



The 2009 Influenza Pandemic: An Overview

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Summary

On April 29, 2009, in response to the global spread of a new strain of influenza, the World Health Organization (WHO) raised its influenza (“flu”) pandemic alert level to Phase 5, one level below declaring that a global influenza pandemic was underway. On June 11, as the virus continued to spread on several continents, WHO declared the outbreak to be an influenza pandemic (Phase 6). WHO’s pandemic declaration is based on the geographic spread of the virus, not on a worsening of the severity of the illnesses it causes.

Officials now believe the outbreak of the new flu strain began in Mexico in March 2009, or perhaps earlier. The novel “H1N1 swine flu” was first identified in California in late April. Health officials quickly linked the new virus to many of the illnesses in Mexico. Since then, cases have been reported around the world. As of June 11, 2009, almost 29,000 cases were reported in 74 countries, on all continents but Antarctica. Most of the reported cases are in Mexico, the United States, and Canada. However, increasing numbers of cases are now reported in Argentina, Chile, Australia, and other countries in the Southern Hemisphere, as their winter approaches and flu transmission becomes more efficient. Health officials note that reported cases likely represent only a fraction of actual infections. For example, a U.S. official commented in May that there may actually have been upwards of 100,000 cases thus far in the United States.

Investigations to date suggest that human infections with the new flu strain are usually mild, although severe illnesses and deaths have been reported. This pattern is similar to the behavior of seasonal flu, which circulates the globe each year. It is also consistent with the likelihood of substantial underreporting, as noted above. Health officials continue to monitor the situation, saying that the efficiency of viral transmission and the severity of illness could change.

When the outbreak began in late April, U.S. federal agencies adopted a pandemic response posture under the overall coordination of the Secretary of Homeland Security. Among other things, officials have released antiviral drugs from the national stockpile, and launched efforts to develop and manufacture a vaccine. The Obama Administration has requested about \$9 billion in emergency supplemental appropriations and contingent budget transfer authorities to address the threat. House and Senate appropriators have included pandemic flu funding in pending FY2009 supplemental appropriations. Congressional committees in both chambers have convened hearings to assess the situation.

This report first provides a synopsis of key events, actions taken, and authorities invoked by WHO, the U.S. federal government, and state and local governments. It then discusses the WHO process to determine the phase of a flu pandemic, and selected actions taken by the Departments of Homeland Security and Health and Human Services, and by state and local authorities. Next, it lists congressional hearings held to date, and provides information about appropriations and funding for pandemic flu activities. Finally, it summarizes U.S. government pandemic flu planning documents and lists sources for additional information about the situation as it unfolds. This report will be continually updated to reflect unfolding events.

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Synopsis

On April 29, 2009, in response to the global spread of a new “H1N1” strain of influenza, the World Health Organization (WHO) raised its influenza (“flu”) pandemic alert level to Phase 5, one level below declaring that a global influenza pandemic was underway. On June 11, as the virus continued to spread on several continents, WHO declared the outbreak to be an influenza pandemic (Phase 6). WHO’s pandemic declaration is based on the geographic spread of the virus, not on a worsening of the severity of illnesses it causes.

Officials now believe the outbreak of the new flu strain began in Mexico in March 2009, or perhaps earlier. The novel “H1N1 swine flu” was first identified in California in late April. Health officials quickly linked the new virus to many of the illnesses in Mexico. Since then, cases have been reported around the world. As of June 11, 2009, almost 29,000 cases were reported in 74 countries, on all continents but Antarctica. Most of the reported cases are in Mexico, the United States, and Canada. However, increasing numbers of cases are now reported in Argentina, Chile, Australia, and other countries in the Southern Hemisphere, as their winter approaches and flu transmission becomes more efficient. Health officials note that reported cases likely represent only a fraction of actual infections. For example, a U.S. official commented in May that there may actually have been upwards of 100,000 cases thus far in the United States.

2009 Influenza Pandemic Status

International: World Health Organization (WHO): Outbreak Status as of June 11, 2009

(<http://www.who.int/csr/disease/swineflu/en/index.html>)

- WHO declared an influenza pandemic (Phase 6) on June 11, 2009.
- WHO reports almost 29,000 cases in 74 countries around the world, including 144 deaths. Most of the reported deaths occurred in Mexico.
- WHO advises no restriction of regular travel or closure of borders; however, sick individuals are advised to delay travel. No infection risk from consumption of well-cooked pork products.

United States Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA): Outbreak Status as of June 5, 2009

(<http://www.cdc.gov/h1n1flu>; <http://www.fda.gov/h1n1flu>)

- CDC reports a total of 13,217 cases in all 50 states, DC, and PR, including 27 deaths. Officials say that reported cases most likely underestimate the actual number of infections.
- The Acting Health and Human Services Secretary declared a public health emergency on April 26.
- CDC has released to states 11 million treatment courses of the antiviral drugs Tamiflu and Relenza, and sent an additional 400,000 courses to Mexico.
- FDA has issued Emergency Use Authorizations for certain unapproved uses of Tamiflu and Relenza, and for use of an unapproved diagnostic test for the new H1N1 strain.
- CDC has issued mitigation guidance for the general public; specific guidance for clinicians and laboratories, and regarding pregnant women and other groups; and recommendations for affected schools and communities. CDC rescinded a prior recommendation against non-essential travel to Mexico.
- Federal government and manufacturers are developing a vaccine against the new H1N1 strain.

The new flu strain responsible for the outbreak is an apparent reassortment of several existing strains of influenza A subtype H1N1 virus, including strains typically found in pigs, birds, and humans (see box below). The U.S. Centers for Disease Control and Prevention (CDC) reports that the symptoms and transmission of the novel H1N1 flu from person to person are much like that of seasonal flu. Laboratory testing of the new strain indicates that the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) are expected, in most cases, to be effective in treating illnesses that result from this new strain.

In response to the situation, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), has assumed the role of Principal Federal Official, coordinating federal response efforts. Charles E. Johnson, then the Acting Secretary of Health and Human Services (HHS), declared a public health emergency. Among other things, this allowed the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs), permitting certain unapproved uses of Tamiflu and Relenza (such as in very young children), as well as the use of an unapproved diagnostic test for the new flu strain, and unapproved uses of some types of protective facemasks.

CDC has released stocks of Tamiflu and Relenza, respiratory protection devices, and other medical supplies, from the Strategic National Stockpile (SNS), to help states respond to the outbreak. CDC reports that it has released to state health officials 11 million of the 50 million treatment courses of Tamiflu and Relenza stockpiled in the SNS, and purchased additional courses to replenish the stockpile. CDC also has activated its Emergency Operations Centers to coordinate the agency's response to the outbreak, and sent 400,000 treatment courses of antiviral drugs to Mexico. CDC's initial advice to travelers to postpone all non-essential travel to Mexico has been rescinded, and travelers are now urged to take appropriate precautions while traveling.

According to DHS, U.S. border control agents are visually inspecting incoming travelers from Mexico, and referring those who appear to be sick to CDC quarantine stations or local health officials. Administration officials have resisted calls to implement more aggressive measures such as closing the U.S.-Mexico border, noting that the new flu strain is already in the United States and that the focus of mitigation strategies is on where U.S. illnesses are being reported, and on patients' families and their surrounding communities.

In the United States, many affected communities implemented school closures when students were found to be infected with the new H1N1 flu strain. Those decisions, made by local officials, were based on an initial CDC recommendation that communities with confirmed H1N1 flu cases consider closing schools for up to 14 days, depending on the extent and severity of illness. CDC revised its initial guidance as it became clear that the virus was circulating widely in affected communities and that illnesses caused by the new strain were generally mild. It now recommends against routine school closures when small number of students are infected, arguing that such closures do little to reduce the spread of a virus that is already in circulation while placing a considerable burden on the affected community. CDC's actions and those of local education authorities illustrate the challenges facing government officials as they attempt to make evidence-based decisions about community mitigation interventions in a constantly changing environment.

Health officials note that as the new flu strain spreads and the number of reported cases grows, precise case counts are less meaningful for purposes of disease control. The CDC has begun tracking illnesses at the population (rather than individual) level using its multi-layered surveillance system for seasonal flu, which tracks hospitalizations, outpatient medical visits, and other measures. One CDC official commented that reported cases of H1N1 flu probably represent only a fraction of actual cases, saying that early findings from the seasonal flu surveillance

systems suggest that the actual number of cases in the United States thus far may be upwards of 100,000.¹

The U.S. response to the current situation triggers a slate of pandemic flu plans that were developed, beginning around 2004, to address concerns about the global spread of another novel flu strain, the H5N1 avian flu. In FY2006 supplemental appropriations, Congress provided \$6.1 billion for pandemic planning across several departments and agencies.² These earlier efforts, and others aimed at preparedness for bioterrorism and emerging infections in general, have generally streamlined the response to the new H1N1 flu.

