



The 2009 Influenza Pandemic: An Overview

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October 15, 2009

Congressional Research Service

7-5700

www.crs.gov

R40554

Summary

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be an influenza pandemic, the first since 1968. WHO said that the pandemic declaration was based on the geographic spread of the new virus, not on increasing severity of the illnesses it causes. Officials now believe the outbreak began in Mexico in March, 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.

When the outbreak began in late April, U.S. federal agencies adopted a response posture under the overall coordination of the Secretary of Homeland Security. Among other things, officials established a government-wide informational website (<http://www.flu.gov>), released antiviral drugs from the national stockpile, developed and released diagnostic tests for the H1N1 virus, and developed guidance for the clinical management of patients and the management of community and school outbreaks. The Obama Administration requested about \$9 billion in emergency supplemental appropriations to address the situation. On June 26, the President signed P.L. 111-32, the Supplemental Appropriations Act, 2009, which provided \$1.9 billion immediately, and an additional \$5.8 billion contingent upon a presidential request documenting the need for, and proposed use of, the additional funds.

U.S. health officials have procured millions of doses of pandemic flu vaccine, and have begun a voluntary nationwide vaccination program. It is being coordinated by state health officials and carried out through public clinics, private health care providers, schools, and others. The Secretary of Health and Human Services has implemented waivers of liability and an injury compensation program in the event of unforeseen vaccine safety problems. Allocation schemes have been developed to give priority for limited vaccine doses to high-risk groups.

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, selected activities by the Departments of Homeland Security and Health and Human Services, and selected activities 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. This report will be continually updated to reflect unfolding events.

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Synopsis

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be a flu pandemic, the first since 1968. WHO said that the pandemic declaration was based on the geographic spread of the new virus, not on increasing severity of the illnesses it causes. Officials now believe the outbreak began in Mexico in March, 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.

On July 16, WHO suspended worldwide case counts of illnesses caused by the virus, saying that tracking in this way was no longer helpful in monitoring the pandemic, but was burdensome for reporting countries. Health officials note that reported cases represented only a fraction of actual infections. In May, the U.S. Centers for Disease Control and Prevention (CDC) began 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. (See “CDC: Disease Surveillance.”)

2009 Influenza Pandemic Status as of October 9, 2009

International: World Health Organization (WHO):

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

- WHO declared an influenza pandemic (Phase 6) on June 11. On July 11, WHO asked nations to suspend routine reporting of cases, and stopped publishing case counts, saying they did not accurately reflect pandemic status.
- WHO advises no restriction of regular travel or closure of borders; however, sick individuals are advised to delay travel. Officials report no infection risk from consumption of well-cooked pork products.

United States Government:

(<http://www.flu.gov/>; <http://www.cdc.gov/h1n1flu/>; <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>)

- A Public Health Emergency is in effect (under Section 319 of the Public Health Service Act).
- CDC has released to states 11 million treatment courses of the antiviral drugs Tamiflu and Relenza.
- FDA has issued Emergency Use Authorizations for certain unapproved uses of Tamiflu and Relenza, for use of certain respirator masks, and for use of unapproved diagnostic tests for the H1N1 flu strain.
- CDC has issued guidances for the general public; for clinicians and laboratories; regarding pregnant women and other groups; regarding travel; regarding affected schools and communities; and others.
- Congress provided up to \$7.7 billion in emergency supplemental appropriations (P.L. 111-32).
- FDA has approved four vaccines against H1N1 flu, through the routine flu vaccine licensing process.
- Health officials have launched a vaccination campaign. HHS Secretary Sebelius has waived liability associated with the use of pandemic vaccine, and enabled an injury compensation program. Priority groups have been identified.

The H1N1 pandemic flu strain 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 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 generally effective in treating illnesses caused by the pandemic strain. In contrast to seasonal flu, the pandemic strain appears to cause serious illness more often among children, and less often among the elderly. However, like seasonal flu, pregnant women and individuals with serious chronic diseases appear to be at greater risk of serious illness from the pandemic strain.

In response to the outbreak in April, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), 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) and some types of protective facemasks, and the use of unapproved diagnostic tests for the new flu strain.

CDC released stocks of antiviral drugs, respiratory protection devices, and other medical supplies from the Strategic National Stockpile (SNS), to help states respond to the outbreak. CDC reported that it 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 activated its Emergency Operations Center to coordinate the agency's response activities, 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. HHS established a government-wide informational website (www.flu.gov), with information for planners, health care providers, and the public.

According to DHS, U.S. border control agents are visually inspecting incoming travelers, and following the standard procedure of referring those who appear to be sick to CDC quarantine stations or local health officials. Early in the outbreak, Administration officials resisted calls to implement more aggressive measures such as closing the U.S.-Mexico border, noting that the new flu strain was already in the United States and that the focus of mitigation strategies was on controlling the spread of infection in affected communities.

Many U.S. communities closed schools when students were found to be infected with the new flu strain. School closure decisions, made by local officials, were based on initial CDC guidance, which was revised as it became clear that the virus was in wide circulation, and that the illnesses it caused were generally mild. CDC now recommends against routine school closures when small numbers of students are infected, arguing that such closures may do little to reduce the spread of the virus, while placing a considerable burden on the affected community. This instance illustrates the challenges facing government officials as they attempt to make evidence-based decisions about community mitigation interventions in a constantly changing environment. (See "Pandemic Preparedness and Response in Schools.")

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

To address the situation, the Obama Administration requested about \$9 billion in emergency supplemental appropriations and transfer authority. On June 26, the President signed P.L. 111-32, which provides \$1.9 billion in FY2009 supplemental appropriations immediately, and an additional \$5.8 billion contingent upon a presidential request documenting the need for additional funds. The President has twice requested portions of the contingent funding. (See "Emergency Supplemental Appropriations for FY2009.")

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, however. 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 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*.)

A voluntary national pandemic vaccination campaign is underway. In June, HHS Secretary Kathleen Sebelius issued a declaration waiving liability and enabling a compensation program in the event injuries result from use of the vaccine. CDC has developed recommendations for groups that should be given priority in the event that vaccine becomes available in limited amounts. Costs associated with the program are being funded through both public and private sources. (See “Vaccination Program.”)

In August, the President’s Council of Advisors on Science and Technology (PCAST) released a report assessing preparations for a resurgence of pandemic flu in the fall, and recommending additional actions. The report also laid out a “plausible scenario” for a fall resurgence that could result in 30% to 50% of the U.S. population being infected, with up to 1.8 million hospitalizations and 90,000 deaths. The Council warned of the possibility of considerable strain on the nation’s health system. (See “Government-wide Pandemic Preparedness and Response.”)

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 DHS and HHS, and by state and local authorities; lists congressional hearings held to date; and provides information about appropriations and funding for pandemic flu preparedness and response activities. Finally, the report summarizes U.S. government pandemic flu planning documents, and lists sources for additional information about the situation. All dates in this report 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 the phases of a flu pandemic, as defined by WHO.

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 29.¹ 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.

On June 11, WHO raised the level to Phase 6, declaring that an influenza pandemic, caused by the new H1N1 strain, was underway. 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.²

¹ WHO, “Pandemic (H1N1) 2009,” <http://www.who.int/csr/disease/swineflu/en/index.html>.

² 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>.

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 by CRS 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 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, had come to think of any flu pandemic as a catastrophic incident on the scale of the one that occurred in 1918, or that many feared could result from the deadly H5N1 avian flu if it became transmissible among humans. Some argued that the definition of a pandemic should be rewritten to take severity into account, and that a Phase 6 pandemic designation for the H1N1 flu situation would trigger over-reactions that were more disruptive than the disease.³

³ 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>.

