with disease prevention, management, and eradication activities. USDA also implements training activities for scientists in those countries.

Through FY2006 emergency supplemental appropriations, Congress directed \$91.3 million to USDA for avian flu and pandemic preparedness initiatives, of which approximately \$18 million was reserved for international efforts. The Administration request \$5 million for USDA international avian flu activities in FY2007.

Department of Defense (DoD)

The Department of Defense Global Emerging Infections Surveillance and Response System (DoD-GEIS) supports and coordinates DoD global surveillance, training, public health research and outbreak response capabilities.²⁰ Specifically, DoD-GEIS projects support outbreak response preparation, detection, clinical investigation, microbial agent identification, and communicable disease control and prevention. GEIS has a network of overseas medical research laboratories that track, prevent, and treat infectious diseases around the world. The objective is to ensure national security, protect the U.S. military and strengthen its ability to address the challenges related to a potential pandemic influenza, including compromised military force health and readiness.

GEIS is also a critical partner in the WHO's Global Outbreak Alert and Response Network (GOARN) (described below). In FY2005, the GEIS global

¹⁹ USDA, Transcript of Technical Briefing regarding Avian Influenza. October 26, 2005. [<http://www.usda.gov/birdflu>]

²⁰ GEIS website, [<http://www.geis.fhp.osd.mil/>].

professional network isolated influenza viruses from approximately 1,800 individuals from about 20 countries; these influenza isolates were made available to CDC and world public health officials for molecular analysis and for consideration in the formulation of vaccination preparations.²¹ Key DoD-GEIS activities to combat the spread of H5N1 and prepare for an influenza pandemic have included:

- the provision of influenza data analyses, surveillance information, and influenza isolates for WHO, DoD, and CDC through cooperative relationships that included sharing weekly surveillance reports;
- the development of pandemic influenza emergency response plans for various DoD branches;
- surveillance for incidence of influenza among military populations;
- training and education sessions for healthcare workers that would aid in rapid detection and management of influenza illnesses;
- implementation of cooperative influenza surveillance activities in seven countries in the Middle East and in the Central Asian Republics, notably providing laboratory and epidemiological support in the identification of the avian influenza A H5N1 virus from wildfowl specimens in Kazakhstan;
- implementation of cooperative projects with the government of Indonesia, WHO and CDC, including providing diagnostic support for avian influenza (H5N1); and
- the evaluation of 29 emergency response plans from foreign governments, federal agencies, and international organizations.²²

The DoD overseas medical research laboratories are another critical part of DoD's avian flu containment and pandemic preparedness efforts. These Navy and Army laboratories support the GEIS mission through four programs: emerging diseases, enteric diseases, parasitic diseases, and virology. The overseas laboratories, based in Egypt, Indonesia, Kenya, Peru, and Thailand, collect and analyze biological samples. The overseas laboratories have been critical in U.S. government H5N1 surveillance efforts. DoD also maintains related research activities in Southeast Asia and the Pacific Islands, and supports a satellite laboratory in Phnom Penh, Cambodia, in collaboration with the DoD overseas laboratory in Indonesia (Navy Medical Research Unit 2) and the Cambodian National Institute of Public Health. Key activities include:

- bolstering local, national, and regional diagnostic and epidemiological capacity;
- assisting in the development of new surveillance strategies, such as the novel syndromic surveillance initiative Early Warning Outbreak Recognition System (EWORS);

²¹ DoD-GEIS FY2005 Annual Report.
[http://www.geis.fhp.osd.mil/GEIS/DoDGEISNews/GEIS_AR_05.pdf]

²² Ibid.

- implementing a comprehensive influenza surveillance project in Indonesia, which provides prevalence data and temporal, genotype data of circulating strains;
- collaborating with CDC in its FY2005 and FY2006 global influenza activities; and
- facilitating the transformation of outbreak response structures into more effective, multidisciplinary, centrally directed ones.²³

According to the FY2007 DoD Budget Justification, the department received \$130 million from FY2006 emergency supplemental appropriations for avian flu activities, of which \$120 million has been allocated to the Defense Health Program and \$10 million to Operation and Maintenance. The FY2007 budget request did not include a specific amount for avian flu.

International Response

The United Nations Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), and the World Health Organization (WHO) have been working closely to prevent and respond to the threat of an avian influenza pandemic. The FAO and OIE coordinate global surveillance and response activities related to animals transmission of H5N1. WHO focuses on coordinating the international response to H5N1 infection in humans. This section describes the roles of these three organizations in responding to and containing the global spread of H5N1. An analysis of the World Bank and its work in this area is also explored.

United Nations Food and Agriculture Organization

FAO coordinates global surveillance and response activities for animal influenza strains with pandemic potential, such as H5N1.²⁴ To accomplish its mission, FAO works closely with OIE.²⁵ Specifically, FAO and OIE work with other agencies to assist regional and national authorities in developing appropriate avian influenza prevention and control plans and strategies. Rapid detection of avian influenza outbreaks is key to controlling the disease both in poultry and in people, and is therefore key to preventing and controlling a potential influenza pandemic.

On March 17, 2006, FAO released a proposal for a global avian influenza control and eradication plan.²⁶ The plan outlined what activities FAO would

²³ DoD, Global Emerging Infections System Annual Report Fiscal Year 2004. [http://www.geis.fhp.osd.mil/GEIS/aboutGEIS/annualReports/GEIS_AR_04.pdf].

²⁴ See FAO avian influenza home page at [http://www.fao.org/ag/againfo/subjects/en/health/diseases-cards/special_avian.html].

²⁵ See OIE avian flu home page at [http://www.oie.int/eng/AVIAN_INFLUENZA/home.htm].

²⁶ FAO, "Avian Influenza Control and Eradication: FAO'S Proposal for a Global Program." March 17, 2006. [<http://www.fao.org/ag/againfo/subjects/documents/ai/>]

implement and how much funds would be needed to support the program. The report emphasized that as the virus spreads needs change, making it increasingly difficult to predict sufficient levels of logistical and budgetary resources. FAO pointed out that in November 2005, it was estimated that FAO would need \$494 million over three years to implement a global program. However, after the rapid spread of the virus to Europe and Africa, the three-year budget estimate jumped to \$882 million.²⁷ FAO anticipates involvement in implementing 25% of donor-assisted projects in infected countries, and 50% of assistance to non-infected countries in preparedness outbreaks.

The World Organization for Animal Health

OIE, an intergovernmental organization established in 1924 and based in France, seeks to collect, analyze, and disseminate the latest scientific information on animal disease control. There are 167 member countries in OIE, one of which is the United States. The organization establishes guidelines to help countries improve disease control and eradication methods. OIE also provides technical support to member countries requesting assistance with animal disease control and eradication operations. According to the OIE website, one of its most critical functions is to establish international standards for adequate veterinary services and to assist member countries to implement the standards.²⁸

In December 2005, the OIE Director General Dr. Bernard Vallat released a statement arguing that globalization facilitates the appearance of emerging and reemerging diseases and greatly increases their impact. Furthermore, it was argued that national veterinary services are the “very core body for the prevention, detection, and control of animal diseases, including those transmissible to humans. Veterinary services play a major role in every country as guarantors of animal health and associated public health issues.”²⁹ Furthermore, OIE presses for greater public investment in veterinary services, deeming it a global public good of great importance.