Influenza Defined

Influenza (“flu”) is a respiratory illness that can be transmitted from person to person. Flu viruses are of two main genetic types: Influenza A and B. Influenza A strains are further identified by two important surface proteins that are responsible for virulence: hemagglutinin (H) and neuraminidase (N).

Seasonal flu circulates each year in the winter in each hemisphere. The dominant flu strains in global circulation change from year to year, but most people have some immunity; infection can be fatal. CDC estimates that there are about 36,000 deaths from seasonal flu each year, on average. Vaccines are made each year based on predictions of the strains that are most likely to circulate in the upcoming flu season.

Avian flu (“bird flu”) is caused by viruses that occur naturally among wild birds, and that may also affect domestic poultry. In 1997 a new H5N1 strain of avian flu emerged in Asia, and has since caused millions of deaths among domestic poultry, and hundreds of deaths in humans. Health officials have been concerned that this strain could cause a human pandemic, and governments around the world have carried out a number of preparedness activities, including vaccine development and stockpiling, and planning for continuity of services.

Swine flu occurs naturally and may cause outbreaks among wild and domestic swine. People do not normally get swine flu, but each year CDC identifies a few isolated cases of human flu that are caused by flu strains typically associated with swine.

Pandemic flu is caused when a novel strain of human flu (i.e., one that spreads from person to person) emerges and causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease is often more severe than is typical of seasonal flu.

(Adapted from HHS, “Flu Terms Defined,” <http://www.pandemicflu.gov>. For more information about pandemic flu, see “Understanding Pandemic Influenza” in CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*.)

To address the threat, the Obama Administration has requested more than \$4 billion in emergency supplemental appropriations, and has asked for budget transfer authorities to mobilize additional amounts. Funds were also requested in regular FY2010 appropriations. House and Senate appropriators have included pandemic flu funding in pending FY2009 supplemental appropriations legislation. Congressional committees in both chambers have convened hearings to assess the situation.

Efforts to prepare for a possible mass vaccination campaign are underway, including development of and clinical trials on a prototype vaccine, and limited mass production of pilot lots. Federal officials note that a decision to actually administer vaccine broadly across the population would be made separately, based on circumstances in the future.

¹ Comments of Dr. Dan Jernigan, deputy director of CDC’s influenza division, “CDC Telebriefing on Investigation of Human Cases of H1N1 Flu,” transcript, May 15, 2009, <http://www.cdc.gov/media/>.

² CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

This report describes the WHO process to determine the phase of a threatened or emerging flu pandemic and touches on several related issues. It then provides additional information about selected actions taken by the Departments of Homeland Security (DHS) and Health and Human Services (HHS), and by state and local authorities; lists congressional hearings held to date; and provides information about appropriations and funding for pandemic flu activities. Finally, the report summarizes U.S. government pandemic flu planning documents and lists sources for additional information about the situation as it unfolds. All dates refer to 2009 unless otherwise specified. This report will be continually updated to reflect unfolding events.

Key Official Actions by WHO

Determination of Influenza Pandemic Phase

The World Health Organization is the coordinating authority for health within the United Nations system. It is responsible for providing leadership, guiding a research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. WHO does not have enforcement powers.

An influenza pandemic occurs when a novel flu strain emerges and spreads across the globe, causing human illnesses. For that to happen, the virus must have the following features: it must be genetically novel so that there is a lack of preexisting immunity; it must be pathogenic (i.e., capable of causing illness in humans); and it must be easily transmitted from person to person.

WHO, in consultation with experts in member countries, monitors the spread of influenza among human populations, and has developed a scale to monitor pandemic risk. It consists of five “pre-pandemic” phases with increasing incidence of animal and then human illness and transmission, and a sixth phase that represents a full-blown human pandemic, with sustained viral transmission and outbreaks in most or all regions of the world. Historically, flu pandemics have occurred in multiple waves before subsiding. **Table 1** describes WHO’s phases of a flu pandemic.

As a result of the rapid spread of the new flu strain, WHO raised the pandemic alert level from Phase 3, where it had been for several years because of the threat of H5N1 avian flu, to Phase 4 on April 27, and then to Phase 5 on April 29.³ Phase 3 meant that a novel flu strain was causing sporadic small clusters of human illness, but was not sufficiently transmissible to sustain community-level outbreaks. Phase 4, by contrast, signaled that human-to-human transmission of the new H1N1 virus was sufficient to sustain community-level outbreaks. According to WHO, raising the alert level to Phase 5 meant that there was sustained community-level transmission in two or more countries within one WHO region, and that a pandemic could be imminent. The pandemic phases are depicted in graphical form in **Figure 1**. The figure displays Phases 5 and 6 together, signifying that Phase 5 is a call for concerted global pandemic response efforts.⁴

³ WHO, “Influenza A(H1N1),” <http://www.who.int/csr/disease/swineflu/en/index.html>.

⁴ WHO, and its regional office for the Americas, the Pan American Health Organization (PAHO), have also developed interactive maps to track the locations of cases of the new H1N1 flu strain. WHO maps are updated and linked from daily situation updates at <http://www.who.int/csr/disease/swineflu/en/index.html>; see, also, PAHO, “Laboratory Confirmed Human Cases of Influenza A/H1N1,” <http://ais.paho.org/flu/sm/en/atlas.html>.

On June 11, WHO raised the level to Phase 6, declaring that an influenza pandemic, caused by the new H1N1 strain, was underway.⁵ According to WHO Director General Dr. Margaret Chan:

Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable.... The world is now at the start of the 2009 influenza pandemic. We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch. No previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning. The world can now reap the benefits of investments, over the last five years, in pandemic preparedness.⁶

Table I. WHO Influenza Pandemic Phases
(current alert level is highlighted)

Phase	Description
Phase 1	No animal influenza virus circulating among animals has been reported to cause infection in humans.
Phase 2	An animal influenza virus circulating in domesticated or wild animals is known to have caused infection in humans and is therefore considered a specific potential pandemic threat.
Phase 3	An animal or human-animal influenza reassortant ^a virus has caused sporadic cases of small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.
Phase 4	Human-to-human transmission of an animal or human-animal influenza reassortant ^a virus able to sustain community-level outbreaks has been verified.
Phase 5	The same identified virus has caused sustained community-level outbreaks in two or more countries in one WHO region. ^b
Phase 6	An influenza pandemic. In addition to the criteria defined in Phase 5, the same virus has caused sustained community-level outbreaks in at least one other country in another WHO region. ^b
Post-peak Period	Levels of pandemic influenza in most countries with adequate surveillance have dropped below peak levels.
Possible New Wave	Level of pandemic influenza activity in most countries with adequate surveillance rising again.
Post-pandemic Period	Levels of influenza activity have returned to the levels seen for seasonal influenza in most countries with adequate surveillance.

Source: Adapted from WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Table I, p. 13, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

- a. A reassortant virus results from a genetic reassortment process in which genes from animal and human influenza viruses mix together to create a new strain.
- b. WHO governs through six regional offices that do not strictly correspond with the world's continents. The WHO regions are the African Region; the Region of the Americas; the South-East Asia Region; the European Region; the Eastern Mediterranean Region; and the Western Pacific Region. See "WHO—Its People and Offices," <http://www.who.int/about/structure/en/index.html>.

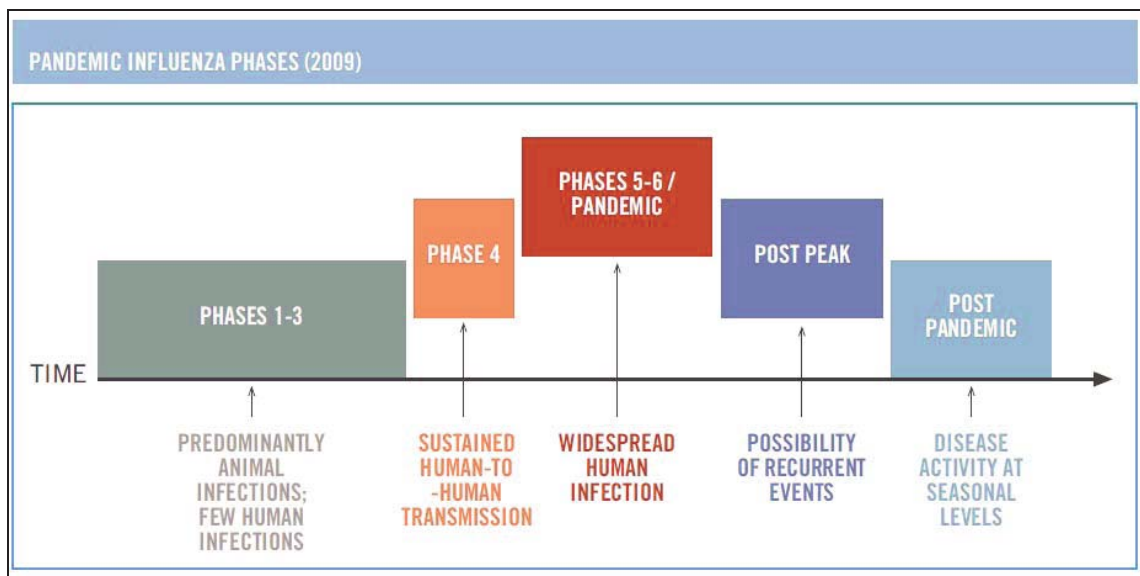
For several years, WHO urged governments, corporations, and other interests to develop pandemic influenza preparedness and response plans. Generally these plans are staged according

⁵ WHO, "World Now at the Start of 2009 Influenza Pandemic" (Statement of Dr. Margaret Chan), press release, June 12, 2009, <http://www.who.int/csr/disease/swineflu/en/index.html>.