International Health Regulations

In 2005, the World Health Assembly adopted revised International Health Regulations (IHR), revising the roles and responsibilities of WHO and member states in 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 relevant information. 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 (which are to be no more restrictive than necessary to achieve the desired level of health protection) and others.⁴ 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 H1N1 flu outbreak a Public Health Emergency of International Concern, thereby calling upon signatories to provide timely and transparent notification of events to WHO, to collaborate in disease reporting and control, and to adopt effective risk communication strategies to reduce the potential for international disease spread and the unilateral imposition of trade or travel restrictions by other countries.⁵

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.⁶

Food Safety Guidance⁷

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.⁸

⁴ For more information, see CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

⁵ WHO, *International Health Regulations*, <http://www.who.int/ihr/en/>. See, also, Rebecca Katz, “Use of Revised International Health Regulations during Influenza A (H1N1) Epidemic,” *Emerging Infectious Diseases*, vol. 15, no. 8 (August 2009), <http://www.cdc.gov/eid/content/15/8/1165.htm>.

⁶ WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

⁷ For more information, see CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”*: *Questions and Answers*, by Renée Johnson.

Key U.S. Government Activities

Government-wide Pandemic Preparedness and Response

Under current law, the Secretary of Homeland Security leads all federal incident response activities, while the Secretary of HHS leads all federal public health and medical incident response activities under the overall leadership of the Secretary of Homeland Security.⁹ The Government Accountability Office (GAO) has noted, in the context of pandemic flu planning, that “these federal leadership roles involve shared responsibilities between [HHS] and [DHS], and it is not clear how these would work in practice.” GAO recommended that HHS and DHS conduct training and exercises to ensure that federal leadership roles are clearly defined and understood. As recently as July 2009, GAO testified that although some recommended exercises had been undertaken, it was unclear whether they rigorously tested federal leadership roles in a pandemic.¹⁰

GAO also recommended, among other things, that federal pandemic plans published in 2006 be updated.¹¹ In July, DHS Deputy Secretary Jane Holl Lute testified that an implementation plan for response to the current pandemic was being finalized under the leadership of the National Security Council.¹²

In August, the President’s Council of Advisors on Science and Technology (PCAST) released a report assessing preparations for a possible resurgence of H1N1 flu and recommending additional actions.¹³ PCAST also noted the potential ambiguity in the leadership roles of DHS and HHS, and recommended that the Homeland Security Advisor¹⁴ be given primary responsibility for decision making during the pandemic response, saying:

The Working Group has some concerns, based on conversations with representatives of the various agencies involved, that decision-making authorities and processes may not be completely clear in all cases. Primary Federal responsibilities for response to an epidemic are

(...continued)

⁸ 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.

⁹ See CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

¹⁰ See, for example, U.S. Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed*, GAO-09-909T, July 29, 2009, pp. 6-7, <http://www.gao.gov>.

¹¹ Ibid.

¹² Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

¹³ Executive Office of the President, President’s Council of Advisors on Science and Technology, *Report to the President on U.S. Preparations for 2009-H1N1 Influenza*, August 7, 2009, press release and link to full report at http://www.whitehouse.gov/the_press_office/Presidents-Council-of-Advisors-on-Science-and-Technology-PCAST-releases-report-assessing-H1N1-preparations/ (hereafter referred to as PCAST report).

¹⁴ This designation presumably refers to John Brennan, who serves as Assistant to the President for Homeland Security and Counterterrorism. For more information on the organization of the Homeland Security Council and its staff under the Obama Administration, see The White House, Office of the Press Secretary, “Statement by the President on the White House Organization for Homeland Security and Counterterrorism,” press release, May 26, 2009, http://www.whitehouse.gov/briefing_room/PressReleases/.

lodged in two departments ([HHS] and DHS), with significant involvement of others (Education, Defense, State, Agriculture, Labor), and coordination by White House staff. While the National Strategy for Pandemic Influenza Implementation Plan provides a comprehensive list of assignments for a multitude of offices, agencies, and departments involved in the Federal planning process, the large number of tasks and responsible units tends to obscure the primary seat of responsibility.... The Working Group believes it would be valuable to clarify these matters before events accelerate in September and assign to the Homeland Security Advisor the responsibility for ensuring that all of the important decisions are made in a timely fashion and with appropriate consultation with the President.¹⁵

The PCAST report also laid out a “plausible scenario” for a fall resurgence that could result in 30% to 50% of the U.S. population being infected with H1N1 pandemic flu, with up to 1.8 million hospitalizations and 90,000 deaths.¹⁶ The Council warned of the possibility of considerable strain on the nation’s health system. Although the Council made clear that these projections were provided for planning purposes and did not represent its prediction of a likely scenario, the report led to some alarm among readers, prompting Dr. Thomas Frieden, the CDC Director, to say that unless the behavior of the H1N1 virus changed, the situation was not expected to be as serious as the Council’s scenario portrayed.¹⁷

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 outbreak, having assumed the role of Principal Federal Official (PFO).¹⁸ 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.¹⁹

Applicability of the Stafford Act

The Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act) authorizes federal assistance to public and private not-for-profit entities affected by catastrophes, upon a presidential declaration. Two levels of declaration may be made, based on the scope and severity of an incident: a declaration of *emergency*, which provides a lower level of assistance, and a declaration of *major disaster*, which provides a higher level. The Stafford Act is

¹⁵ Ibid, p. 32.

¹⁶ PCAST report, p. viii.

¹⁷ “No Flu Vaccines Before Mid-October, CDC Predicts,” *Reuters*, August 26, 2009.

¹⁸ Department of Homeland Security, *Remarks by Secretary Napolitano at Media Briefing on H1N1 Flu Outbreak*, April 27, 2009, <http://www.dhs.gov/ynews/>.

¹⁹ 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).

administered by the Federal Emergency Management Agency (FEMA), which can draw from a Disaster Relief Fund to provide assistance for activities that are eligible under the Act.²⁰

Major disaster declarations under the Stafford Act have historically involved common meteorological or geological disasters, wildfires, and terrorist acts such as bombings. The applicability of major disaster assistance to infectious disease threats—whether natural (e.g., a flu pandemic) or intentional (bioterrorism)—has been a matter of debate. Historically, major disaster assistance has been tailored to address disaster consequences such as the destruction of infrastructure or the displacement of victims, neither of which is a likely consequence of infectious disease outbreaks.

A legal analysis by CRS concluded that emergency assistance under the Stafford Act could be provided by the President in the event of a flu pandemic, but also noted that whether major disaster assistance would be authorized is not clear. There is no precedent for a major disaster declaration in response to an infectious disease threat. Furthermore, the legislative history of the Stafford Act suggests that this issue was not addressed by Congress when it drafted the current definition of a major disaster, and neither inclusion nor exclusion of flu pandemics from major disaster assistance is required as a matter of statutory construction.²¹

In the *National Strategy for Pandemic Influenza: Implementation Plan*, the George W. Bush Administration assumed that the President's authority to declare a major disaster pursuant to the Stafford Act could be applied to a flu pandemic.²² In 2007, FEMA issued a Disaster Assistance Policy regarding Stafford Act assistance that may be provided during a flu pandemic, which includes costs associated with emergency medical care when provided by an eligible entity (generally, a public or non-profit private entity).²³

There has not, at this time, been a Stafford Act emergency or major disaster declaration in response to the H1N1 flu pandemic. In July, DHS Secretary Janet Napolitano suggested that she did not plan to invoke the Stafford Act for the pandemic response.²⁴ However, DHS Deputy Secretary Jane Holl Lute has testified that the Stafford Act may be invoked for the pandemic response under certain circumstances, and that DHS has planned accordingly.²⁵

²⁰ CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by Keith Bea; and CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

²¹ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

²² Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, Appendix C, "Authorities and References," p. 212.

²³ FEMA, "Emergency Assistance for Human Influenza Pandemic," Disaster Assistance Policy 9523.17, March 31, 2007, at <http://www.fema.gov/pdf/government/grant/pa/policy.pdf>.