In April 2006, OIE launched “Safe Supply of Affordable Food for Everyone Everywhere.” The initiative seeks to facilitate and strengthen the global food safety system, enhance animal disease prevention and control efforts worldwide; and leverage resources from public-private partnerships. OIE argues that this initiative is critical to countering the affects avian influenza has had on the animal kingdom, which if not addressed could have significant global consequences for agricultural

²⁶ (...continued)
Global_Programme_March06.pdf]

²⁷ Ibid.

²⁸ OIE, “OIE at a Glance.” Accessed on April 28, 2006.
[http://www.oie.int/eng/OIE/en_oie.htm]

²⁹ OIE, “Prevention, detection, and control of animal diseases, including zoonoses: Veterinary Services, the core of the global system.” December 2005. [http://www.oie.int/eng/edito/en_lastedito.htm]

economies, food security, and public health.³⁰ Dr. Vallat asserts that the initiative is crucial, because many governments in developing countries are incapable of raising their animal health and public health infrastructures to international standards, which outline how to address avian influenza and other emerging animal diseases, without cooperation with the private sector.³¹

The World Health Organization

The World Health Organization, established in 1948, is the U.N. system's authority on international public health issues. It assists governments to improve national health services and establish worldwide standards for foods, chemicals, and biological and pharmaceutical products. WHO concentrates on preventive rather than curative programs, including efforts to eradicate endemic and other widespread diseases, stabilize population growth, and improve nutrition, sanitation, and maternal and child care. WHO works through contracts with other agencies and private voluntary organizations. The United States has been a member of WHO since its inception.

WHO is a central actor in the global response to the outbreak of H5N1 avian influenza. WHO seeks to mitigate the risks avian influenza and infectious diseases pose to international public health, and to assure the availability of appropriate containment mechanisms, particularly since global travel has become the primary means of spreading disease around the world. With the exception of SARS and HIV/AIDS, H5N1 is viewed by some as the most serious challenge facing WHO.

In September 2005, U.N. Secretary-General Kofi Annan appointed Dr. David Nabarro as the Senior U.N. System Coordinator for Human and Avian influenza. Dr. Nabarro, seconded from the WHO, is responsible for coordinating the avian influenza containment efforts of various U.N. agencies. Dr. Nabarro is also tasked with encouraging global support and implementation of the WHO Global Influenza Preparedness Plan. The plan outlines WHO goals and actions, as well as recommended actions for individual nations at each pandemic phase. The plan contains an annex of recommendations to nations for "non-pharmaceutical public health interventions," such as isolation, quarantine and travel restrictions. The annex stresses the use of voluntary rather than compulsory measures. Additionally, it stresses that nations implement infection-specific responses, noting the lack of demonstrated utility of certain practices. For example, certain SARS control measures, such as temperature screening at airports, would not be expected to effectively control influenza spread.³²

³⁰ OIE, "World Organization for Animal Health (OIE) launches a global alliance against animal diseases, including zoonoses. April 21, 2006. [http://www.oie.int/eng/press/en_060420.htm]

³¹ Ibid.

³² See WHO, Department of Communicable Disease Surveillance and Response Global Influenza Programme, "Responding to the Avian Influenza Pandemic Threat: Recommended Strategic Actions," WHO/CDS/CSR/GIP2005.8.

WHO is establishing a global stockpile of influenza vaccines and treatments.³³ WHO officials underscore that wealthy and poor countries must develop pandemic preparedness plans collectively to reduce national and international viral transmission. The organization envisions using the stockpile to arrest a potential pandemic by containing the virus at the first sign of an outbreak. In the event of an outbreak, WHO asserts that a pandemic could potentially be averted if antiviral drugs were quickly distributed in a poor country without access to them.³⁴ Roche, the patent holder of Tamiflu, announced that it would donate 3 million courses of the drug to WHO.³⁵ On January 17, 2006, WHO announced that Roche would donate an additional 2 million treatment courses of Tamiflu for use in developing countries — bringing the total of donated courses to 5 million.³⁶ Roche officials announced on April 19, 2006, that 3 million Tamiflu courses were ready to be shipped to an influenza outbreak site at WHO's request.³⁷

International Health Regulations. An outbreak of infectious diseases raises many public health questions including the application of international law, particularly as it affects three main areas — International Health Regulations (IHR); public health measures and civil and political rights; and principles of state responsibility.³⁸ This section will focus on the IHR because of its relevance to WHO.

On May 23, 2005, the World Health Assembly revised the IHR, adding novel influenza strains (those with pandemic potential) and SARS to the list of “notifiable diseases” that WHO urges countries to report. In addition, the revised IHR include a provision requiring notification of “events of international concern.” This mechanism could strengthen WHO's ability to address emerging diseases, because it requires member States to report unusual health events whether or not they are attributable to a known pathogen. The updated IHR also include expanded requirements for disease surveillance and control activities at points of international travel (airports, border crossings, etc.), and urge developed countries to assist

³³ For more information on the global stockpile see WHO, “Responding to the avian influenza pandemic threat: recommended strategic actions.” [http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_05_8-EN.pdf]

³⁴ WHO, “Donation of three million treatments of oseltamivir to WHO will help early response to an emerging influenza pandemic.” August 24, 2005. [<http://www.who.int/mediacentre/news/releases/2005/pr36/en/index.html>].

³⁵ Roche, “Roche donates 3 million treatments of antiviral Tamiflu to the WHO for use in an influenza pandemic.” August 24, 2005. [<http://www.roche.com/med-cor-2005-08-24>]

³⁶ WHO, “Additional two million treatment courses of oseltamivir donated to WHO to help countries which cannot afford the treatment.” January 17, 2006. [<http://www.who.int/mediacentre/news/notes/2006/np01/en/index.html>]

³⁷ Roche press release, “Rapid response stockpile of Tamiflu now ready and available to the World Health Organisation (WHO).” April 19, 2006. [<http://www.roche.com/med-cor-2006-04-19>]

³⁸ The American Society of International Law, *SARS and International Law*, April 2003, see [<http://www.asil.org/insights>].

developing countries to gain the capacities needed to meet the new disease control guidelines.³⁹

The revised IHR are to replace the existing IHR (adopted in 1969) on June 15, 2007, when the revised regulations come into force. Considered an international legal instrument, the revised IHR will be binding on all WHO member States who have not stated a reservation or rejected them altogether, and on non-member States that have notified the Director-General of WHO that they agree to be bound by the revised IHR.⁴⁰ Between now and June 2007, WHO and Member States may take concrete steps towards implementation of the revised IHR and to improve their capacity to respond to international health risks and emergencies.⁴¹ The revised IHR do not include an enforcement mechanism. However, for states to respond appropriately and avoid potentially harmful consequences, much of the encouragement to comply will likely come from international pressure, as the SARS outbreak demonstrated.

At the Executive Board's semi-annual session, from January 23-28, 2006, the Board discussed a number of issues, including how to reduce the risk of a global influenza pandemic. During the 117th Session, the Board discussed strategies to encourage countries to immediately voluntarily comply with provisions of the revised IHR related to a possible flu pandemic. Member countries, such as Canada, are reportedly among those who advocate for the revised IHR to be adopted earlier than 2007.⁴² During the session, the 32 Board Members backed and released *WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment*. The draft protocol must be ratified by the General Assembly in May 2006. The protocol seeks to "facilitate rapid detection and assessment of potential 'signals' that the virus is improving its transmissibility, and to guide implementation of effective response interventions before an emerging pandemic virus has spread beyond an initial outbreak zone."⁴³ Former Ambassador Nancy Powell stated at a House Foreign Operations subcommittee hearing that the U.S. is working with countries to help them comply with the IHR. Ambassador Powell pointed out that in the Caucuses there is a lack of boxes used for sending viral samples to WHO, and a lack of information on how to adhere to the IHR. Various U.S. government agencies are

³⁹ The revised International Health Regulations, approved by the World Health Assembly on May 23, 2005, are available at [<http://www.who.int/csr/ihr/en/>].