⁶ Ibid.

to WHO pandemic phases. WHO has noted that under the current definitions, pandemic phases do not reflect the severity of illness, but rather the global extent of sustained community-level outbreaks. Some members of the public, however, have come to think of any flu pandemic as a catastrophic incident on the scale of the one that occurred in 1918, or that many have feared might result from the deadly H5N1 avian flu if it became transmissible among humans. Some have argued that the definition of a pandemic should be rewritten to take severity into account, and that a Phase 6 pandemic designation for the current H1N1 flu situation could trigger over-reactions that were more disruptive than the disease.⁷

Figure 1. WHO Influenza Pandemic Phases



Source: WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Figure 3, p. 31, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

International Health Regulations

In 2005, the World Health Assembly adopted a revision of the International Health Regulations (IHR), giving a new mandate to WHO and member states to increase their respective roles and responsibilities for the protection of international public health. The IHR(2005) require signatory nations (which include the United States) to notify WHO of all events that may constitute a “Public Health Emergency of International Concern,” and to provide information regarding such events. The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and signatories to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.⁸

⁷ See, for example, Robert Roos, “WHO Drawing Closer to Declaring a Pandemic,” *CIDRAP News* (Center for Infectious Disease Research and Policy), June 2, 2009, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>.

⁸ For more information, see CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

On April 25, 2009, upon the advice of the Emergency Committee called under the rules of the IHR(2005), the WHO Director-General declared the global threat of H1N1 flu a Public Health Emergency of International Concern. This designation calls upon signatories to provide timely and transparent notification of events to WHO, to collaborate with other countries in disease reporting and control, and to adopt effective risk communication strategies to reduce the potential for international disease spread and the likelihood of unilateral imposition of trade or travel restrictions by other countries.⁹

Travel Guidance

A number of governments have instituted enhanced passenger screening practices at their borders, and policymakers have debated more extensive prohibitions against the entry of travelers from countries or areas affected by the outbreak. The WHO has consistently advised against movement restrictions as a means to control influenza, citing a lack of evidence of their effectiveness, coupled with their potentially harmful effects on public confidence, local economies, and trade.¹⁰

Food Safety Guidance

WHO has published a joint statement with Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (known by its French acronym, OIE), and the World Trade Organization (WTO), saying:

In light of the spread of influenza A(H1N1), and the rising concerns about the possibility of this virus being found in pigs and the safety of pork and pork products, we stress that pork and pork products, handled in accordance with good hygienic practices recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, will not be a source of infection.

To date there is no evidence that the virus is transmitted by food. There is currently therefore no justification in the OIE Terrestrial Animal Health Standards Code for the imposition of trade measures on the importation of pigs or their products.¹¹

Key U.S. Government Actions

Department of Homeland Security (DHS)

Leadership Designation

On April 27, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), stated in a press briefing that she was serving as the coordinator of the federal response to the flu

⁹ WHO, *International Health Regulations*, <http://www.who.int/ihr/en/>.

¹⁰ WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

¹¹ *Joint FAO, OIE, WHO and WTO Statement on A(H1N1) virus*, May 2, 2009, http://www.wto.org/english/news_e/news09_e/jt_stat_02may09_e.htm. See, also, CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 "Swine Flu": Questions and Answers*, by Renée Johnson.

outbreak, having assumed the role of Principal Federal Official (PFO).¹² According to the National Response Framework (NRF), which guides a coordinated federal response to disasters and emergencies in general, the Secretary of Homeland Security leads federal incident response.¹³

Customs and Border Protection (CBP) Activities

Customs and Border Protection (CBP), in DHS, is reportedly monitoring incoming travelers at ports of entry (typically a visual inspection for possible symptoms), providing information about disease control measures, and referring symptomatic persons to a CDC quarantine station¹⁴ or a local public health official for evaluation. According to CBP, “at this time all U.S. ports of entry are open and operating as normal with officers using risk based border screening.”¹⁵

Administration officials resisted calls to implement more aggressive measures such as closing the U.S.-Mexico border. They commented that such a measure could be highly disruptive and not necessarily effective at controlling the spread of disease, and argued instead that the new flu strain is already in the United States, and that the focus of mitigation strategies is on where U.S. illnesses are being reported, and on patients’ families and their surrounding communities.¹⁶ WHO and CDC officials have commented that scientific evidence does not support closure of a border to travelers as an effective means of controlling the spread of influenza.¹⁷

Department of Health and Human Services (HHS)

Determination of a Public Health Emergency

On April 26, Charles E. Johnson, then the Acting HHS Secretary, who is responsible for coordinating the public health and medical response to the flu outbreak, declared a public health emergency pursuant to Section 319 of the Public Health Service Act.¹⁸ Among other things, this authority enables FDA to implement an authority in the Federal Food, Drug, and Cosmetic Act—the so-called Emergency Use Authorization (discussed below)—allowing for the use of unapproved medical treatments and tests, under specified conditions, if needed during an incident.

¹² Department of Homeland Security, *Remarks by Secretary Napolitano at Media Briefing on H1N1 Flu Outbreak*, April 27, 2009, <http://www.dhs.gov/ynews/>.

¹³ CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by Bruce R. Lindsay. The PFO position has been controversial, however, because it may conflict with the role of the Federal Coordinating Officer (FCO), a leadership position established in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).

¹⁴ CDC, *Quarantine Stations*, http://www.cdc.gov/ncidod/dq/quarantine_stations.htm.

¹⁵ U.S. Customs and Border Protection, *CBP Monitors H1N1 Flu Outbreak; All Ports Operating Routinely*, April 30, 2009, <http://www.cbp.gov/xp/cgov/newsroom/alerts/flu/>.

¹⁶ See also “Closing the Border” in CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

¹⁷ Donald G. McNeil, “Containing Flu Is Not Feasible, Specialists Say,” *The New York Times*, April 29, 2009. See also WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

¹⁸ HHS, “HHS Declares Public Health Emergency for Swine Flu,” press release, April 26, 2009, <http://www.hhs.gov/news>. More information about this authority is available in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister, and CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

FDA: Emergency Use Authorizations

If an emerging public health threat is identified for which no licensed or approved product exists, the Federal Food, Drug and Cosmetic Act authorizes the FDA Commissioner to issue an Emergency Use Authorization (EUA) so that unapproved but potentially helpful countermeasures can be used to protect the public health.¹⁹ On April 27, pursuant to authority provided by the prior public health emergency determination, FDA issued EUAs to allow emergency use of (1) oseltamivir (Tamiflu) and zanamivir (Relenza) for the treatment and prophylaxis of influenza; (2) disposable respirators for use by the general public; and (3) an unapproved diagnostic test for the new flu strain.²⁰

CDC: Travel Notices

On April 27, CDC issued a Travel Health Warning, its highest advisory level, recommending that U.S. travelers avoid all nonessential travel to Mexico.²¹ (The agency had issued a Travel Health Precaution, the next lower advisory level, on April 25.) On April 28, the Department of State issued a travel alert to U.S. citizens of the health risks of travel to Mexico due to the flu outbreak, noting the CDC's Travel Health Warning of the previous day.²² On May 15, CDC downgraded the Travel Health Warning for Mexico, returning to the precaution level, and the Department of State lifted its travel alert. Travelers to Mexico are advised to be alert regarding local conditions, practice good hygiene, and consult with their physicians regarding any health conditions that could put them at higher risk of illness.²³ Each of these advisories regarding travelers leaving the United States is voluntary.

CDC: Disease Surveillance

Because illnesses with the novel H1N1 flu have generally been mild, health officials acknowledge that the disease may be substantially underreported. It is likely that for every infection that results in a health care encounter and a confirmed laboratory test, there are many mild infections for which victims don't seek care, and silent infections in which individuals may be infectious to others in the absence of symptoms. Health officials in many U.S. states and cities have stopped running confirmatory tests on every suspected case of H1N1 influenza, feeling that better use of epidemiology and laboratory resources can be made by monitoring disease spread to new areas, rather than repeatedly confirming its presence in an affected area.²⁴

¹⁹ Food and Drug Administration, *Guidance: Emergency Use Authorization of Medical Products*, July 2007, <http://www.fda.gov/oc/guidance/emergencysue.html>.