²⁴ Kevin Robillard, "Officials Say Swine Flu Vaccine is Coming," *CQ Homeland Security*, July 9, 2009. For more information, see CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

²⁵ Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

Customs and Border Protection (CBP) Activities

When the novel H1N1 flu outbreak began in the United States, Customs and Border Protection (CBP), in DHS, reported 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 station²⁶ or a local public health official for evaluation. According to DHS, “There are no border restrictions in effect. U.S. Customs and Border Protection continues to monitor the health status of incoming visitors at our land, sea and air ports watching out for illness as part of their standard operating procedure.”²⁷

Administration officials resisted calls for more aggressive measures such as closing the U.S.-Mexico border. WHO and CDC officials commented that scientific evidence does not support closure of a border to travelers as an effective means of controlling the spread of influenza.²⁸ Also, as a matter of law, U.S. citizens cannot be barred from entering the United States, so any border closure could only exclude aliens.²⁹ Finally, any such measures would likely be resource-intensive, involving considerable disruption of trade and other economic interests.³⁰

Department of Health and Human Services (HHS)

Determination of a Public Health Emergency

On April 26, Charles E. Johnson, then the Acting HHS Secretary, declared a public health emergency pursuant to Section 319 of the Public Health Service Act.³¹ Among other things, this enabled FDA to implement an authority in the Federal Food, Drug, and Cosmetic Act (discussed below) allowing for the emergency use of unapproved medical treatments and tests, under specified conditions, if needed during an incident. The determination, which would have expired after 90 days, was renewed by HHS Secretary Kathleen Sebelius on July 24.³²

FDA: Emergency Use Authorizations

If an emerging defense, national security, or public health threat is identified for which no licensed or approved medical product exists, the Federal Food, Drug and Cosmetic Act authorizes

²⁶ CDC, “Quarantine Stations,” http://www.cdc.gov/ncidod/dq/quarantine_stations.htm.

²⁷ DHS, “Department Response to H1N1 (Swine) Flu,” July 24, 2009, <http://www.dhs.gov/files/programs/swine-flu.shtm>.

²⁸ 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.

²⁹ See “Closing the Border” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

³⁰ See “Port of Entry Policies and Procedures” in CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.

³¹ 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 Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

³² HHS, “Determination that a Public Health Emergency Exists,” July 24, 2009, http://www.hhs.gov/secretary/phe_swh1n1.html.

the FDA Commissioner, under certain conditions, to issue an Emergency Use Authorization (EUA) so that unapproved but potentially helpful countermeasures can be used to protect the public health.³³ On April 27, pursuant to authority provided by the prior public health emergency determination, FDA issued EUAs to allow emergency use of (1) the antiviral drugs 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.³⁴ Although Tamiflu and Relenza are already approved for use in the United States, the EUA supported federal recommendations to use them in ways not explicitly approved on the product label, such as the use of the product in young children, or beyond a certain duration of a patient's symptoms.

The EUA authority could be invoked for a pandemic flu vaccine if it is developed using approaches that are not used in currently licensed products, such as the addition of adjuvants to the vaccine to enhance the immune response. At this time, however, none of the pandemic vaccines that have been approved by the FDA for domestic use contain adjuvants. Each of these vaccines was approved through the routine licensing process used for seasonal flu vaccines. (See the subsequent section "Vaccination Program.")

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.³⁵ 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.³⁶ On May 15, CDC downgraded the Travel Health Warning for Mexico, and the Department of State lifted its travel alert. Travelers to Mexico are now 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.³⁷ Advisories regarding travelers leaving the United States are voluntary. CDC has also published a number of guidance documents for travelers and the travel industry, including information regarding passenger screening practices in other countries, and guidance for airline and cruise ship operators.³⁸

³³ See CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones. See, also, Food and Drug Administration (FDA), *Guidance: Emergency Use Authorization of Medical Products*, July 2007, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>; and FDA/CDC, online course on Emergency Use Authorization, 2009, <http://www.bt.cdc.gov/training/eua/index.html>.

³⁴ Information is available at FDA, "Emergency Use Authorizations Questions and Answers," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153297.htm>. Emergency use of a second unapproved test was authorized on July 24. FDA, "FDA Authorizes Emergency Use of Another Test for 2009 H1N1 Influenza Virus," press release, July 24, 2009, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>.

³⁵ CDC, "Travel Health Warning: Travel Warning: Swine Influenza and Severe Cases of Respiratory Illness in Mexico—Avoid Nonessential Travel to Mexico," April 27, 2009.

³⁶ U.S. Department of State, "Travel Alert: Mexico - 2009-H1N1 Influenza," April 28, 2009.

³⁷ 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.

³⁸ CDC, "Novel H1N1 Flu and Travel," <http://www.cdc.gov/travel/content/novel-h1n1-flu.aspx>.

CDC: Disease Surveillance

Because illnesses with the novel H1N1 flu have generally been mild, health officials note that the disease may be substantially underreported. Also, health officials in many U.S. states and cities have stopped running confirmatory tests on suspected cases of H1N1 flu, 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.³⁹

To get a clearer picture of the spread of H1N1 influenza in the United States, CDC has continued using its multi-layered surveillance system for seasonal flu (which is normally suspended each year in the spring), to which it has added an additional surveillance component to better track the pandemic. (See box below.) According to CDC, “Routine seasonal surveillance does not count individual flu cases, hospitalizations or deaths (except for pediatric influenza deaths) but instead monitors activity levels and trends and virus characteristics through a nationwide surveillance system.”⁴⁰

CDC’s Influenza Surveillance Activities

Regular surveillance components used during each annual flu season:

- Viral surveillance, which monitors the percentage of specimens tested for flu that are positive; the types and subtypes of flu viruses circulating; resistance to antiviral medications; and the emergence of new flu strains.
- Selected physician surveillance for influenza-like illness (ILI), which monitors the percentage of visits for symptoms that could be the flu.
- Hospitalization surveillance, which tracks numbers of hospitalizations with laboratory-confirmed flu infections among adults and children.
- Summary of the geographic spread of flu, which tracks the number of states affected by flu, and the degree to which they are affected.
- Deaths from 122 cities that report the total number of deaths and the percentage of those that are coded as influenza or pneumonia.
- The number of laboratory-confirmed deaths from flu among children.

Added surveillance component for the H1N1 flu pandemic:

- Reports by states of either laboratory-confirmed hospitalizations and deaths from flu, or syndromic cases, i.e. cases of presumed influenza and/or pneumonia based on ICD-9 coded hospitalizations or death reports.

Source: Adapted from CDC, “Reporting of Influenza and Pneumonia-Associated Hospitalizations and Deaths for the 2009-2010 Season,” September 11, 2009, <http://www.cdc.gov/h1n1flu/reportingqa.htm#surveillancesystems>.

On August 30, CDC added the new surveillance component, accepting reports from states of all influenza- and pneumonia-associated hospitalizations and deaths for the 2009-2010 season. This

³⁹ This approach should not affect medical care. Clinicians are advised to provide care, including treatment with 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.

⁴⁰ CDC, “Reporting of Influenza and Pneumonia-Associated Hospitalizations and Deaths for the 2009-2010 Season,” September 11, 2009, <http://www.cdc.gov/h1n1flu/reportingqa.htm#surveillancesystems>.

component tracks both laboratory-confirmed cases of influenza and “syndromic” reports (i.e., cases coded as having pneumonia or influenza whether or not they were laboratory-confirmed as having influenza). Reporting only laboratory-confirmed cases underestimates the burden of illness due to influenza. In contrast, syndromic reporting captures some cases of pneumonia that are due to causes other than influenza. As CDC notes, although each measure is imperfect, tracking each one nonetheless provides useful information about trends in the spread of the pandemic, and the burdens experienced by the health care system in responding to it.