⁴⁰ If a State makes a reservation that is compatible with the "object and purpose of IHR (2005)" and at least one-third of other States have not objected to the reservation within six months of notification, the revised IHR will enter into force for that State, subject to its reservation. WHO, "Frequently Asked Questions About IHR." [<http://www.who.int/csr/ihr/howtheywork/faq>].

⁴¹ WHO, "Frequently Asked Questions About IHR." [<http://www.who.int/csr/ihr/howtheywork/faq>].

⁴² Nebehay, Stephanie, "WHO backs early adoption of bird flu rules." Reuters, January 26, 2006. [<http://www.alertnet.org/thenews/newsdesk/L26248393.htm>]

⁴³ WHO, "WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment." January 27, 2006. [http://www.who.int/csr/disease/avian_influenza/guidelines/RapidResponse_27%2001.pdf]

reportedly working with countries to demonstrate how to safely handle and transport viral samples to WHO.

The World Bank

The World Bank provides low-interest loans to countries heavily affected by H5N1. Additionally, the Bank coordinates efforts between countries, and encourages them to develop pandemic plans that connect sectors, such as health and rural development. In September 2005, representatives from the WHO, FAO, OIE and the World Bank met with health experts from the United Nations, European Commission and H5N1-affected countries to discuss the global spread of H5N1, to emphasize the importance of pandemic planning, and to prepare a coordinated response. On November 4, 2005, the World Bank announced that it would provide \$500 million in loans to poor southeast Asian countries that are struggling to combat avian influenza. The funds will be used to supplement government resources, strengthen veterinary systems, and assist in culling and animal vaccination programs.⁴⁴ Although the World Bank has agreed to provide \$500 million in loans to affected countries, the Bank estimates that \$1 billion could be needed over the next three years.⁴⁵ The \$1 billion does not include the cost of financing human or animal vaccine development, purchasing antiviral medicine, or compensating farmers for loss of income.

On January 17-18, 2006, the World Bank, the European Commission, and the Chinese government co-hosted the “International Pledging Conference on Avian and Human Influenza.” The conference’s stated goal was to raise between \$1.2-\$1.4 billion from the global community to combat avian flu in developing and middle-income countries.⁴⁶ Representatives from approximately 100 countries and 20 international organizations attended, ultimately pledging \$1.9 billion in avian flu assistance.

Details on how the money will be spent are scant; however, David Nabarro, the U.N. bird flu coordinator, stressed that “there will be very clear procedures for the monies being applied to particular programs.” Among the donors, the World Bank reportedly promised \$500 million, the U.S. pledged \$334 million, Japan offered \$159 million, EU member states donated \$138 million, and the European Commission, the EU’s executive body, pledged \$121 million. Although China is struggling to contain the spread of H5N1, it pledged \$10 million.⁴⁷ It is anticipated that \$635.2 million

⁴⁴ World Bank Press Release, “New Global Program to Deal with Avian Flu.” November 4, 2005. [<http://www.worldbank.org>]

⁴⁵ UN News Service, “Bird flu: UN-sponsored conference draws up six-point action plan.” November 9, 2005. [<http://www.un.org/apps/news/>]

⁴⁶ “Avian and Human Influenza: Financing Needs and Gaps,” World Bank, January 12, 2006, pp. 10-11. [<http://siteresources.worldbank.org/PROJECTS/Resources/40940-1136754783560/AHIFinancingGAPSFINAL.pdf>]

⁴⁷ Information in this paragraph was compiled from the Wall Street Journal, “Donors Pledge \$1.9 billion to Fight Avian Flu in Developing Nations.” January 19, 2006.

(continued...)

would go to East Asia and the Pacific, \$224.6 million to Eastern Europe and Central Asia, \$147.1 million to Africa, \$110.1 million to the Middle East and Africa, \$76.0 million to South Asia, and \$9.2 million to Latin America and the Caribbean.⁴⁸

The World Bank has already begun plans for distributing the \$1.9 billion raised. In February 2006, the World Bank announced that it would provide the Kyrgyz Republic \$4 million, the first of the \$500 million in avian flu assistance grants. The grant is intended to support national efforts to strengthen veterinary services, enhance information dissemination, and improve disease surveillance.⁴⁹ The World Bank also announced in February that it is planning to provide \$50 million in emergency funds to Nigeria for culling and farmer compensation, as well as vaccination assistance.⁵⁰

Issues for Congress

Some experts point out that in order to effectively contain the spread of H5N1 and prepare for pandemic influenza, the U.S. government would need to develop a plan that integrates domestic and international policy. Some of the policy responses may originate domestically, but resonate globally. For example, issues related to U.S. drug policy, such as vaccine technology and intellectual property rights could impact access to antiviral drugs and vaccines in countries where H5N1 is endemic — particularly since some of the most affected countries do not have the capacity to produce or purchase sufficient quantities of the drugs.⁵¹ One article in the *Journal of Public Health Policy* pointed out that “almost 40% of the world’s supply of inter-pandemic influenza vaccines is used in countries that do not produce their own vaccines.”⁵² Below are some issues that particularly impact the most affected countries in Asia, and other parts of the world.

Patent Protections

Intellectual property rights has become an increasingly contentious issue in global health, particularly since companies began threatening to ignore patents for HIV/AIDS treatments. In an effort to expand global access to flu drugs, the United

⁴⁷ (...continued)

[<http://www.wsj.com>]

⁴⁸ BBC, “\$1.9bn pledged for bird flu fight.” January 18, 2006. [<http://news.bbc.co.uk/go/pr/fr/-/1/hi/world/asia-pacific/4622982.stm>]

⁴⁹ World Bank press release, “First World Bank Avian Flu Grant to Kyrgyz Republic.” February 9, 2006. [<http://www.worldbank.org>]

⁵⁰ World Bank press release, “Emergency Aid for Nigeria to Combat Avian Flu.” February 24, 2006. [<http://www.worldbank.org>]

⁵¹ For more information on these issues see CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah Lister.

⁵² Fedson, David, “Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development.” *Journal of Public Health Policy* 2005, Volume 26, Issue 1, April 2005. p.11.