²⁰ Information is available at CDC, "Swine Flu: Emergency Use Authorization (EUA) of Medical Products and Devices," <http://www.cdc.gov/swineflu/eua/>, and FDA, "2009 H1N1 (Swine) Flu Virus," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>.

²¹ CDC, "Travel Health Warning: Travel Warning: Swine Influenza and Severe Cases of Respiratory Illness in Mexico—Avoid Nonessential Travel to Mexico," April 27, 2009.

²² U.S. Department of State, Bureau of Consular Affairs, "Travel Alert: Mexico - 2009-H1N1 Influenza," April 28, 2009.

²³ CDC, "Travel Health Precaution: Travel Health Warning for Novel H1N1 Flu in Mexico Removed," May 15, 2009, <http://www.cdc.gov/travel/content/travel-health-precaution/novel-h1n1-flu-mexico.aspx>; and U.S. Department of State, Bureau of Consular Affairs, "Travel Alert: Mexico - 2009-H1N1 Influenza," May 15, 2009, http://travel.state.gov/travel/cis_pa_tw/pa/pa_3028.html.

²⁴ This approach should not affect medical care. Clinicians are advised to provide care, including treatment with (continued...)

To get a clearer picture of the magnitude and spread of disease in the United States, CDC has begun tracking the H1N1 outbreak using its multi-layered surveillance system for seasonal flu.²⁵ The system showed that during the week ending May 30, 2009, there were higher levels of flu-like illness than is normal for this time of year, that flu activity had decreased in comparison to the previous few weeks, and that approximately 82% of all flu viruses reported to CDC that week were the new H1N1 strain.

To track seasonal flu, CDC collects, compiles, and analyzes information from various sources year round, and publishes a weekly report from October through mid-May. The surveillance system is a collaboration between CDC and state and local health departments, public health and private clinical laboratories, vital statistics offices, health care providers, clinics, and emergency departments. Information is collected from several different data sources, as follows:

- *Viral Surveillance:* About 80 U.S. WHO Collaborating Laboratories and 70 National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories across the country report the number of respiratory specimens tested and the number positive for flu virus. All state public health laboratories participate as WHO collaborating laboratories, along with some county public health laboratories and some large medical centers. Most NREVSS participants are hospital laboratories.
- *Outpatient Illness Surveillance:* Information on patient visits to health care providers for influenza-like illness (ILI) is collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet).
- *Mortality Surveillance:* Rapid tracking of influenza-associated deaths is done through two systems: (1) The 122 Cities Mortality Reporting System. Each week, the vital statistics offices of 122 cities report the total number of death certificates received and the number of those for which pneumonia or influenza was listed as the underlying or contributing cause of death; (2) Surveillance for Influenza-associated Pediatric Mortality. Influenza-associated deaths in children is a nationally notifiable condition. Laboratory-confirmed influenza-associated deaths in children are reported through the National Notifiable Disease Surveillance System.²⁶
- *Hospitalization Surveillance:* Two systems monitor hospitalizations with laboratory confirmed flu infections: (1) The Emerging Infections Program (EIP) Influenza Project conducts surveillance for laboratory-confirmed influenza-related hospitalizations in children and adults in 60 counties covering 12 metropolitan areas of 10 states.²⁷ (2) The New Vaccine Surveillance Network (NVSN) provides

(...continued)

antiviral drugs, based on the severity of a patient's symptoms, the presence of conditions that would place a patient at greater risk of severe infection, and other clinical considerations. It is not necessary that H1N1 flu be confirmed in order for appropriate treatment to be provided.

²⁵ Information in this section is drawn from CDC, "Novel Influenza A (H1N1) – Congressional Update," Issue #13, May 13, 2009; and CDC, "FluView: A Weekly Influenza Surveillance Report Prepared by the Influenza Division," <http://www.cdc.gov/flu/weekly/>.

²⁶ For more information, see CDC, "National Notifiable Diseases Surveillance System," <http://www.cdc.gov/ncphi/diss/nmdss/nmdsshis.htm>.

²⁷ San Francisco CA, Denver CO, New Haven CT, Atlanta GA, Baltimore MD, Minneapolis/St. Paul MN, Albuquerque NM, Las Cruces, NM, Albany NY, Rochester NY, Portland OR, and Nashville TN.

estimates of laboratory-confirmed flu hospitalization rates for young children in three counties: Hamilton County, OH; Davidson County, TN; and Monroe County, NY.

- *Summary of the Geographic Spread of Influenza:* State health departments report the estimated level of spread of flu activity in their states each week through the state and territorial epidemiologists' reports.

Vaccine Development and Use

Vaccination is considered the best preventive measure against influenza. But, because of continuous changes in the genes of flu viruses, vaccines must be “matched” to strains in circulation to provoke good immunity. Vaccine is currently produced through a time-consuming process, using chicken eggs, with a lead time of four months or more. Since a vaccine cannot be produced for a flu pandemic until that strain emerges, a matched vaccine would not be available for initial global pandemic response.²⁸ Recent U.S. pandemic planning efforts have focused on (1) expanding domestic capacity to mass-produce flu vaccine in the near term; (2) developing approaches to speed up and “stretch” existing production capacity, such as through the use of *adjuvants*, vaccine additives that boost the immune response so that a lower virus dose is effective; and (3) developing better approaches for flu vaccine production in the future. Although recent progress has been made to improve domestic production capacity, a vaccine for the current H1N1 pandemic will still be made using the egg-based process, with its significant lag time.

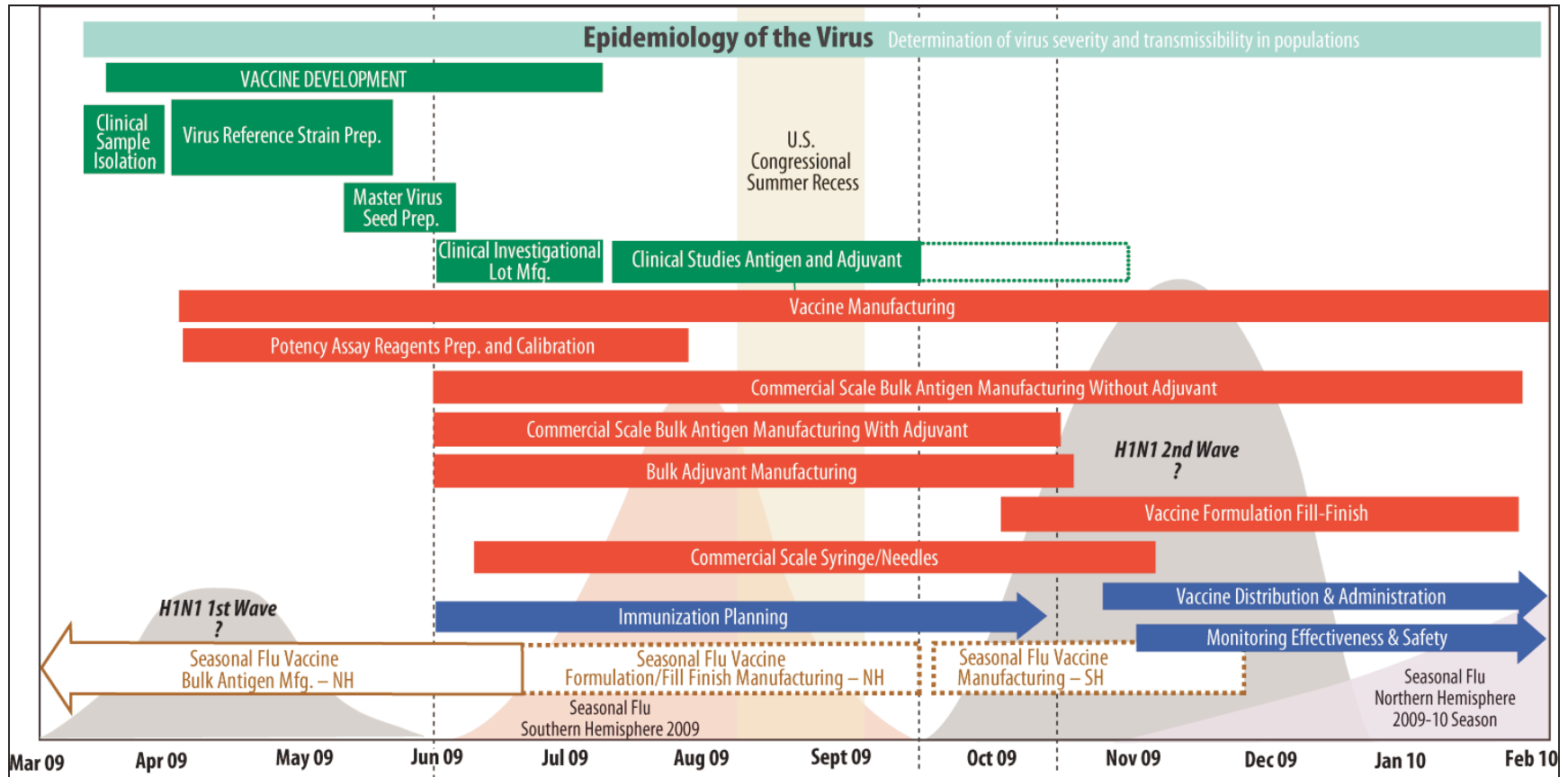
U.S. efforts to make a vaccine against H1N1 pandemic flu are underway. Federal officials have said that there are three key decision points in developing and using vaccines in response to a flu pandemic: (1) to develop prototype or “seed strain” viruses with the proper characteristics to produce a safe and effective vaccine, to develop a prototype vaccine(s), and to conduct clinical trials on the prototype(s); (2) to purchase and mass-produce large amounts of a promising vaccine; and (3) to administer the vaccine widely, that is, to conduct a mass-vaccination campaign. These decision points are presented, in a timeline of the U.S. pandemic flu vaccine strategy, in **Figure 2**. Each of these decision points is distinct. The first step has begun, and the second is partly underway. Officials note that it is important to begin production of a pandemic vaccine at this time, but that a decision to administer the vaccine, once it were available, would be made separately, based on conditions at the time.²⁹