CDC’s surveillance systems showed that during the week ending October 3, 2009, almost all of the flu viruses reported nationwide were the H1N1 pandemic strain. More than 75 laboratory-confirmed or syndromic influenza and/or pneumonia deaths were reported, including 19 laboratory-confirmed pediatric deaths. Almost all of the flu viruses tested were sensitive to the antiviral drug oseltamivir (Tamiflu). Nationwide, the percentage of hospitalizations for influenza-like illness reached its highest point since the H1N1 pandemic flu strain was recognized in April. Thirty-seven states reported widespread influenza activity. However, flu-associated hospitalizations in New York and New Jersey were on the decline, compared with previous weeks. Also, several states in the Northeast (namely Connecticut, Maine, Massachusetts, New Jersey, Rhode Island, and Vermont) did not report widespread influenza activity, but rather activity that was regional or local.⁴¹

Vaccination Program

In September, the FDA licensed four vaccines against the H1N1 pandemic flu strain. As vaccine became available in early October, federal, state, and local health officials began a voluntary nationwide vaccination campaign, which some have said is the most extensive such effort ever undertaken in the United States. This section discusses the production of influenza vaccines in general, and various activities involved in conducting the vaccination campaign.

Overview

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, and new vaccines must be developed for each year’s flu season. Flu vaccine production is time-consuming and involves several steps. First, the virus strain must be adapted for mass production and suitability for use in a vaccine. (The adapted virus is called a “seed” virus.) Next, the adapted virus must be grown in large amounts. All flu vaccines that are currently licensed for use in the United States contain adapted flu virus that is grown in chicken eggs. Next, small amounts of finished vaccine are produced for use in clinical trials. Finally, if trials demonstrate that the vaccine is safe and effective, then finished vaccine is mass produced.⁴² Production capacity is finite, so vaccine becomes available in batches. In a typical flu

⁴¹ Information in this section is drawn from CDC, “FluView,” <http://www.cdc.gov/flu/weekly/>. The more limited recent impacts of the pandemic in states in the Northeast, compared with other areas of the country, has led some to speculate that populations in these states, some of which experienced widespread transmission in the spring, may now have “herd immunity” and are less affected by the current wave of transmission as a result. See, for example, Anemona Hartocollis and Donald G. McNeil, Jr., “Areas Hit Hard by Flu in Spring See Little Now,” *The New York Times*, October 8, 2009. Federal health officials urge people in those areas to receive the pandemic vaccine nonetheless.

⁴² See, for example, the figure by Sanofi Pasteur (a flu vaccine manufacturer), “A(H1N1) Vaccine Production Process,” May 2009, <http://www.vaccineplace.com/docs/H1N1productionprocess.pdf>. For additional information about flu (continued...)

season, vaccine is produced and becomes available over a period of several months, typically from September through December of each year.

Adapting and growing the virus can take variable amounts of time, and different flu strains “behave” differently during this process. In the best case, all of the steps described above take at least four months. More typically, about six months is required. Therefore, since a vaccine cannot be produced for a flu pandemic until the pandemic flu strain emerges, a matched vaccine would not be available for initial pandemic response. 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;⁴³ and (3) developing better approaches for flu vaccine production in the future. Although recent progress has been made to improve domestic production capacity, the vaccines developed for use in the United States against the H1N1 pandemic strain used the egg-based process, with its significant lag time.

Vaccine Development, Procurement, Production, and Licensing

Federal officials have said that there are three key decision points in developing and using pandemic vaccines: (1) to develop adapted “seed” viruses and a prototype vaccine(s), and to conduct clinical trials; (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 1**. The figure also shows that a second wave of heightened transmission of H1N1 flu in the United States in the fall could precede the peak of seasonal flu activity and the initial availability of pandemic vaccine. Finally, the figure shows the overlap between the production of seasonal flu vaccine for the Northern Hemisphere and production of H1N1 pandemic vaccine.

Over the spring and summer, HHS issued purchase orders for H1N1 pandemic vaccine, based on existing contracts with producers of seasonal flu vaccines that are currently licensed in the United States.⁴⁴ Development and procurement efforts are led by the HHS Biomedical Advanced Research and Development Authority (BARDA), in coordination with the National Institutes of Health (NIH), FDA, CDC, and other HHS agencies.

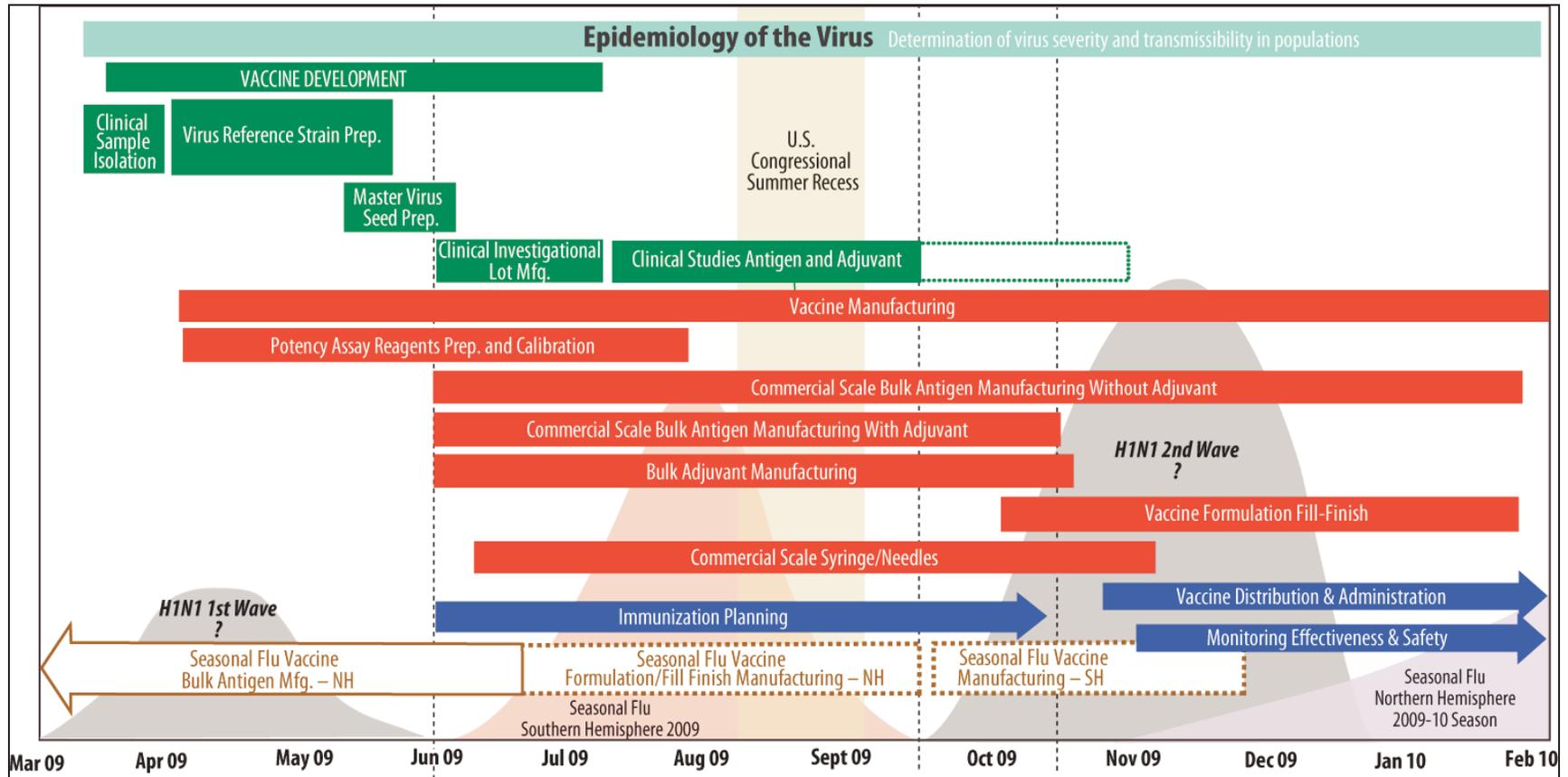
(...continued)

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>.