Nations had been encouraging Roche — the patent holder of Tamiflu — to license other companies to produce generic versions of the drug. Roche announced on October 21, 2005 that U.S. pharmaceutical companies could manufacture a generic version of Tamiflu.⁵³ Legislation introduced in the first session of the 109th Congress aims to permit the United States to invoke a compulsory license and export generic versions of the drug to non-producing countries.⁵⁴ Some speculate that Roche has been increasing efforts to license its products in other countries, in part because an Indian pharmaceutical company, Cipla, has threatened to manufacture a generic version of the drug — in spite of Roche’s patent rights. Underscoring that Tamiflu is too expensive for many of the least developed countries, a Cipla representative said that the company would sell the generic version of Tamiflu “at a humanitarian price” in developing nations, and not in the United States or Europe.⁵⁵ Two Indian pharmaceutical companies are reportedly negotiating with Roche to produce generic versions of Tamiflu.⁵⁶ Roche also reached an agreement with a Chinese pharmaceutical company to make the drug.⁵⁷

Health experts predict that patent protections will continue to be a contentious issue as poorer countries seek to protect themselves against virulent diseases. Some analysts contend that Congress faces an issue of whether to help countries where H5N1 is endemic gain greater access to generic versions of Tamiflu and other antivirals if licensed drugs are not accessible.⁵⁸ Supporters assert that the precedent for greater access to generics by poorer countries had already been established on December 6, 2005, when World Trade Organization (WTO) members approved changes to the intellectual property agreement making permanent a decision on patents and public health.⁵⁹ The General Council decision means that for the first time a core WTO agreement will be amended. The decision directly transforms the August 30, 2003 waiver to Section 31(f) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁶⁰ The waiver permits a country without manufacturing

⁵³ Alonso-Zaldivar, Ricardo, “Roche agrees to generic version of Tamiflu drug.” *Baltimore Sun*, October 21, 2005. [<http://www.baltimoresun.com>].

⁵⁴ H.R. 4392, *To provide for the importation of pharmaceutical products under a compulsory license as provided for under the World Trade Organization*.

⁵⁵ McNeil Jr., Donald, “Indian Company to Make Generic Version of Flu Drug Tamiflu.” *New York Times*. October 14, 2005. [<http://www.nytimes.com>].

⁵⁶ Jack, Andrew, “India drugs groups in Tamiflu talks.” *Financial Times*. December 12, 2005. [<http://news.ft.com/home/us/>]

⁵⁷ Wright, Tom, “Roche to Let Chinese Producer Make Flu Drug.” *New York Times*. December 13, 2005. [<http://nytimes.com>]

⁵⁸ For more information on influenza and patent issues, see CRS Report RL33159, *Influenza Antiviral Drugs and Patent Law Issues*.

⁵⁹ WTO, “Members OK amendment to make health flexibility permanent.” December 6, 2005. [http://www.wto.org/english/news_e/pres05_e/pr426_e.htm]

⁶⁰ Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. The concern was that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper
(continued...)

capacity to obtain cheaper generic versions of patented medicines from countries under compulsory licenses. The waiver enables the country to receive generic versions of drugs in situations of “national emergency or other circumstances of extreme urgency.”⁶¹ A separate statement describes members’ “shared understanding” on how the decision is interpreted and implemented. Particularly, the statement points out that the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives.⁶² Although the waiver was seen as a tool to enable largely poorer countries to import generic versions of licensed drugs, one piece of legislation proposes that the U.S. Trade Representative inform WTO that the United States declares itself an “eligible importing member” to import pharmaceutical products, largely because Roche is unable to meet the “public health needs” of the United States.⁶³

WTO members voted against delineating which drugs should be included in the waiver agreement. Consequently, there is not consensus on which drugs are considered critical in protecting public health. Advocates argue that in the event of a pandemic, the new WTO amendment should apply to antiviral drugs and H5N1 vaccines for use in animals. Opponents are concerned that some might abuse and undermine the agreement by reselling the drugs and vaccines for profit. In the event of a pandemic, Congress might be faced with the decision on whether to support or oppose the export of generic antivirals. Additionally, increased pressure might be placed on Congress to encourage USDA to share with other countries some of its H5N1 vaccine for use in animals.

Global Data Sharing

In spite of Tamiflu stockpiling efforts, it is unknown if the medicine will be broadly useful in treating human H5N1 victims in a pandemic scenario. Some health experts were reportedly alarmed when two patients in Vietnam who were infected with H5N1 and aggressively treated with Tamiflu later died. Some are beginning to question if the recommended dosage should be changed, as doctors reportedly adhered to the recommended regimen when treating the two patients.⁶⁴ Health experts point out that more information is needed on patients who have already been treated for H5N1 with Tamiflu. Data from the subjects would help in determining if the drug remains effective in fighting H5N1 and if changes to dosage regimens are required.

⁶⁰ (...continued)

generics from countries where pharmaceuticals are patented.

⁶¹ For more information on this issue see CRS Report RS21609, *The WTO, Intellectual Property Rights, and the Access to Medicines of Controversy*, by Ian F. Fergusson.

⁶² WTO, “Members OK amendment to make health flexibility permanent.” December 6, 2005. [http://www.wto.org/english/news_e/pres05_e/pr426_e.htm]

⁶³ H.R. 4392, *To provide for the importation of pharmaceutical products under a compulsory license as provided for under the World Trade Organization*.

⁶⁴ Chang, Alicia, “Bird Flu Victims Die After Drug Resistance.” *Washington Post*. December 21, 2005. [<http://www.washingtonpost.com>]

Those pressing for greater international data sharing point to new research that might counter previous findings on the limited effectiveness of amantadine. The New York Times reported in September 2005 that researchers found that amantadine was no longer effective against H5N1. WHO reportedly spent \$1.3 million to stockpile the drug when it was used during the 1997 H5N1 outbreak. The Times article asserted that in 2005, laboratory research found that all human viral samples of H5N1 were resistant.⁶⁵ Before 2000, almost no influenza virus was resistant to the drug. Some experts speculated that viral resistance occurred in part, because China reportedly used amantadine, intended solely for humans, on animals. (See “Affected Countries’ Response” section). However, the Wall Street Journal quoted Dr. Shu Yuelong, the Director of China’s national influenza laboratory, as stating that preliminary evidence indicates that amantadine might be effective in treating avian influenza in people.⁶⁶ Dr. Shu reported that all of the viral samples that have been isolated from patients in China were sensitive to amantadine. Those findings conflicted with previous research on virus samples that were taken from patients in Indonesia and found to be resistant to the drug. The new research has reportedly prompted WHO and other officials to consider whether amantadine might eventually play a role in fighting H5N1. The article underscores that there are currently too few samples to draw any firm conclusions.

Some believe that some countries are intentionally withholding viral samples of H5N1 cases. One article stated that countries with human H5N1 cases do not want to send viral samples to the WHO or other industrialized countries, because they fear the samples will be used to develop up-to-date vaccines which they will not have access to.⁶⁷ Others have speculated that China is withholding its samples, because it is trying to produce an H5N1 vaccine.⁶⁸

Some analysts propose that the United States and other countries should vote to provide WHO with enforcement mechanisms. Supporters argue that WHO should be able to force countries to share viral samples. Others contend that Congress should provide greater support and resources to WHO, particularly for strengthening global laboratory and testing capabilities. Skeptics point out that WHO has not provided transparent, detailed data on the adequacy of funds or how funds are spent.

Global Disease Surveillance

A number of analysts have argued that due to insufficient investment in disease surveillance and health care in many of the countries where H5N1 is endemic, a

⁶⁵ Rosenthal, Elisabeth, “Two Studies Find Flu Treatments Fall Far Short.” September 22, 2005. [<http://www.nytimes.com>].

⁶⁶ Zamiska, Nicholas, “Scientists Says Bird-Flu Virus Appears to Be Stable in China; No Signs that Avian Strain Is Easily passed by People; Old Drug Shows Promise.” December 12, 2005.

⁶⁷ Globe and Mail, “Chinese officials haven’t shared samples of H5N1: experts.” November 18, 2005. [<http://www.theglobeandmail.com>].