Figure 2 also shows that there may be a second wave of transmission of H1N1 flu in the United States in the fall, which could occur between peaks of seasonal and pandemic flu activity in the Southern Hemisphere (i.e., during summer in the United States), and seasonal flu activity in the Northern Hemisphere (i.e., during our upcoming winter). The figure illustrates the three types of activities corresponding to the decision points noted earlier: (1) vaccine development; (2) vaccine manufacturing; and (3) vaccine distribution and administration. Each type of activity involves several distinct steps, some of which must be carried out sequentially, and others of which could be carried out simultaneously. The figure also shows the overlap between the production of seasonal flu vaccine for the Northern Hemisphere, and production of a vaccine against the pandemic strain.

²⁸ For more information about flu vaccine development and manufacturing, see Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines*, September 2008, <https://www.cbo.gov/ftpdocs/95xx/doc9573/09-15-PandemicFlu.pdf>.

²⁹ See, for example, transcript of CDC media briefing, comments of Dr. Anne Schuchat, June 11, 2009, <http://www.cdc.gov/media/>.

Figure 2. Proposed Timeline for H1N1 Vaccine Development, Manufacturing, and Possible Distribution and Administration



Source: Adapted by CRS from background material provided for a meeting of the National Biodefense Science Board (administered by HHS) regarding the U.S. 2009 H1N1 vaccine strategy, May 22, 2009, <http://www.hhs.gov/aspr/conferences/nbsb/090522-nbsb-meeting.html>.

On May 22, HHS Secretary Kathleen Sebelius announced that approximately \$1 billion in existing funds were to be used for clinical trials on H1N1 prototype vaccines, to be conducted over the summer, and for commercial-scale production of two potential vaccine ingredients for the pre-pandemic influenza stockpile.³⁰ Also in May 2009, HHS issued new orders on existing contracts with several flu vaccine manufacturers to produce a bulk supply of vaccine antigen and adjuvant and to produce pilot (also called investigational) lots of a 2009 H1N1 vaccine. Most of this would be stored in bulk, and a small amount would be prepared as vaccine for use in clinical studies to evaluate vaccine safety and the dosage required for a protective effect. This research is to include studies with adjuvant to determine its safety and the effect it would have on the immune system's response.³¹ These efforts are led by the HHS Biomedical Advanced Research and Development Authority (BARDA), in coordination with FDA, CDC, and other HHS agencies.

If federal officials decide to request and purchase enough vaccine against H1N1 flu to support a mass vaccination campaign, sufficient doses³² would not be available until the fall of 2009, because of the timing and capacity limitations discussed earlier. Financing for this purchase would also have to be established. President Obama has requested substantial funding and budget transfer authority in pending FY2009 supplemental appropriations, which could support this objective. (See the section "Emergency Supplemental Appropriations for FY2009".)

If federal officials also decide to launch a mass vaccination campaign, several key decisions would have to be made. It is not yet clear whether such a campaign would use the private-sector distribution mechanism that delivers seasonal flu vaccine each year, or the public sector mechanism that CDC, state, and local officials have practiced to distribute countermeasures from the Strategic National Stockpile. This key decision would affect several others, including how to prioritize vaccine (which would become available in phases) to those most in need,³³ and how to track who has received the vaccine, and any adverse events that occur in those who receive it.

Naming the Virus Strain

When news of the outbreak of a new flu strain emerged, WHO, CDC, and others referred to the virus as H1N1 "swine influenza" or "swine-origin influenza." This is based on the presumed evolutionary origin of the strain from strains that circulate in swine, since it contains genetic material typically found in North American and Eurasian swine flu strains. There has been no

³⁰ HHS, "HHS Takes Additional Steps Toward Development of Vaccine for the Novel Influenza A (H1N1)," press release, May 22, 2009, <http://www.hhs.gov/news/>.

³¹ HHS, Biomedical Advanced Research and Development Authority (BARDA), "HHS 2009 H1N1 Vaccine Development Activities," <https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/factsheet.aspx>, and "2009-H1N1 Influenza Vaccine Development Next Steps: Questions and Answers," <https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/nextsteps.aspx>.

³² Presuming that two doses of vaccine per person would be needed to provoke good immunity, approximately 600 million doses would be needed for a universal vaccination campaign in the United States.

³³ If necessary, CDC would provide guidance based on the epidemiology of infections at the time. Currently, people with underlying chronic health conditions appear to be at greater risk from severe illness from H1N1 flu, and the elderly appear to be at lower risk than is typically seen with seasonal flu. These patterns could change as the pandemic progresses. For information about possible approaches to the prioritization of vaccine, see CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones; and "Rationing Scarce Resources" in CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.

evidence to date that pigs are involved in the transmission of this virus to humans, however. There have been concerns that the term “swine flu” has had unwarranted economic and trade implications for swine and pork products, among other concerns.³⁴ Others have raised concerns that because of religious practices that call for the avoidance of swine and pork products by some persons of Jewish or Muslim faiths, disease control measures may be compromised in these groups if illness is perceived as a social stigma. On April 29, 2009, officials from HHS, DHS, and other federal agencies referred to the virus as “2009 H1N1.”³⁵ On April 30, 2009, WHO began referring to the new strain as influenza A(H1N1).

On May 2, the Canadian Food Inspection Agency reported finding the H1N1 outbreak strain in a swine herd in Alberta, the first time the strain has been identified in swine. Preliminary investigation suggests that the herd was exposed to the virus from a Canadian worker who had recently returned from Mexico and had been exhibiting flu-like symptoms when he worked in proximity to the swine.³⁶

Key State and Local Actions

School Closures³⁷

When the H1N1 outbreak first began in the United States, many affected communities closed schools when students were found to be infected with the new flu strain. Legal authority to close schools rests with state or local officials and is highly variable among the states. A CDC-requested study found that school closure is legally possible in most jurisdictions during both routine and emergency situations.³⁸ The study also indicated that state authority for closure may be vested at various levels of government and in different departments, generally the state or local education agencies or state or local departments of health.

In keeping with its obligation to provide public health assistance to states, on May 1, CDC, in consultation with the U.S. Department of Education, issued guidance with respect to school closures during the outbreak, recommending that “affected communities with laboratory-confirmed cases of influenza A H1N1 consider adopting school dismissal and childcare closure measures, including closing for up to 14 days depending on the extent and severity of illness.”³⁹

³⁴ CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”*: *Questions and Answers*, by Renée Johnson.

³⁵ See, for example, HHS, “Secretary of Health and Human Services Kathleen Sebelius Holds News Conference on Swine Flu,” transcript, comments of Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health, April 29, 2009.

³⁶ Canadian Food Inspection Agency, “An Alberta Swine Herd Investigated for H1N1 Flu Virus,” press release, May 2, 2009, <http://www.inspection.gc.ca/english/animad/disemala/swigri/swigrie.shtml>.

³⁷ For more information, see “School Closures” in CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones, and CDC, “Guidance for Child Care Programs, Schools, Colleges and Universities,” <http://www.cdc.gov/h1n1flu/guidance/>.