⁴³ For more information about the use of adjuvants, including safety concerns and possible effects on the global supply of pandemic flu vaccine, see Declan Butler, “Regulators Face Tough Flu-jab Choices,” *Nature News*, July 21, 2009, <http://www.nature.com/news/2009/090721/full/460446a.html>.

⁴⁴ See HHS, “HHS Takes Additional Steps Toward Development of Vaccine for the Novel Influenza A (H1N1),” press release, May 22, 2009; and HHS, “HHS Purchases Additional H1N1 Vaccine Ingredients,” press release, July 13, 2009, (each at <http://www.hhs.gov/news/>). See, also, HHS, Biomedical Advanced Research and Development Authority (BARDA), “H1N1 Vaccines,” <http://www.hhs.gov/aspr/barda/index.html>.

Figure 1. 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>.

The NIH National Institute of Allergy and Infectious Diseases (NIAID) is responsible for coordinating clinical trials to determine the safety, effectiveness, and optimum dosing for the H1N1 pandemic vaccine.⁴⁵ Trials conducted in late summer on healthy adults yielded favorable results. First, the same dose of virus that is used in seasonal flu vaccines was protective when used for the pandemic vaccine. Second, one pandemic vaccine provided protection; a “booster” would not be needed. Third, no serious safety concerns were noted. As a result, large numbers of pandemic vaccines could be produced quickly with existing capacity. Also, adjuvants would not be needed, which meant that pandemic vaccines could be evaluated for licensing through the usual process for seasonal flu vaccines; namely, as amendments to the existing product licenses. Emergency use authorizations would not be necessary. (See the prior section, “FDA: Emergency Use Authorizations,” for more information about this authority.) H1N1 vaccine clinical trials on children, pregnant women, and individuals with HIV are also underway or nearing completion. Finally, NIAID has begun clinical trials on H1N1 vaccines containing adjuvant. Officials have said that although they do not think that adjuvanted vaccine will be needed for the domestic pandemic vaccination campaign, it could be useful to have the option to use adjuvanted vaccine if the virus mutates to a different form (potentially rendering the non-adjuvanted vaccines less effective). They have also said that research on adjuvants contributes to the knowledge base to improve influenza vaccine production in general.

On September 16, the FDA announced that it had approved H1N1 pandemic flu vaccines made by four companies: Sanofi Pasteur Inc., CSL Limited, Novartis Vaccines and Diagnostics Limited, and MedImmune LLC.⁴⁶ The first three products are injectable vaccines. The fourth is an intranasal vaccine. The approved uses of each product vary somewhat. In general, for the injectable vaccines, healthy adults should receive one dose, and children aged six months to nine years of age should receive two, in order to raise protective immunity. None of the four products is approved for use in infants under six months of age. The approved uses for the intranasal vaccine are more narrow than for the injectable products. In general, the intranasal vaccine is approved for use in healthy individuals aged 2 to 49 years. None of the products contains an adjuvant. The injectable products are available in both multi-dose vials containing a preservative, and in single-dose syringes without a preservative.⁴⁷

⁴⁵ Information in this paragraph is drawn from NIH, National Institute of Allergy and Infectious Diseases (NIAID): “H1N1 Clinical Studies” at <http://www3.niaid.nih.gov/topics/Flu/>; and news releases at <http://www3.niaid.nih.gov/news/newsreleases/>.

⁴⁶ FDA, “Vaccines Approved for H1N1 Influenza Virus,” press release, September 15, 2009, <http://www.fda.gov/NewsEvents/Newsroom>. See, also, FDA, “Influenza A (H1N1) 2009 Monovalent,” which includes questions and answers and other information about the licensed pandemic vaccines, at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

⁴⁷ In the United States, seasonal flu vaccine is produced in multi-dose vials containing the preservative thimerosal, and in preservative-free single dose syringes. Thimerosal contains mercury. According to CDC, there is no convincing scientific evidence of harm caused by thimerosal in vaccines, but in 1999, the CDC, other federal agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. As is the case for seasonal flu vaccine, a portion of the pandemic vaccine is being produced without preservatives for use in children and pregnant women. See CDC, “Mercury and Vaccines (Thimerosal),” <http://www.cdc.gov/vaccinesafety/updates/thimerosal.htm>.

*Vaccine Financing*⁴⁸

Congress provided up to \$7.65 billion in FY2009 supplemental appropriations to HHS for the pandemic response, part of which has been used to support the purchase of vaccine and associated costs of planning and carrying out a nationwide vaccination campaign. (See the subsequent section “Emergency Supplemental Appropriations for FY2009.”) There are two types of costs associated with furnishing vaccinations to individuals: the costs of the vaccine and associated supplies, and the costs for administration of the vaccine, which typically include the value of a provider’s time, costs for refrigerated storage and recordkeeping, and related costs.

According to CDC, all pandemic flu vaccines and necessary supplies—syringes, needles, sharps containers, and alcohol swabs—have been purchased by the federal government and are being made available to vaccinators across the country at no cost. In no cases may a provider or insurer charge individuals for these costs. Plans for payment of administration costs vary. Medicare, the Department of Veterans Affairs, and many private insurers have said they will cover the costs of administration for seasonal flu vaccine and one or more pandemic vaccines. Private providers (including physicians and chain pharmacies) may charge appropriate fees for the costs of administration if public or private insurance is not available, or they may waive these fees. States are expected to use a portion of the federal funds they received for pandemic planning to support clinics at which individuals who are uninsured can be vaccinated without charge. Also, Federally Qualified Health Centers are expected to provide services, including vaccination for pandemic flu, regardless of ability to pay.

*Vaccine Distribution*⁴⁹

Federal officials are working with state and local health officials to implement a “blended” public- and private-sector distribution approach to provide pandemic vaccines to any individuals who want to be vaccinated. During each flu season, much of the vaccine is purchased and delivered through private-sector distributors and providers. For the response to unanticipated threats such as bioterrorism, CDC maintains the Strategic National Stockpile (SNS) of drugs and medical supplies, and provides training and technical assistance to state and local health officials, who are responsible for distribution of stockpile materiel within their jurisdictions. Under the Vaccines for Children program, CDC distributes recommended pediatric vaccines (financed by the Medicaid program) to private providers for administration to eligible low-income children. The blended approach being used for the pandemic vaccination campaign would use portions of each of these mechanisms to make vaccine available quickly to a variety of public- and private-sector providers and clinics.

In early October, limited amounts of the approved intranasal H1N1 pandemic vaccine became available, and was provided to states according to their populations. CDC reported that injectable vaccine would become available shortly thereafter, but that the amounts of available vaccine could be quite limited initially. CDC also said that it planned to begin providing detailed weekly

⁴⁸ Information in this paragraph is drawn from CDC, “Questions and Answers on 2009 H1N1 Vaccine Financing,” October 7, 2009, http://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm.

⁴⁹ Unless otherwise noted, information in this paragraph is drawn from CDC, “H1N1 Flu Vaccination Resources,” <http://www.cdc.gov/h1n1flu/vaccination/>.

reports of vaccine distribution to states, and that enough vaccine had been ordered that eventually anyone who wanted to be vaccinated could be.⁵⁰

Despite some statements to the contrary, the civilian vaccination campaign for the H1N1 pandemic is voluntary. There have been no plans at the federal, state, or local level to require that members of the general public be vaccinated. However, requirements have been established by the Department of Defense, and by some states and private health systems, for the vaccination of health care workers. Public health officials recommend that health care workers be vaccinated against influenza (including pandemic flu) not only for their own protection, but also in order to protect patients from infection by their providers, and to prevent levels of absenteeism among providers that could threaten the quality of patient care.⁵¹

*Allocation to Priority Groups*⁵²

CDC advises that anyone who wishes to be vaccinated for seasonal and/or pandemic influenza should seek the vaccine(s) when adequate supplies are available. Certain groups, however, are especially advised to be vaccinated due to their risk of more serious complications from influenza, the risk that they would transmit influenza to others, or both. Because the H1N1 pandemic vaccine is becoming available in phases, initial demand has exceeded supply. Anticipating this, authorities had earlier considered which groups should be given priority when supplies are limited.