⁶⁸ China Daily, “China: Bird flu vaccine for human use developed.” November 15, 2005. [http://www.chinadaily.com.cn/english/doc/2005-11/15/content_494593_3.htm].

pandemic may progress before it is discovered. In this view, ill-equipped surveillance systems will be slow to determine the source of a pandemic, evaluate the rate of viral transmission, ascertain whether H5N1 has become efficiently transmissible among humans, or rate the effectiveness of anti-flu initiatives. Senate Majority Leader Bill Frist has proposed \$1 billion for a real-time international threat detection system.⁶⁹

USAID and other U.S. government officials suspect that the lack of documented human cases of H5N1 in Laos has more to do with inadequate surveillance and reporting systems than an absence of infection.⁷⁰ The New York Times reported that Laos has 69 veterinarians in the entire country, and all but two of them were trained in other Communist countries before the collapse of the former Soviet Union. Additionally, Laos reportedly has no veterinary school.⁷¹ Some health experts believe that H5N1 transmission could already be underway in Laos, since surrounding countries have already had human and animal outbreaks. Key U.S. agencies and international organizations have determined that Laos is a country that needs critical prevention, monitoring, and surveillance support in order to prevent full-blown human-to-human transmission of H5N1 that could emerge and sweep across the region without warning.⁷² U.N. officials argue that Laos exemplifies the sort of long-term assistance that other poorer countries will require, such as training in veterinary services and surveillance systems, provision of surveillance and testing equipment, and support for farmer compensation.⁷³

Some experts have expressed increasing concern about the capacity of poorer countries that have not yet had H5N1 cases to effectively contain the spread of the virus and plan for pandemic influenza, particularly in sub-Saharan Africa. FAO is particularly wary of the virus spreading across Africa, as the surveillance capacities and veterinary services in those countries are limited. According to Reuters, a WHO representative declared that an H5N1 outbreak would likely be initially missed in Africa, as bird nutrition is poor and high mortality among poultry is common. Concurrently, human cluster cases are likely to be missed due to poor surveillance systems. South Africa is reportedly the only country in sub-Saharan Africa to have drawn up a pandemic preparedness plan.⁷⁴ Some experts fear that an unabated H5N1 outbreak in Africa could make the bird flu endemic there. “If the virus were to become endemic in Africa, it could increase the risk that the virus would evolve

⁶⁹ Honorable Bill Frist website, “First Addresses National Press Club on Avian Flu — Pandemic: The Economy Killer.” December 8, 2005. The Senate passed S. 2170 on December 22, 2005.

⁷⁰ Interview with USAID official, October 11, 2005.

⁷¹ Bradsher, Keith, “*Health Officials Call for Long-Term Spending on Bird Flu.*” January 17, 2006. [<http://www.nytimes.com>]

⁷² Ibid.

⁷³ Bradsher, Keith, “*Health Officials Call for Long-Term Spending on Bird Flu.*” January 17, 2006. [<http://www.nytimes.com>]

⁷⁴ Reuters, “Bird Flu in Africa Could Swamp Health Systems: WHO.” November 27, 2005. [http://www.nlm.nih.gov/medlineplus/news/fullstory_27731.html]

through mutation or reassortment into a strain that could be transmitted to and between humans.”⁷⁵

The press reported on December 20, 2005 that a bird suspected of having contracted H5N1 in Ethiopia, tested negative of the virus.⁷⁶ Experts are concerned that birds in Ethiopia and other countries in the Rift Valley, including Kenya, Tanzania, and Uganda, are at particular risk of avian flu infection due to the large numbers of migratory birds that fly to the region during the European winter. Those concerned about insufficient surveillance and diagnostic equipment and expertise, point out that Ethiopia had to use health experts and equipment from Egypt to determine what caused a rash of bird deaths in December 2005. USAID with support from the U.S. Navy Medical Research Unit (NAMRU) in Cairo reportedly provided \$15,000 in emergency funding to analyze the viral samples of dead pigeons found in Addis Ababa and the Eastern Somali region for H5N1 infection. Additionally, USAID has reportedly reprogrammed \$600,000 from existing surveillance funds for bird flu initiatives in Ethiopia.⁷⁷ The funds are to help provide technical assistance to the Ministries of Agriculture and Health, develop laboratory and communications capacity, and procure Personal Protective Equipment for first responders.

Many of the countries in which H5N1 is endemic have complained that they can not afford to implement the strategies recommended by the international community. Furthermore they are hesitant to divert their limited budgets — already struggling to contend with AIDS, child and maternal health, tuberculosis, and other health challenges — to something that might not occur. Advocates of greater assistance to the region, point out that countries with more resources for pandemic planning than neighboring poorer countries have also acknowledged difficulties in responding to the H5N1 threat. A news report cited a South Korean health worker who stated that his country is ill-equipped to respond to a pandemic citing insufficient supplies of medication, hospital beds, and ventilators.⁷⁸

On December 22, 2005, the Senate passed S. 2170, which would help developing countries bolster their disease surveillance programs, and establish fellowships for citizens of those countries to study epidemiology and public health in the United States. Additionally, some in Congress have advocated for greater U.S. spending on fighting the global spread of H5N1 avian flu. Press reports quoted Representatives Henry Hyde and Tom Lantos, Chairman and Ranking Member of the House International Relations Committee respectively, stating concern about the level of funding the Administration proposes to provide for global efforts in

⁷⁵ “UN agency says risk of bird flu spreading to Middle East, Africa rises markedly.” U.N. News Center, October 19, 2005. [<http://www0.un.org/apps/news/story.asp?NewsID=16037&Cr=bird&Cr1=flu>]

⁷⁶ Reuters Foundation, “ETHIOPIA: Birds Test Negative for avian flu.” December 20, 2005. [<http://www.alertnet.org>]

⁷⁷ USAID, *H5N1 Avian Influenza (AI) Most Recent Developments and Actions*. November 26 - December 19, 2005.

⁷⁸ Grudgings, Stuart, “Rich-poor divide hobbles Asia’s bird flu plans.” Reuters, September 13, 2005. [<http://www.reuters.com>]

FY2006⁷⁹. Advocates assert that the Administration requests for international H5N1 initiatives will not sufficiently address the significant needs of countries with H5N1-endemic stocks. Particularly, experts add that the threat of an H5N1 or other influenza pandemic illuminates the neglect that health care systems in many southeast Asian countries have faced over the last couple of decades. Proponents argue that if the United States would increase its funding to support global health care systems the global community could benefit from efficient outbreak reporting and control measures, accurate diagnoses, enhanced case management, and improved disease surveillance and monitoring.

Global Pandemic Planning

Some experts caution that pandemic preparedness plans must extend beyond procuring and stockpiling antiviral drugs and vaccines. In this view, governments must also develop detailed vaccine and treatment distribution plans. Particular attention has been paid to H5N1-affected countries that have communication and infrastructure barriers, especially between urban and rural areas (where many of the backyard poultry farms exist). Many Asian countries have significant income and infrastructure gaps between rural and urban areas. In the rural areas, there are often few hospitals and treatment centers. Equipment can be outdated or lacking. Veterinary and animal health services can be limited. Additionally, in many cases rural governments operate independently from urban governments, which tend to receive larger portions of national resources. Farmers in rural areas may not adhere to government H5N1 initiatives, exacerbating the problem. One infectious disease expert in Hong Kong asserted that the communication problem is particularly acute in China. “I trust and believe the central government has very good intentions, but unfortunately, it is a very big country. At the district, regional levels, the failure to communicate continues.”⁸⁰

Pandemic planners are warning that no country has the surge capacity to meet national demands for consumer products and medical services for the full term of an influenza pandemic (an estimated six months to a year). The United States, and other industrialized nations, rely on a range of critical products from H5N1-affected countries, such as medical supplies, military parts, and sanitation equipment. These supply chains are replenished “just-in-time” to minimize costs. If an outbreak were to occur, hospitals, food and water systems, and the military could all be vulnerable to interrupted supply due to absenteeism, border closures, and other supply chain disruptions. Therefore, the private sector, as well as national and international trade organizations have been urged to participate in pandemic planning.