³⁸ James G. Hodge, Jr., Dhruvajyoti Bhattacharya, and Jennifer Gray, “Legal Preparedness for School Closures in Response to Pandemic Influenza and Other Emergencies,” <http://www.pandemicflu.gov/plan/school/schoolclosures.pdf>.

³⁹ CDC, “Change in CDC’s School and Childcare Closure Guidance,” press release, May 5, 2009, <http://www.cdc.gov/media/>. See, also, U.S. Department of Education, “H1N1 Flu Information,” <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>.

The guidance for this particular outbreak was derived from earlier broad guidance for pandemic planners, issued by CDC in 2007.⁴⁰

School closures are challenging for all parties involved. Among other things, parents must find alternate arrangements for care of their children, educators must adopt alternate means of delivering their services, and children's education may be compromised. On May 5, CDC officials reissued their guidance regarding school closures. Noting that the disease appeared to be widespread and generally mild, CDC said that under the circumstances, widespread school closures may be more burdensome than beneficial to affected communities. The revised guidance recommended against closures based on individual cases of H1N1 flu. It recommended instead that emphasis be placed on keeping sick students and employees home, and that closings be considered if the burdens of infection and absenteeism were substantial.⁴¹

Early in the H1N1 outbreak, officials in some school districts were criticized for being too aggressive, sometimes closing schools in entire districts for isolated cases in individual schools. Since then, New York City has continued to struggle with H1N1 outbreaks in schools, prompting "some parents, school staff and teachers' union officials [to wonder] whether the city was moving too slowly to close schools with high absenteeism."⁴² CDC's actions and those of local education authorities illustrate the challenges facing government officials as they attempt to make evidence-based decisions about community mitigation interventions in a constantly changing environment.

As with CDC guidance in general, recommendations regarding school closure are intended to be weighed by local officials in light of local circumstances. In the original guidance, as quoted above, CDC recommended that state and local officials "consider adopting school dismissal and childcare closure measures, including closing for up to 14 days depending on the extent and severity of illness."⁴³ Although this language placed considerable discretion in local hands, local officials may initially have been reluctant to scale back from immediate 14-day closures when the virus was detected. In addition to initial uncertainty about the outbreak's severity, there may also have been uncertainty about local decision-making protocols. In an assessment of state pandemic flu preparedness conducted by HHS and DHS in 2007 through 2008, planning for student dismissal and school closure was found to be a weakness among the states. More than half of them were graded as having either "many major gaps" or "inadequate preparedness" for this planning task.⁴⁴ The H1N1 outbreak will inform efforts by CDC, the Department of Education, and state and local officials to study "lessons learned" and refine their plans for future incidents.

⁴⁰ CDC, *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States - Early Targeted Layered use of Non-Pharmaceutical Interventions*, Appendix 6, Pandemic Influenza Community Mitigation Interim Planning Guide for Elementary and Secondary Schools, February 2007, pp. 87-91, <http://www.pandemicflu.gov/plan/community/index.html>.

⁴¹ CDC, "Update on School (K-12) and Child Care Programs: Interim CDC Guidance in Response to Human Infections with the Novel Influenza A (H1N1) Virus," May 5, 2009 (continually updated), http://www.cdc.gov/h1n1flu/K12_dismissal.htm.

⁴² Anemona Hartocollis and Javier C. Hernandez, "Fears of Swine Flu Close Three More Schools," *The New York Times*, May 15, 2009.

⁴³ CDC, "Change in CDC's School and Childcare Closure Guidance," press release, May 5, 2009, <http://www.cdc.gov/media/>.

⁴⁴ HHS and DHS, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, "Operating Objective B.4-Enhance State Plans to Enable Community Mitigation through Student Dismissal and School Closure," January 2009, pp. 25-26, http://www.pandemicflu.gov/plan/states/state_assessment.html.

Congressional Hearings

Congressional committees in both chambers have convened or planned hearings to assess the emergence of the new strain of H1N1 influenza. Hearings are listed below.

Senate

Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *The Public Health Response to the Swine Flu Epidemic*, April 28, 2009.

Committee on Health, Education, Labor, and Pensions, *The Swine Flu Epidemic: The Public Health and Medical Response*, April 29, 2009.

Committee on Homeland Security and Governmental Affairs, *Swine Flu: Coordinating the Federal Response*, April 29, 2009.

Appropriations Agriculture, Rural Development, and FDA Subcommittee, *Hearing to Discuss the 2009 H1N1 Virus*, May 7, 2009.

Homeland Security and Governmental Affairs, Subcommittee on State, Local and Private Sector Preparedness and Integration, *Pandemic Flu: Closing the Gaps*, June 3, 2009.

Homeland Security and Governmental Affairs, Subcommittee on Oversight of Government Management, the Federal Workforce and the District of Columbia, *Pandemic Flu Preparedness and the Federal Workforce*, June 16, 2009.

House

Committee on Energy and Commerce, Subcommittee on Health, *Swine Flu Outbreak and the U.S. Federal Response*, April 30, 2009.

Foreign Affairs Committee, Subcommittee on Africa and Global Health, *Global Health Emergencies Hit Home: The Swine Flu Outbreak*, May 6, 2009.

Committee on Education and Labor, *Ensuring Preparedness Against the Flu Virus at School and Work*, May 7, 2009.

Committee on Oversight and Government Reform, Subcommittee on the Federal Workforce, Postal Service, and the District of Columbia, *Protecting the Protectors: An Assessment of Front-Line Federal Workers in Response to the H1N1 Flu*, May 14, 2009.

Committee on Oversight and Government Reform, *State and Local Pandemic Preparedness*, May 20, 2009.

Appropriations and Funding

Public Health Emergency Funding Mechanisms

For the response to a public health incident the HHS Secretary may, under certain conditions, use two designated emergency funds, discussed below. Neither has received a prior appropriation, however, so the Secretary is not currently able to use these funding mechanisms for the response to the H1N1 flu outbreak.

The first mechanism is a no-year “Public Health Emergency Fund,” which becomes available to the HHS Secretary upon the determination of a public health emergency pursuant to Section 319 of the Public Health Service Act. This authority was invoked with respect to the H1N1 flu outbreak on April 26. (See the earlier section “Determination of a Public Health Emergency.”)⁴⁵

The other mechanism is the “Covered Countermeasure Process Fund,” which would be used to provide compensation to individuals for serious physical injuries or deaths from the use of medical countermeasures, as identified in a declaration issued by the HHS Secretary.⁴⁶ A declaration was issued for the use of the antiviral drugs Tamiflu and Relenza for a possible pandemic flu virus in October 2008.⁴⁷ If funds were available, compensation could be provided for serious physical injuries or deaths resulting from the use of these drugs in this situation, including for unapproved uses pursuant to the Emergency Use Authorization discussed earlier. (See “FDA: Emergency Use Authorizations.”) On May 7, the Administration released its FY2010 budget request, which included \$5 million for the fund.⁴⁸ On May 14, the House passed H.R. 2346, the Supplemental Appropriations Act, 2009, which would provide \$1.85 billion in supplemental appropriations to HHS for the response to the H1N1 outbreak and pandemic flu preparedness in general, and would allow some of the monies to be used for the Covered Countermeasure Process Fund. The version of H.R. 2346 passed by the Senate on May 21 would provide \$900 million to HHS for pandemic preparedness, but does not specifically mention the Covered Countermeasure Process Fund.⁴⁹

⁴⁵ For more information, see “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

⁴⁶ CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows. The compensation program is administered by the Health Resources and Services Administration (HRSA) in HHS.

⁴⁷ HHS, “Declaration Under the Public Readiness and Emergency Preparedness Act” (notice regarding use of Tamiflu and Relenza), 73 *Federal Register* 61861-61864, October 17, 2008.

⁴⁸ HHS, Health Resources and Services Administration, “Justification of Estimates for Congressional Committees, FY2010,” pp. 352-357, <http://www.hrsa.gov/about/budgetjustification/>.

⁴⁹ Information on the FY2009 supplemental appropriation is tracked in CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

Emergency Supplemental Appropriations for FY2009⁵⁰

On April 27, Representative Obey, the Chairman of the House Appropriations Committee, and Senator Harkin, the Chairman of the Senate Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, both suggested that Congress might add funds to the pending FY2009 defense supplemental appropriations request to respond to the H1N1 flu outbreak. On April 30, President Obama sent a letter to House Speaker Nancy Pelosi formally requesting \$1.5 billion for this purpose.