Table 2 displays CDC's recommendations regarding groups for which seasonal flu vaccination is recommended, and the subset of those who should be given priority for H1N1 pandemic vaccine when the supply is limited. These recommendations are intended to protect groups that have been at risk of more serious illness from H1N1 flu infection up to this point, and/or to prioritize groups that could amplify the transmission of infection. Health officials intend to monitor the spread and patterns of severity of illness, and may modify recommended priority schemes accordingly, depending on the availability of vaccine. Although federal authorities provide guidance on vaccine allocation, final allocation decisions, and any enforcement of them, would be made at the state and local levels.⁵³ Also, available vaccine may be either the injectable or intranasal formulation. In general, the injectable vaccine may be given to anyone in one of the pandemic priority groups who does not have a specific contraindication (such as an allergy to eggs). However, the intranasal vaccine is not licensed for use in some individuals within the pandemic priority groups. Prioritized individuals who should not receive the intranasal vaccine include pregnant women, children younger than two years of age, individuals of any age who have

⁵⁰ See CDC, transcript of weekly 2009 H1N1 Flu Media Briefing, October 09, 2009, <http://www.cdc.gov/media/transcripts>.

⁵¹ For information about public health recommendations for flu vaccination among health care workers, see CDC, "2009 H1N1 Vaccination Recommendations," <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>. For information about the legal basis for mandatory vaccines, see CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones; and CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.

⁵² Unless otherwise noted, information in this paragraph is drawn from CDC, "H1N1 Flu Vaccination Resources," <http://www.cdc.gov/h1n1flu/vaccination/>.

⁵³ For a discussion of applicable state activities during the seasonal flu vaccine shortage of 2004-2005, see "Vaccine Rationing" in CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by Sarah A. Lister and Erin D. Williams.

chronic illnesses, and health care workers who care for severely immunocompromised patients, such as those who have recently undergone bone marrow transplantation.

Table 2. CDC Recommendations for Influenza Vaccination, 2009-2010

Group	Seasonal Flu Vaccine	Initial Priority for Pandemic Vaccine ^a
Pregnant women	X	X
People who live with or care for infants less than 6 months of age	X	X
Children 6 months to 18 years of age	X	X
Young adults 19 to 24 years of age	X	X
People 25 to 64 years of age with medical conditions that increase their risk of flu complications	X	X
People of any age with certain chronic medical conditions	X	
People 50 years of age and older	X	
People who live with or care for others at high risk of flu complications	X	
Health care workers	X	X

Source: Adapted by Congressional Research Service from CDC, 2009 H1N1 influenza update for congressional staff (weekly e-mail), Fall 2009, Issue #2, October 9, 2009.

a. Intranasal flu vaccine may not be approved for use in some or all individuals in these groups.

Adverse Event Monitoring

Although clinical trials were conducted on the approved H1N1 pandemic vaccines, and did not show that any serious adverse events (i.e., side effects) resulted, rare adverse events would not necessarily manifest until a product was widely used. As the H1N1 pandemic vaccination gets underway, health officials plan to monitor for any possible adverse events among persons who are vaccinated, using, among other approaches, the existing Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program co-sponsored by CDC and FDA.⁵⁴ VAERS accepts reports from patients, providers, public health officials, and others through a website and toll-free number.⁵⁵

In 1976, a U.S. vaccination campaign was carried out for a pandemic flu threat that did not materialize (also called “Swine Flu”). However, evidence suggested that among those vaccinated, there may have been an increased risk of a serious and sometimes fatal neurologic side effect, a form of paralysis called Guillain-Barre Syndrome. The vaccination campaign was called off, and the credibility of public health officials was significantly compromised by the incident.⁵⁶

⁵⁴ CDC, “Influenza A (H1N1) 2009 Monovalent Vaccine Safety Monitoring: CDC Planning Recommendations for State, Local, Tribal, and Territorial Health Officials,” August 21, 2009, http://www.cdc.gov/h1n1flu/vaccination/safety_planning.htm.

⁵⁵ See <http://vaers.hhs.gov/contact.htm>.

⁵⁶ For more information, see Richard Neustadt and Harvey Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease* (U.S. Department of Health, Education, and Welfare, 1978), reprinted electronic edition at <http://www.iom.edu/?id=65926>.

Liability and Compensation

On June 25, HHS Secretary Kathleen Sebelius issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act, Division C of P.L. 109-148) regarding the H1N1 pandemic vaccine.⁵⁷ The PREP Act waives liability and establishes an injury compensation program for the use of certain “covered countermeasures.” The June 25 declaration eliminates liability (with the exception of willful misconduct) for the United States, and for manufacturers, distributors, program planners, persons who prescribe, and employees of any of the above, who administer or dispense an H1N1 pandemic vaccine that qualifies as a “covered countermeasure” under conditions specified by the Secretary in the declaration.⁵⁸ Under the law, claims under state law are preempted.

In addition, the declaration establishes a federal program to compensate individuals who are vaccinated for any serious injuries or death that occurs as a result of the H1N1 vaccine, and authority for a fund to pay claims. The compensation program would be administered by the HHS Health Resources and Services Administration (HRSA), using the Smallpox Vaccine Injury Compensation Program as an administrative model.⁵⁹ The fund, called the Covered Countermeasure Process Fund (CCPF), did not have a balance of funds when the H1N1 pandemic began. However, in providing emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the CCPF.⁶⁰ On July 16, President Obama requested additional contingent funding under the new law, to be used for several activities, including funding for the CCPF.⁶¹

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 clear evidence to date that pigs are involved in the transmission of this virus to humans, although there have been several instances of infection in swine herds believed to have resulted from contact with infected humans. There have been concerns that the term “swine flu” has had unwarranted economic and trade implications for swine and pork products, among other concerns.⁶² Others have raised concerns that because of religious practices that call for the

⁵⁷ Department of Health and Human Services, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

⁵⁸ For more information, see CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows, and “The Public Readiness and Emergency Preparedness Act (PREP Act)” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

⁵⁹ Health Resources and Services Administration, “Preparedness Countermeasures Injury Compensation,” <http://www.hrsa.gov/countermeasurescomp/default.htm>.

⁶⁰ H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

⁶¹ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009, http://www.whitehouse.gov/the_press_office/Letter-from-the-President-regarding-H1N1/.

⁶² CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”*: *Questions and Answers*, by Renée Johnson.

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” or “H1N1 flu.” On April 30, 2009, WHO began referring to the new strain as influenza A(H1N1).

Key State and Local Activities

State Pandemic Preparedness and Response

Since FY2002, all states have received HHS funds to prepare their public health and health care systems for public health threats and emergencies.⁶³ Beginning with FY2004, states were required, as a condition of these funds, to develop plans specifically for the response to a flu pandemic. Subsequently, Congress provided \$600 million in FY2006 emergency supplemental appropriations for states to continue their pandemic planning efforts.⁶⁴ When the H1N1 flu outbreak emerged, Congress provided an additional \$350 million in FY2009 emergency supplemental appropriations for state pandemic response.⁶⁵ (See the subsequent section “Emergency Supplemental Appropriations for FY2009.”)

Based on an analysis of state pandemic flu plans available as of July 2006, CRS found the plans to be more robust in their discussion of core public health activities such as disease surveillance and laboratory activities, and less robust in aspects of multi-sector preparedness, such as leadership designation, incident management, certain aspects of health care surge planning, and continuity planning for essential services such as food distribution.⁶⁶

In January 2009, HHS and DHS published *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council* (state assessment report), the findings of their comprehensive joint assessment of state pandemic planning through 2008.⁶⁷ This assessment echoed the findings of CRS, saying that preparedness was most advanced with respect to objectives that are exclusively or primarily the responsibility of state public health agencies, namely infectious disease surveillance and clinical laboratory operations; distribution of antiviral drugs and vaccines; mass vaccination; and public communications. In contrast, the assessment found that states were having difficulty planning for surges in health care and emergency medical services, and were especially having difficulty planning for continuity of non-health services, such as continuity of state agency operations; coordination of military support to civil authorities; law enforcement continuity; and ensuring the safety of the food supply.