Some analysts argue that resources allocated to containing the spread of H5N1 have been insufficient in part, because many countries have funded the response primarily through the ministries of agriculture and health. Some experts point out that an influenza pandemic will likely impact the animal and health sectors, as well

⁷⁹ GovEXEC.com, “House panel calls plan for tracking avian influenza ‘inadequate’.” December 7, 2005. [<http://govexec.com/dailyfed/1205/120705cdpm2.htm>]

⁸⁰ Grudgings, Stuart, “Rich-poor divide hobbles Asia’s bird flu plans.” Reuters. September 13, 2005. [<http://www.reuters.com>]

as trade, security, hospitality, and labor. Consequently, they say, governments should develop pandemic plans that utilize the resources of other ministries that are often better funded, such as ministries of trade, tourism, and commerce. Some analysts note that U.S. officials, such as the U.S. Trade Representative and the Secretary of Commerce should be engaged in U.S. international pandemic influenza planning efforts. Others would like Congress to encourage public-private partnerships that augment U.S. international avian flu and pandemic preparedness efforts.

Combating Bird Flu Among Animals in Affected Countries

Most countries have used mass culling to prevent viral spread when avian influenza outbreaks are detected. However, some countries have not been able to rely on this process as a primary containment measure, because the governments might not have been able to compensate farmers for slaughtering their stocks. Scientists have also found that mass culling is sometimes not feasible when wild birds are involved in transmission. Some health experts assert that there should be more research on more affordable methods of preventing pandemics at their source — in the animals that carry the virus. Strategies such as implementing cleaning days (when all live markets are simultaneously emptied and cleaned), and separating ducks and chickens in live poultry markets may decrease viral transmission among animals. Some countries (including China) propose using vaccination to control avian influenza in poultry. Skeptics warn that animal vaccination is a risky strategy, as it is often difficult to distinguish infected from vaccinated animals, complicating efforts to track the disease. Additionally, vaccination campaigns, if not carried out properly, could result in entrenchment of the disease rather than eradication, further threatening public health.⁸¹

Cost of Culling. It has been suggested that a global fund should be established to compensate farmers for culling their poultry in countries whose governments can not afford to compensate the farmers. The WHO has already expressed concern that some farmers in poorer countries may not cull their poultry, because their livelihoods depend on poultry farming. For example, Indonesia has carried out only a limited culling drive, because it lacks the funds to compensate farmers.⁸² Farmers in some parts of Romania reportedly failed to cull their birds despite government orders to do so. In some affected countries, public and animal health authorities are reluctant to destroy their population's dominant protein source and income. A number of bills, such as H.R. 4062 and its counterpart S. 1821, have been introduced that support the concept of a "Pandemic Fund", which could include funds for farmer compensation.

The World Bank announced that it would provide \$500 million in loans to poor countries struggling to fund national avian flu and pandemic preparedness plans —

⁸¹ Ilaria Capua and Stefano Manganon, "Vaccination for Avian Influenza in Asia," *Vaccine*, Vol. 22, 2004, pp. 4137-4138.

⁸² Perry, Michael, "Poor Asian farmers are weak link in bird flu fight." Reuters. September 19, 2005. [<http://www.alertnet.org/thenews/newsdesk/SYD28137.htm>]

a portion of which could be used to support poor farmers.⁸³ However, the Bank noted that \$1 billion could be needed over the next three years to help countries contain the spread of H5N1. The Asia Development Bank (ADB) also announced that it is prepared to provide at least \$470 million to support Asian anti-H5N1 and pandemic preparedness efforts.⁸⁴

Some have suggested that the United States target some foreign aid funds to help the affected governments — including Vietnam, Indonesia, Cambodia, and Laos — cover the cost of compensating individuals and companies for the destruction of their birds. In this view, such assistance could help the image of the United States in the region by demonstrating American concern and could minimize reluctance to slaughter infected flocks. Others would like to see increased assistance to prevent the spread of H5N1 among animals.

Global Economic Impacts

The International Monetary Fund recently released a report which outlined the potential global economic and financial impact of an avian flu pandemic. The report outlines some possible effects of a severe pandemic. According to the report, government finances might sharply deteriorate due to increased expenditure on health and public safety. Concurrently, IMF asserts that governments could experience a decrease in revenues as businesses and consumers avoid purchases, firms scale back production as employee attendance drops, and borders close. There could also be disruptions in payment systems leading to less revenue flow to national treasuries, the report predicts. Governments might also be indirectly affected if poultry businesses demand compensation, or if tourism, transport, retail, and insurance industries become bankrupt. Ultimately, the IMF document predicts that a severe avian flu pandemic could trigger a “sharp but short-lived impact” on the global economy. However, the report asserts that financially stable economies might be better equipped to contend with sharp fluctuations in GDP from quarter to quarter. The IMF document reported that countries previously affected by SARS, some countries that had recently dealt with avian flu outbreaks, and several countries with large, complex financial systems generally had more advanced preparations.⁸⁵

Many economists assert that health and non-health related sectors could be severely affected by a global influenza pandemic, though it would be difficult to predict the costs of those effects. For example, Canadian and Asian hospitality and tourism sectors were considerably impacted during the SARS outbreak. In 2002 and 2003, SARS cost the Asia-Pacific region about \$40 billion.⁸⁶ Additionally, flights

⁸³ World Bank, “New Global Program to Deal with Avian Flu.” November 4, 2005. [<http://www.worldbank.org>]

⁸⁴ ADB, “ADB Support for Asia’s Fight Against Avian Flu Could Reach \$470 Million.” November 9, 2005. [<http://www.adb.org/Documents/News/2005/nr2005173.asp>]

⁸⁵ IMF, *The Global Economic Impact of an Avian Flu Pandemic and the Role of the IMF*. February 28, 2006. [<http://www.imf.org/external/pubs/ft/afp/2006/eng/022806.htm>]

⁸⁶ Osterholm, Michael, “Preparing for the Next Pandemic.” *Foreign Affairs*, July/August (continued...)

to the region fell by about 45%, crippling the airline and hotel industries. Canada estimated that it lost approximately \$1.2 billion, with about \$763 million spent on the health-care system.⁸⁷ In the event of a flu pandemic, researchers expect Britain, Greece, Spain, Italy, and other countries that rely heavily on tourism, to be most affected economically. One economist estimated that a flu pandemic could force Britain's GDP to fall by 8% or \$168 billion (about 95 billion pounds), and result in the loss of almost 1 million jobs (about 3% of all employment).⁸⁸

The World Bank estimates that a global influenza pandemic could cost the global economy about \$200 billion in one quarter or \$800 billion over a year (about 2% of the global GDP). The Bank based its estimate on the economic losses induced by the SARS pandemic, which caused GDP to fall by 2% in Asia over a three month period in 2003. However, the Bank underscored that it is virtually impossible to accurately determine how much a global influenza pandemic would cost the world, because experts assume that the immediate shock during a flu epidemic could be larger and last longer than SARS. The 1918 pandemic, for example, came in three waves, and spread over two years.⁸⁹ Some economists have advised the United States to identify source countries for key imports and develop a detailed plan that would ensure continuity.