On May 14, the House passed H.R. 2346, the Supplemental Appropriations Act, 2009, which would provide more than \$2 billion for the current outbreak and pandemic preparedness, \$550 million above the request. The bill would provide the following amounts, with instructions:⁵¹

- \$1.85 billion to HHS for the Public Health and Social Services Emergency Fund, including no less than \$200 million to CDC for a number of specified activities, and no less than \$350 million to upgrade state and local public health capacity for responding to the outbreak.
- Of the \$1.3 billion to HHS that is not specifically designated, funds may be transferred to other HHS accounts and to other federal agencies, pursuant to certain notification requirements. These funds may also be used for purchases for the Strategic National Stockpile, and for construction or renovation of privately owned vaccine production facilities. Funds may also be provided to the Covered Countermeasure Process Fund, discussed above.
- \$200 million to the President for the Global Health and Child Survival account, to support global efforts to control the spread of the outbreak.

On May 14, the Senate Committee on Appropriations marked up and reported S. 1054, the Supplemental Appropriations Act, 2009, which would provide \$1.5 billion for influenza activities, the amount requested by the Administration.⁵² The committee recommended the funding for a new account under the Executive Office of the President, as requested. On May 21, the Senate passed an amended version of H.R. 2346, including the flu provisions in S. 1054, as follows:

- \$900 million to HHS for the Public Health and Social Services Emergency Fund, for allocation by the Secretary for pandemic preparedness and response activities including vaccine development, purchase of antivirals and medical equipment, diagnostic and vaccine delivery equipment, antiviral research, and support for state and local preparedness; and an additional \$50 million to the FDA for activities including vaccine and antiviral development, manufacturer assistance, approval reviews, and safety activities, including blood and consumer protection response.
- \$190 million to DHS for activities including planning and coordination, and purchasing personal protective equipment and antivirals for DHS personnel and state and local responders.

⁵⁰ Information in this section is tracked in greater detail in CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

⁵¹ H.Rept. 111-105, pp. 38-40 and 53-54.

⁵² S.Rept. 111-20, pp. 58-60.

- \$100 million to the Secretary of Agriculture for activities including animal health surveillance and disease investigation, and impacts resulting from misinformation about flu transmission.
- \$110 million for the Department of Veterans Affairs (VA), Veterans Health Administration, for activities including purchasing protective equipment for high-risk populations and occupations, expanding its antiviral stockpile, and improving information technology capabilities.
- \$150 million to the President for Global Health and Child Survival account, to facilitate information sharing, limit the spread of the virus, reduce mortality and the social and economic impacts, and respond to emergency needs in affected countries.

On June 2, while the House and Senate bills were in conference, President Obama sent another request to Speaker Pelosi, requesting the higher amount of \$2.05 billion provided in the House-passed bill, along with additional funding and transfer authorities, to address the current H1N1 flu outbreak and prepare for a possible pandemic.⁵³ The new request sought an additional \$2.0 billion in appropriations, and transfer authorities that could potentially mobilize more than \$6 billion in additional funding, all to be used only if the President were to determine that the additional resources were “required to address critical needs related to emerging influenza viruses....”⁵⁴

The magnitude of funds that could be mobilized under the requested transfer authorities suggests that the Administration may be looking for a means to purchase a large number of vaccines against the H1N1 virus. Funds currently available to HHS could support vaccine development and modest procurements, but would not be adequate for procurements and related activities sufficient to support a mass-vaccination campaign, if one were needed. GAO has noted that the *National Strategy for Pandemic Influenza: Implementation Plan* (2006), which lays out 324 action items for federal agencies to prepare for and respond to a flu pandemic, contains no discussion of the possible costs of these actions, or how they would be financed.⁵⁵ There has not been a Stafford Act declaration for the current flu outbreak, so disaster relief funds administered by the Federal Emergency Management Agency (FEMA) are not available for response efforts. Many relevant activities, such as vaccine purchase, would probably not be eligible for the use of these funds, even if they were available.⁵⁶

⁵³ Executive Office of the President, Office of Management and Budget, Estimate #5, 111th Cong., 1st Sess., June 2, 2009, http://www.whitehouse.gov/omb/assets/budget_amendments/supplemental_06_02_09.pdf.

⁵⁴ Ibid.

⁵⁵ U.S. Government Accountability Office, *Influenza Pandemic: Continued Focus on the Nation’s Planning and Preparedness Efforts Remains Essential*, GAO-09-760T, June 3, 2009, pp. 10-11, <http://www.gao.gov>. See also Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, <http://www.pandemicflu.gov/plan/federal/pandemic-influenza-implementation.pdf>.

⁵⁶ The Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) authorizes assistance to federal, state, and local governments, and private non-profit entities, upon a Presidential declaration of emergency or disaster. See “Federal Statutory Authorities for Disaster Response” and “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister. See also CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

Prior Funding for Pandemic Flu Preparedness

In the fall of 2005, in the aftermath of Hurricane Katrina, and as H5N1 avian flu was spreading across several continents, Congress provided \$6.1 billion in FY2006 supplemental appropriations for pandemic planning across several federal departments and agencies.⁵⁷ Since then, annual funding has been provided to CDC, FDA, and for other activities in HHS to continue work on vaccine development, stockpiling of countermeasures, and assistance to states. In total, from FY2004 through FY2009, HHS has received almost \$7 billion for pandemic flu preparedness.⁵⁸ (See **Table 2.**) The U.S. Departments of Agriculture and the Interior have also received annual funding to monitor avian flu in domestic poultry and wild birds, respectively. The U.S. Agency for International Development (USAID) has received funds to assist other countries in managing avian flu transmission to humans, and preparing for a possible pandemic.⁵⁹

In addition to amounts it specifically appropriates, Congress is also interested in how agencies budget for influenza within their existing activities. However, defining such amounts is difficult, for two reasons. First, for about 15 years, domestic public health capacity for infectious disease control has moved away from “categorical” funding and programs (i.e., one disease at a time), and toward the development of flexible capacity that can adapt to new, unanticipated threats. These flexible surveillance systems, laboratory networks, communications platforms, and other capabilities, can pivot rapidly to address new threats. But because pandemic planning efforts are tightly woven into the fabric of these flexible capabilities, it is not easy to tease out threads that describe the nation’s investment solely for pandemic flu preparedness. Any attempt to do so requires making judgments about what is “in” and “out” of scope that are somewhat arbitrary.

Second, for similar reasons, it can be difficult to tease apart investments made for pandemic flu, versus seasonal flu, versus avian or swine flu, versus investments in drug and vaccine development in general. Because different agencies use different methods and assumptions to account for their influenza spending, these amounts are not necessarily comparable between agencies, and caution is advised in adding such amounts together as if they were comparable.

HHS has tracked its pandemic influenza funding for the past several fiscal years, using comparable criteria from year to year. These amounts are presented in the department’s annual budget requests, in sections designated for pandemic influenza, and are presented in **Table 2.**

⁵⁷ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

⁵⁸ This amount is exclusive of any funds that may be provided in pending FY2009 supplemental appropriations.

⁵⁹ Information can be found in CRS Reports on the applicable appropriations bills, at http://apps.crs.gov/cli/level_2.aspx?PRDS_CLI_ITEM_ID=73, and: CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2004-FY2009*, by Tiaji Salaam-Blyther.

Table 2. HHS Funding for Pandemic Influenza, FY2004-FY2010

(dollars in millions, rounded)

Agency/Activity	FY2004	FY2005	FY2006 ^a	FY2007	FY2008	FY2009 ^b	FY2009 supp. req. ^c	FY2010 req.
OS and/or PHSSEF	50	99	5,152	0	75	585	0	354
CDC	0	0	400	70	155	156	0	156
FDA	0	0	20	33	35	39	0	39
NIH	0	0	18	35	34	35	0	35
Executive Office of the President	0	0	0	0	0	0	4,050	0
TOTAL, Program Level	50	99	5,590^d	138	299	815	4,050	584

Source: Compiled by Congressional Research Service from HHS annual "Budget in Brief" documents at <http://www.hhs.gov/asrt/ob/docbudget/>, unless otherwise noted below.

Notes: OS is Office of the HHS Secretary. PHSSEF is Public Health and Social Services Emergency Fund, an account administered by the Secretary, which Congress has typically used to provide one-time funding for non-routine activities. NIH is the National Institutes of Health.

- a. Appropriated in P.L. 109-148, the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, and P.L. 109-234, the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006. Funds are available until expended.
- b. Appropriated in P.L. 111-8, the Omnibus Appropriations Act, 2009. Pandemic flu funding was not included in P.L. 111-5, the American Recovery and Reinvestment Act of 2009 (ARRA), or other supplemental appropriations for FY2009.
- c. Amount requested includes \$2.05 billion as recommended by the House, and an additional contingent \$2 billion, to be used if needed. The President also requested the authority to mobilize several billion more dollars, if needed, through specified transfers. Executive Office of the President, Office of Management and Budget, Estimate #5, 111th Cong., 1st Sess., June 2, 2009, http://www.whitehouse.gov/omb/assets/budget_amendments/supplemental_06_02_09.pdf. For information on congressional actions, see CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.
- d. Total does not include \$30 million in supplemental funding to HHS that was transferred to the U.S. Agency for International Development (USAID).