⁶³ Funds are provided to the 50 states, DC, the territories, New York City, Chicago, and Los Angeles County.

⁶⁴ For more information, see the Appendix in CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale; and CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

⁶⁵ Award amounts are available at HHS, “States Eligible to Receive \$350 Million for H1N1, Seasonal Flu Preparedness Efforts,” press release, July 10, 2009, <http://www.hhs.gov/news/>.

⁶⁶ CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

⁶⁷ HHS and DHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January, 2009, <http://www.pandemicflu.gov/plan/states/index.html>. (Hereafter state assessment report)

Thus far, dedicated federal funding to state and local governments for pandemic preparedness has been provided only through HHS grants. Noting the challenges states face in assuring preparedness in non-health sectors, the state assessment report comments, “The [U.S. Government] has provided guidance and technical assistance for many of these activities but generally has not been in a position to award funds to help States develop them in the context of pandemic influenza preparedness.”⁶⁸

If the pandemic continues to unfold as it has, producing generally mild to moderate illness, the pandemic’s effects on non-health sectors such as transportation and public utilities could be minimal. Based on the track record of the pandemic thus far, however, considerable challenges could persist for state and local officials responsible for the public health and health care sectors, and for schools (discussed in the next section).

Pandemic Preparedness and Response in Schools⁶⁹

When the H1N1 outbreak first began in the United States, many affected communities closed schools when students were found to be infected. 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.⁷⁰ 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.”⁷¹ The guidance for this particular outbreak was derived from earlier broad guidance for pandemic planners, issued by CDC in 2007.⁷²

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

⁶⁸ State assessment report, p. 43.

⁶⁹ For more information, see “School Closures” in CRS Report R40560, *The 2009 Influenza Pandemic: 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/>.

⁷⁰ 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>.

⁷¹ 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>.

⁷² 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>.

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.⁷³

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.”⁷⁴ 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.⁷⁵

Outbreaks in schools largely subsided over the summer. Outbreaks emerged at summer camps, however, posing additional challenges for residential camps in providing care for ill campers. CDC has developed infection control guidance for day and residential camps; and for colleges and universities.⁷⁶ Transmission of the H1N1 virus re-emerged in a number of elementary and secondary schools and in colleges and universities as students returned for the fall. The American College Health Association (ACHA) began tracking voluntary reports of pandemic flu activity at colleges and universities.⁷⁷ For the week ending October 2, ACHA said that 92% of reporting colleges and universities reported influenza activity, with the highest rates of activity in states in the Mid-Atlantic region (Virginia, District of Columbia, South Carolina, North Carolina, and Pennsylvania), and declining rates in most states in the Southeast.

Congressional Hearings

Congressional committees in both chambers have convened hearings to assess the emergence of the new strain of H1N1 influenza. Hearings are listed in **Table 3**.

⁷³ 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.

⁷⁴ CDC, “Change in CDC’s School and Childcare Closure Guidance,” press release, May 5, 2009, <http://www.cdc.gov/media/>.

⁷⁵ 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.

⁷⁶ CDC, “H1N1 Flu Clinical and Public Health Guidance,” <http://www.cdc.gov/h1n1flu/guidance/>.

⁷⁷ American College Health Association, “Pandemic Influenza Surveillance: Influenza Like Illness (ILI) in Colleges and Universities,” http://www.acha.org/ILI_Surveillance.cfm.

Table 3. Congressional Hearings on the 2009 Influenza Pandemic

Date	Committee (/Subcommittee)	Topic
SENATE		
Apr. 28, 2009	Appropriations / Labor, HHS, Education, and Related Agencies	The Public Health Response to the Swine Flu Epidemic
Apr. 29, 2009	Health, Education, Labor, and Pensions	The Swine Flu Epidemic: The Public Health and Medical Response
Apr. 29, 2009	Homeland Security and Governmental Affairs Committee (HSGAC)	Swine Flu: Coordinating the Federal Response
May 7, 2009	Appropriations / Agriculture, Rural Development, and FDA	Hearing to Discuss the 2009 H1N1 Virus
June 3, 2009	HSGAC / State, Local and Private Sector Preparedness and Integration	Pandemic Flu: Closing the Gaps
June 16, 2009	HSGAC / Oversight of Government Management, the Federal Workforce and the District of Columbia	Pandemic Flu Preparedness and the Federal Workforce
Sept. 21, 2009	HSGAC	H1N1 Flu: Protecting Our Community ^a
HOUSE		
Apr. 30, 2009	Energy and Commerce / Health	Swine Flu Outbreak and the U.S. Federal Response
May 6, 2009	Foreign Affairs / Africa and Global Health	Global Health Emergencies Hit Home: The Swine Flu Outbreak
May 7, 2009	Education and Labor	Ensuring Preparedness Against the Flu Virus at School and Work
May 14, 2009	Oversight and Government Reform / 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 20, 2009	Oversight and Government Reform	State and Local Pandemic Preparedness
July 29, 2009	Homeland Security	Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza
Sept. 9, 2009	Small Business	The Challenges of the 2009-H1N1 Influenza and its Potential Impact on Small Businesses and Healthcare Providers
Sept. 15, 2009	Energy and Commerce	Preparing for the 2009 Pandemic Flu
Sept. 29, 2009	Oversight and Government Reform	The Administration's Flu Vaccine Program: Health, Safety, and Distribution

Source: Compiled by Congressional Research Service.

Notes: Hearings were held in Washington, DC unless otherwise noted.

a. Field hearing in Hartford, CT.

Appropriations and Funding

Public Health Emergency Funding Mechanisms

The Secretary of HHS does not have a dedicated source of funds to support the response to public health emergencies such as the current flu pandemic. Funds available to HHS from prior-year appropriations for pandemic flu could have supported vaccine development and modest procurements, but would not have been adequate for procurements and related activities sufficient to support a mass-vaccination campaign. 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.⁷⁸

Upon the determination of a public health emergency pursuant to Section 319 of the Public Health Service Act, the Secretary of HHS may access a no-year Public Health Emergency Fund. Such a determination was made with respect to the H1N1 flu outbreak on April 26. (See the earlier section “Determination of a Public Health Emergency.”)⁷⁹ The fund has not received a recent appropriation and does not have a balance, however, so the Secretary is not currently able to use this funding mechanism for the pandemic response.

There has not been a Stafford Act declaration for the current flu pandemic, so disaster relief funds administered by the Federal Emergency Management Agency (FEMA) are not available for response efforts. Many relevant activities may not be eligible for Stafford funds, even if they were available.⁸⁰ (See the earlier section, “Applicability of the Stafford Act.”)

The Secretary has authority to use a Covered Countermeasure Process Fund to compensate individuals for harm that results from their use of medical countermeasures, as identified in a declaration issued by the HHS Secretary.⁸¹ A declaration was issued for the use of the antiviral drugs Tamiflu and Relenza for a possible pandemic flu virus in October 2008.⁸² As noted earlier, a declaration was issued for the use of an H1N1 pandemic vaccine in June, 2009.⁸³ Compensation could be provided for serious physical injuries or deaths resulting from the use of these products

⁷⁸ 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>.

⁷⁹ 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.

⁸⁰ 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.

⁸¹ 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.

⁸² 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.