Economists point out that an Asian economy crippled by an influenza pandemic could impact the U.S. economy, even if a significant number of Americans was not sickened or killed by H5N1. According to U.S. Trade Representative (USTR) Robert Portman, South Korea and Malaysia are the 7th and 10th largest trading partners for the United States, respectively. The United States earned \$72 billion and \$40 billion from South Korea and Malaysia, respectively, in 2004. Both countries have had H5N1 cases among their flocks.⁹⁰ Additionally, U.S. exports to China, one of the most threatened countries, grew 76 percent between 2000 and 2003, while sales to the rest of the world declined by 9 percent. China is now the sixth largest market for U.S. exports and America's third largest trading partner overall — surpassing Japan in 2003.⁹¹ In 2004, U.S. exports to China grew to \$33 billion, more than double the

⁸⁶ (...continued)

2005. [<http://www.foreignaffairs.org>].

⁸⁷ Ibid. Country-specific SARS-related information, including costs and fatalities can be found in CRS Report RL32072, *Severe Acute Respiratory Syndrome (SARS): The International Response*, by Rhoda Margesson and Tiaji Salaam.

⁸⁸ Nordland, Rod and George Wehrfritz, "A Costly Disease: Europe and the rest of the world braces for the economic fallout of a possible bird-flu pandemic." October 24, 2005. [<http://msnbc.msn.com/id/9711926/site/newsweek/>]

⁸⁹ World Bank East Asia and Pacific Region, "Spread of Avian Flu Could Affect Next Year's Economic Outlook." November 2005. [<http://siteresources.worldbank.org/INTEAPHALFYEARLYUPDATE/Resources/EAP-Brief-avian-flu.pdf>]

⁹⁰ U.S. Trade Representative Robert Portman discussion at the US-ASEAN Business Council Second Annual Asia Forum, November 1, 2005.

⁹¹ USTR website, "America's Trade with China." April 21, 2004. [<http://www.ustr.gov>]

level in 2001.⁹² Therefore, any pandemic related disruption of bilateral trade could have a large impact. Alternatively, some economists predict that U.S. poultry exports could increase as countries move to ban imported birds from countries with H5N1-endemic stocks.

CLSA Asia-Pacific Markets, the Asian investment banking arm of Crédit Agricole of France, estimates that H5N1 has already cost the region between \$8 billion and \$12 billion, citing the prolonged poultry ban by the European Union from eight Asian countries and the death or destruction of some 140 million chickens and other poultry. The Prime Minister of Thailand stated that the avian flu has already cost his country some \$1.09 billion, in addition to the \$55.78 million the government paid to farmers for a mass chicken cull.⁹³

Some analysts caution that Congress should be prepared to respond to the impact that potential fluctuations in supply and demand from key Asian markets might have on the U.S. economy. Particularly, some would like Congress to direct the U.S. Trade Representative to prepare a report that comprehensively analyzes the potential economic gains and losses to the U.S. economy in a pandemic scenario due to changes in Asia's economy. Experts point out that the Congressional Budget Office (CBO) report *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues* focuses on possible supply and demand changes in the U.S. economy if an H5N1 pandemic were to reach the United States.⁹⁴ The Wall Street Journal reported that the U.S. poultry industry currently exports about 15% of its chicken meat annually, earning \$2.2 billion in 2004. The article asserted that some poultry-industry executives are concerned that importing countries might reject poultry from states that have vaccinated the animals.⁹⁵ Consequently, many executives in the poultry industry are opposed to vaccinating chickens intended for export. Some would like Congress to require USDA to present clear guidelines on how and when poultry would have to be vaccinated.

Global Biosafety

In October 2005, scientists reported that the 1918 influenza pandemic that had killed between 20 million and 50 million people worldwide may have emerged from an avian flu strain. Health experts have debated whether the genetic sequence of the 1918 influenza should be published. Some were concerned that the information

⁹² USTR website, "Real Results in U.S. Trade with China." September 9, 2004. [<http://www.ustr.gov>]

⁹³ Bullion, Alan, "Threats on the Wing." *The World Today*, August/September 2005. Also see, Bradsher, Keith, "Some Asian Bankers Worry About the Economic Toll From Bird Flu." *New York Times*. April 5, 2005. [<http://www.nytimes.com>]

⁹⁴ CBO, *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues*. December 8, 2005. [<http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf>]

⁹⁵ Kilman, Scott, "Vaccine Remains Sticking Point in U.S. Defense Against Bird Flu." December 12, 2005. [<http://www.wsj.com>]. Basic screening tests for bird flu used by many importing countries leave ambiguous whether a bird testing positive is infected with H5N1 or has been vaccinated against it.

could be used to construct a biological weapon. However, other scientists argued that sharing such important findings is critical to efficiently identifying dangerous viruses, and to finding ways to disable them. Ultimately, the genetic sequence was published.⁹⁶ Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, and Dr. Julie Gerberding, Director of the CDC, said in a joint statement, “The new studies could have an immediate impact by helping scientists focus on detecting changes in the evolving H5N1 virus that might make widespread transmission among humans more likely.” Furthermore, the HHS National Science Advisory Board for Biosecurity “voted unanimously that the benefits [to making the results public] outweighed the risk that it would be used in a nefarious manner.”⁹⁷ However, the Administration acknowledged that the influenza virus could be used as a biological weapon and added the virus to the Select Agent list on October 20, 2005.⁹⁸ Congress authorized the Select Agent program in the late 1990s to track the movement of certain bacteria and viruses that could potentially be used as bioterrorist weapons.⁹⁹

Health specialists caution that lab safety must be a top priority as other countries begin to develop their own research and vaccine capacities. Some are closely watching Taiwan in its effort to build its own influenza vaccine factory.¹⁰⁰ Japan, already accomplished in viral research, is reportedly helping Vietnam build a biosafety lab to work with the influenza virus.¹⁰¹ If global influenza vaccine production is to increase, disease experts caution that some form of oversight must first be established. Some scientists advocate the development of an international influenza research facility. Supporters envision a global laboratory that could rapidly identify influenza threats, and produce appropriate vaccines. It also could, they say, streamline existing flu monitoring systems. Opponents of this idea believe that current technology, such as the WHO’s Internet-based FluNet, is fully capable of obtaining the same goal. Furthermore, critics believe that scientists might lose interest in sharing viral samples, if they believe their analytical and research capacities will be taken away.¹⁰²

⁹⁶ Kolata, Gina, “Experts Unlock Clues to Spread of 1918 Flu Virus.” *New York Times*, October 6, 2005. [<http://www.nytimes.com>]

⁹⁷ *Ibid.*

⁹⁸ CDC, “Possession, Use, and Transfer of Select Agents and Toxins — Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments.” 70 *Federal Register* 61407, October 20, 2005.

⁹⁹ For more information, see the CDC Select Agent Program page at [<http://www.cdc.gov/od/sap>] and CRS Report RL31719, *An Overview of the U.S. Public Health System in the Context of Emergency Preparedness*, by Sarah A. Lister.