U.S. Pandemic Influenza Preparedness Documents

In the George W. Bush Administration, pandemic flu preparedness efforts were coordinated by the Homeland Security Council.⁶⁰ Numerous federal and other documents that are specific to preparedness and response for a flu pandemic have been published. Selected documents are listed below. These plans are intended to address a pandemic caused by any so-designated flu strain, but

⁶⁰ Incident preparedness and response are different functions. At each level of government, they involve different leadership roles, legal authorities, organizational structures, and funding mechanisms. Generally, during an incident, certain conditions must be met before a jurisdiction can implement response activities, or access funds reserved for that purpose. With respect to the current H1N1 flu outbreak, the U.S. federal government has commenced pandemic flu response activities, under the overall coordination of the Secretary of Homeland Security.

they were written when there was significant global concern about H5N1 avian flu. To date, that flu strain has behaved quite differently from the current H1N1 outbreak strain. In particular, the H5N1 strain has not shown the ability to transmit efficiently from person to person, but human infections that result directly from contact with infected poultry have generally been very severe, and there has been a high fatality rate.⁶¹

Unless otherwise noted, the U.S. pandemic flu plans below can be found on a government-wide pandemic flu website managed by HHS.⁶²

- The *National Strategy for Pandemic Influenza*, November 2005, published by the Homeland Security Council, outlines general responsibilities of individuals, industry, state and local governments, and the federal government in preparing for and responding to a pandemic.
- *National Strategy for Pandemic Influenza, Implementation Plan*, May 2006, published by the Homeland Security Council, assigns more than 300 preparedness and response tasks to departments and agencies across the federal government; includes measures of progress and timelines for implementation; provides initial guidance for state, local, and tribal entities, businesses, schools and universities, communities, and non-governmental organizations on the development of institutional plans; provides initial preparedness guidance for individuals and families. One- and two-year implementation status reports have also been published.
- The *HHS Pandemic Influenza Plan*, November 2005, provides guidance to national, state and local policy makers and health departments, outlining key roles and responsibilities during a pandemic and specifying preparedness needs and opportunities. This plan emphasizes specific preparedness efforts in the public health and health care sectors.
- The *HHS Pandemic Influenza Implementation Plan, Part I*, November 2006, discusses department-wide activities: disease surveillance; public health interventions; medical response; vaccines, antiviral drugs, diagnostic tests, and personal protective equipment (PPE); communications; and state and local preparedness.
- *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early Targeted Layered use of Non-Pharmaceutical Interventions*, February 2007, published by CDC, guidance for “social distancing” strategies to reduce contact between people, with respect to: closing schools; canceling public gatherings; planning for liberal work leave policies; teleworking strategies; voluntary isolation of cases; and voluntary quarantine of household contacts.
- *Department of Defense Implementation Plan for Pandemic Influenza*, August 2006, provides policy and guidance for the following priorities: (1) force health protection and readiness; (2) the continuity of essential functions and services; (3) Defense

⁶¹ For more information about H5N1 avian flu and related public health concerns, see WHO, *Avian influenza*, http://www.who.int/csr/disease/avian_influenza/en/index.html; WHO, *Confirmed Human Cases of Avian Influenza A(H5N1)*, http://www.who.int/csr/disease/avian_influenza/country/en/; and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister (archived).

⁶² See <http://www.pandemicflu.gov/plan/federal/index.html>.

support to civil authorities (i.e., federal, state, and local governments); (4) effective communications; and (5) support to international partners.

- *VA Pandemic Influenza Plan*, March 2006, provides policy and instructions for Department of Veterans Affairs (VA) in protecting its staff and the veterans it serves, maintaining operations, cooperating with other organizations, and communicating with stakeholders.
- *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, published by DHS, September 2006, provides business planners with guidance to assure continuity during a pandemic for facilities comprising critical infrastructure sectors (e.g., energy and telecommunications) and key resources (e.g., dams and nuclear power plants).
- *State pandemic plans*: All states were required to develop and submit specific plans for pandemic flu preparedness, as a requirement of grants provided by HHS.⁶³

Key Information Sources

CRS Reports and Experts

2009 H1N1 “Swine Flu”: CRS Experts: <http://www.crs.gov/experts/WE04022.shtml>

Current CRS Reports on public health and emergency preparedness in general:
http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3276&from=3&fromId=13

Current CRS Reports on specific aspects of the pandemic influenza threat:

- CRS Report R40560, *The 2009 Influenza A(H1N1) Outbreak: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.
- CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.
- CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”:* *Questions and Answers*, by Renée Johnson.
- CRS Report R40588, *The 2009 Influenza A(H1N1) “Swine Flu” Outbreak: U.S. Responses to Global Human Cases*, by Tiaji Salaam-Blyther.
- CRS Report R40619, *The Role of the Department of Defense During A Flu Pandemic*, by Lawrence Kapp and Don J. Jansen.
- CRS Report RL32724, *Mexico-U.S. Relations: Issues for Congress*, by Mark P. Sullivan and June S. Beittel.

⁶³ For more information, see HHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January 2009, at <http://www.pandemicflu.gov/plan/states/index.html>, and CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

- CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?* by Edward C. Liu.
- CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.
- CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.
- CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by Frank Gottron.
- CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro.
- CRS Report RL31873, *Banking and Financial Infrastructure Continuity: Pandemic Flu, Terrorism, and Other Challenges*, by N. Eric Weiss.
- CRS Report RS22264, *Federal Employees: Human Resources Management Flexibilities in Emergency Situations*, by Barbara L. Schwemle.

Archived CRS Reports on the threat of pandemic influenza: These products generally discuss concerns about a possible human flu pandemic resulting from H5N1 avian influenza, and enhanced federal preparedness efforts during 2005 through 2007.

- CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.
- CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther.
- CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

World Health Organization (WHO) Information

- Information about the current H1N1 swine flu situation: <http://www.who.int/csr/disease/swineflu/en/index.html>
- Pandemic Influenza Preparedness and Response: A WHO Guidance Document, (April 2009): <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>
- Current phase of flu pandemic alert: http://www.who.int/csr/disease/avian_influenza/phase/en/index.html
- WHO, interactive world maps of reported cases are updated and linked from daily situation updates at <http://www.who.int/csr/disease/swineflu/en/index.html>
- Pan American Health Organization (PAHO), a regional office of the WHO, H1N1 flu page: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=805&Itemid=569
- PAHO, interactive map of reported cases in the Americas: <http://ais.paho.org/flu/sm/en/atlas.html>

- International Health Regulations (2005): http://www.who.int/topics/international_health_regulations/en/

U.S. Federal Government Information

- DHS, “Department Response to H1N1 (Swine) Flu,” with links to information in other federal departments and agencies: <http://www.dhs.gov/xprepresp/programs/swine-flu.shtm>
- CDC, H1N1 (swine flu) page: <http://www.cdc.gov/h1n1flu/>
- CDC Public Health Law Program, 2009 H1N1 Flu Legal Preparedness, <http://www2a.cdc.gov/phlp/H1N1flu.asp>
- FDA, 2009 H1N1 (Swine) Flu Virus, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>
- Department of Defense Pandemic Influenza Watchboard: <http://fhp.osd.mil/aiWatchboard/>
- Pandemic flu planning information: <http://www.pandemicflu.gov/> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)
- HHS Pandemic Planning Updates, addressing monitoring and surveillance, vaccines, antiviral medications, state and local preparedness, and communications, through January 2009: <http://www.pandemicflu.gov/plan/federal/index.html#hhs> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)

Additional Information

- Mexico, Ministry of Health (in Spanish): <http://portal.salud.gob.mx/>
- Canada: Public Health Agency of Canada: http://www.phac-aspc.gc.ca/alert-alerte/swine_200904-eng.php; Canadian Food Inspection Agency: <http://www.inspection.gc.ca/english/toce.shtml>
- Security and Prosperity Partnership of North America, *North American Plan for Avian and Pandemic Influenza*, August 2007, [http://www.spp-ppsp.gc.ca/eic/site/spp-ppsp.nsf/vwapj/pandemic-influenza.pdf/\\$FILE/pandemic-influenza.pdf](http://www.spp-ppsp.gc.ca/eic/site/spp-ppsp.nsf/vwapj/pandemic-influenza.pdf/$FILE/pandemic-influenza.pdf)
- Center for Infectious Disease Research and Policy (CIDRAP), at the University of Minnesota, frequent updates, including scientific and technical information, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>
- Centers for Law and the Public’s Health: A Collaborative at Johns Hopkins and Georgetown Universities, H1N1 (Swine Flu) Legal Preparedness and Response page: includes updates of “U.S. Federal, State, or Local Declarations of Emergency or Public Health Emergency,” <http://www.publichealthlaw.net/Projects/swinefluphl.php>

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