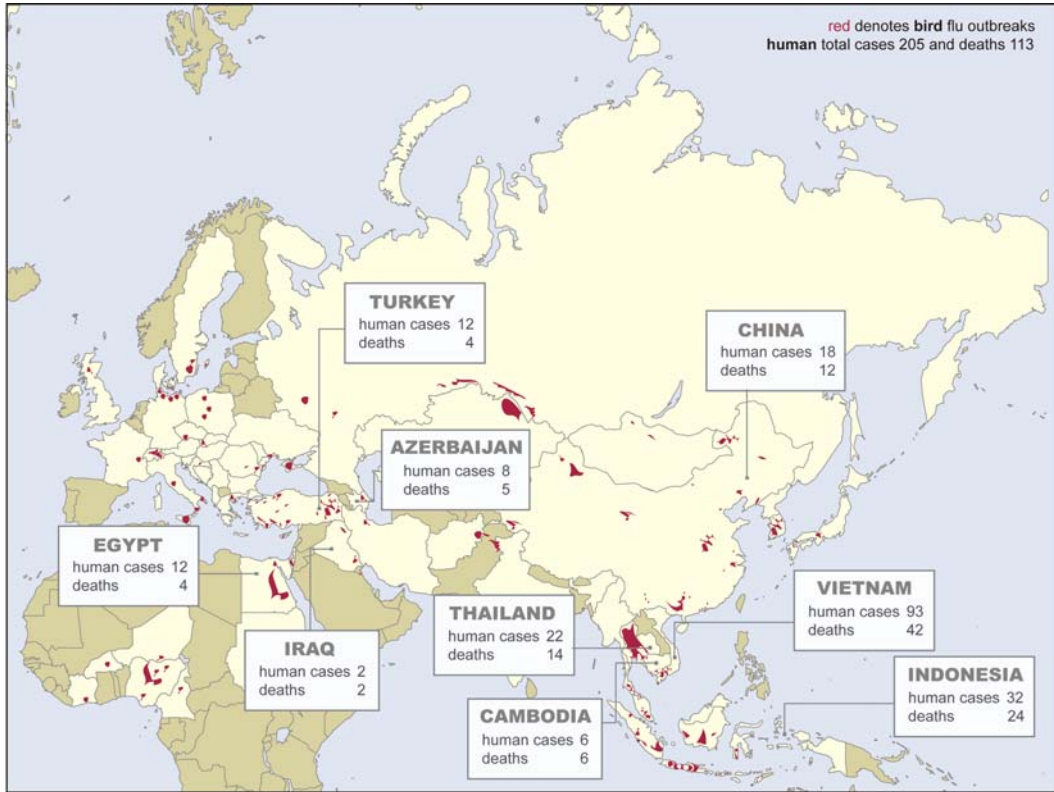
¹⁰⁰ Altman, Lawrence and Keith Bradsher, “Vaccine Alone Won’t Stem Avian Flu, Experts Warn.” *New York Times*. August 8, 2005. [<http://www.nytimes.com>]

¹⁰¹ Interview with State Department staff, October 18, 2005.

¹⁰² Abbott, Alison, “The flu HQ.” *Nature*, Volume 414, November 1, 2001. [<http://www.nature.com>]

Appendix

Figure 1. Map of Human and Animal H5N1 Cases



Source: Information based on the World Health Organization (WHO) website, and the World Organization for Animal Health (OIE) website.
Adapted by CRS. (K.Yancey 5/2/06)

Table 2. WHO Pandemic Phases

Phase	Description	Overarching Public Health Goals
Interpandemic Period		
Phase 1	No new influenza virus strains have been detected in humans. A virus strain that has caused human infection may be present in animals. If so, the risk of human infection is considered to be low.	Strengthen global influenza pandemic preparedness at the global, regional and national levels.
Phase 2	No new influenza virus strains have been detected in humans. However, a circulating animal influenza virus strain poses a substantial risk of human disease.	Minimize the risk of transmission to humans; detect and report such transmission rapidly if it occurs.
Pandemic Alert Period		
Phase 3	Human infection(s) with a new strain, but no human-to-human spread, or at most rare instances of spread to a close contact.	Ensure rapid characterization of the new virus strain, and early detection, notification and response to additional cases.
Phase 4	Small cluster(s) with limited human-to-human transmission, but spread is highly localized, suggesting that the virus is not well adapted to humans.	Contain the new virus within limited foci or delay spread to gain time to implement preparedness measures, including vaccine development.
Phase 5	Larger cluster(s), but human to human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).	Maximize efforts to contain or delay spread, to possibly avert a pandemic, and to gain time to implement pandemic response measures.
Pandemic Period		
Phase 6	Pandemic: increased and sustained transmission in the general population	Minimize the impact of the pandemic.

Source: World Health Organization.

Table 3. FY2005 and FY2006 Enacted Emergency Supplemental and FY2007 Request for Global Avian Influenza Initiatives
(\$ millions)

AGENCY	FY2005 Emergency Appropriations Enacted	FY2006 Emergency Appropriations Enacted	FY2007 Request
Department of Health and Human Services	15.0 ^a	114.0	145.0 ^b
Department of Agriculture		18.0	5.0 ^b
Department of Defense		10.0	Not available ^c
Department of State		6.0	0.0
USAID	16.3 ^d	132.0	55.0 ^b

Source: Prepared by CRS from FY2005 and FY2006 Emergency Supplemental appropriations, FY2007 budget requests were compiled from agency or department justifications, and interviews with CDC Washington officials.

- a. CDC Washington officials indicate that it spent \$6 million on international avian flu activities through FY2005 appropriations. This figure is in addition to the \$15 million provided through the FY2005 emergency supplemental.
- b. U.S. Office of Management and Budget (OMB).
- c. The FY2007 DoD Budget Justification did not specify a request for avian flu efforts.
- d. The FY2005 emergency supplemental permits the Secretary of State to transfer up to \$656 million to various U.S. agencies for avian flu activities. USAID received \$31.3 million of those funds, of which \$15 million was transferred to HHS. See Congressional Response section and Department of State 2007 Budget Request at [<http://www.state.gov/s/d/rm/rls/iab/2007/pdf/>].

Table 4. International Partnership on Avian and Pandemic Influenza (IPAPI) Core Principles

1. International cooperation to protect the lives and health of our people;
2. Timely and sustained high-level global political leadership to combat avian and pandemic influenza;
3. Transparency in reporting of influenza cases in humans and in animals caused by strains that have pandemic potential, to increase understanding, preparedness and, especially to ensure rapid and timely response to potential outbreaks;
4. Immediate sharing of epidemiological data and samples with the World Health Organization (WHO) and the international community to detect and characterize the nature and evolution of any outbreaks as quickly as possible, by utilizing, where appropriate, existing networks and mechanisms;
5. Rapid reaction to address the first signs of accelerated transmission of H5N1 and other highly pathogenic influenza strains so that appropriate international and national resources can be brought to bear;
6. Prevent and contain an incipient epidemic through capacity building and in-country collaboration with international partners;
7. Work in a manner complementary to and supportive of expanded cooperation with and appropriate support of key multilateral organizations (WHO, Food and Agriculture Organization, World Organization for Animal Health);
8. Timely coordination of bilateral and multilateral resource allocations; dedication of domestic resources (human and financial); improvements in public awareness; and development of economic and trade contingency plans;
9. Increased coordination and harmonization of preparedness, prevention, response and containment activities among nations, complementing domestic and regional preparedness initiatives and encouraging where appropriate the development of strategic regional initiatives;
10. Actions based on the best available science.

Source: State Department Press Release, "U.S. Launches International Partnership on Avian and Pandemic Influenza." September 22, 2005. [<http://www.state.gov/r/pa/prs/ps/2005/53865.htm>]