⁸³ HHS, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

in this situation, including for unapproved uses pursuant to an Emergency Use Authorization. (See “FDA: Emergency Use Authorizations.”) The Covered Countermeasure Process Fund does not currently have a balance. However, in providing FY2009 emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the Fund, and President Obama has sought to use contingent funds provided under the law for this purpose.⁸⁴

Emergency Supplemental Appropriations for FY2009⁸⁵

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 appropriation 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. Later, as the outbreak spread around the world, the President increased the request to almost \$9 billion in appropriations and contingent transfer authorities.⁸⁶

On June 26, the President signed P.L. 111-32, which provides \$1.9 billion in FY2009 supplemental appropriations immediately, and an additional \$5.8 billion contingent upon a Presidential request documenting the need for, and proposed use of, the additional funds. Amounts provided are as follows:⁸⁷

- As proposed by the House, \$1.85 billion is provided to HHS for the Public Health and Social Services Emergency Fund, to be available until expended, including not less than \$200 million to CDC for several specified activities, and not less than \$350 million for state and local public health response capacity.
- As proposed by the House, of the \$1.3 billion to HHS that is not specifically designated, the Secretary may transfer funds to other HHS accounts and to other federal agencies. All such transfers require notification to the House and Senate Appropriations Committees. Transfers to other federal agencies also require consultation with the OMB Director.
- As proposed by the House, of the \$1.3 billion to HHS that is not specifically designated, funds may be used for purchases for the Strategic National Stockpile (SNS), for construction or renovation of privately owned vaccine production facilities, and for the Covered Countermeasure Process Fund (CCPF).
- An additional contingent emergency appropriation of \$5.8 billion to HHS for the Public Health and Social Services Emergency Fund would become available for obligation 15 days after the President provided a detailed written request to

⁸⁴ H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

⁸⁵ 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.

⁸⁶ *Ibid.* The President requested \$2 billion in appropriations and almost \$7 billion additional in transfer authority from existing accounts. The request was not fully funded. Also, funds were provided as new appropriations, rather than transfers from existing accounts.

⁸⁷ H.Rept. 111-151, pp. 27-28, 34-35, 110, 114-116, 125-126, and 142.

Congress to obligate specific amounts for specific purposes, and only if needed to address the emergency. If such requirements were met, funds could generally be made available and transferred as per the \$1.3 billion in non-contingent funds provided as above, including for purchases for the SNS and the CCPF. However, authority to use these contingent funds for construction or renovation of privately owned vaccine production facilities is not provided.

- As proposed by the House, the Secretary of HHS is to continue monthly reporting of funds obligated and actions taken using funds designated for pandemic flu preparedness; and, in collaboration with the CDC Director, is to report within 90 days regarding the CDC's initial response to the outbreak in Mexico and the United States.
- To support global efforts to control the spread of the outbreak, \$50 million is provided to the President for the Global Health and Child Survival account.
- The conference report provided that if WHO were to announce that the current outbreak had progressed to a flu pandemic (i.e., Phase 6),⁸⁸ and upon the President's determination and notification to Congress, available funds in four accounts from prior appropriations acts for the Department of State, Foreign Operations, and Related Programs—Global Health and Child Survival; Development Assistance; Economic Support Fund; and Millennium Challenge Corporation—may be used for pandemic response activities. If this authority is used, OMB is directed to replenish any funds reprogrammed from these accounts.

On July 16, President Obama requested \$1.825 billion of the contingent appropriation, to be used for procurement of vaccine adjuvant, immunization campaign planning, FDA regulatory activities, and funding for the CCPF.⁸⁹

On September 2, the President requested an additional \$2.716 billion of the contingent appropriation, to be used for the Departments of Agriculture, Defense, HHS, State, and Veterans Affairs to support the procurement of vaccine product and supplies, antiviral medications, preparations for a vaccination campaign, and agency preparedness activities.⁹⁰

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.⁹¹ Since then, annual funding has been provided to CDC, FDA, and for other activities in HHS to continue work on

⁸⁸ WHO declared the situation to be a flu pandemic, Phase 6, on June 11.

⁸⁹ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009, http://www.whitehouse.gov/omb/budget_amendments/.

⁹⁰ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, September 2, 2009, http://www.whitehouse.gov/omb/budget_amendments/. At this time, the President has requested \$4.541 billion of the \$5.8 billion contingent appropriation, leaving a balance of \$1.259 billion that the President may request at a later date.

⁹¹ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

vaccine development, stockpiling of countermeasures, and assistance to states. In total, from FY2004 through FY2009, HHS has received almost \$9 billion for pandemic flu preparedness.⁹² (See **Table 4.**) 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.⁹³

Table 4. HHS Funding for Pandemic Influenza, FY2004-FY2010
(dollars in millions, rounded)

Agency/Activity	FY2004	FY2005	FY2006 ^a	FY2007	FY2008	FY2009 regular ^b	FY2009 supp. ^c	FY2010 req.
OS and/or PHSSEF	50	99	5,152	0	75	585	6,391	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
TOTAL, Program Level	50	99	5,590^d	138	299	815	6,391^c	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).
- c. Appropriated in P.L. 111-32, the Supplemental Appropriations Act, 2009. The Act provided the Secretary of HHS with \$1.850 billion initially, and an additional \$5.8 billion contingent upon presidential request and demonstration of need. For more information, see CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein. Amount includes the initial amount (i.e., \$1.850 billion) plus \$4.541 billion in contingent appropriations. On July 16, President Obama requested \$1.825 billion in contingent appropriations. On September 2, President Obama requested an additional \$2.716 billion in contingent appropriations. See footnote 89 and footnote 90.
- d. Total does not include \$30 million in supplemental funding to HHS that was transferred to the U.S. Agency for International Development (USAID).

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 many years, domestic public health capacity for infectious disease

⁹² This amount is exclusive of any funds that may be provided through contingent transfer authority as provided in FY2009 supplemental appropriations, discussed in the previous section of this report.

⁹³ Information can be found in CRS Reports on the applicable appropriations bills, at <http://crs.gov/Pages/CLIs.aspx?CLIID=73>, and: CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2010*, by Tiaji Salaam-Blyther.

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. 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 4**.

U.S. Pandemic Influenza Preparedness Documents

In the George W. Bush Administration, pandemic flu preparedness efforts were coordinated by the Homeland Security Council.⁹⁴ 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 they were written when there was significant global concern about H5N1 avian flu. To date, that flu strain has behaved quite differently from the H1N1 pandemic 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.⁹⁵

Unless otherwise noted, the U.S. pandemic flu plans below can be found on a government-wide pandemic flu website managed by HHS.⁹⁶

- 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.

⁹⁴ 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.

⁹⁵ 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).

⁹⁶ See <http://www.pandemicflu.gov/professional/federal/index.html>.

- *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 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.⁹⁷

⁹⁷ 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.

Key Information Sources

CRS Reports and Experts

2009 H1N1 “Swine Flu”: **CRS Experts:** CRS Report R40845, *2009 H1N1 “Swine Flu”*: *CRS Experts*, by Sarah A. Lister.

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 Pandemic: 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 Pandemic: 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 R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.
- CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.
- CRS Report RL32724, *Mexico-U.S. Relations: Issues for Congress*, by Clare Ribando Seelke, Mark P. Sullivan, and June S. Beittel.
- 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 pandemic 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
- 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
- International Health Regulations (2005): http://www.who.int/topics/international_health_regulations/en/

U.S. Federal Government Information

- Government-wide information: <http://www.flu.gov/>
- 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>
- U.S. Department of Education, H1N1 Flu Information, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>
- U.S. Department of Agriculture (USDA), H1N1 Flu, http://www.usda.gov/wps/portal/?navid=USDA_H1N1

- USDA nutrition program policies for pandemic flu, <http://www.fns.usda.gov/disasters/pandemic/default.htm>
- Department of Defense Pandemic Influenza Watchboard: <http://fhp.osd.mil/aiWatchboard/>
- 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

- 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/anima/disemala/swigri/swigrie.shtml>
- Security and Prosperity Partnership of North America, *North American Plan for Avian and Pandemic Influenza*, August 2007, [http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/\\$FILE/pandemic-influenza.pdf](http://www.spp-psp.gc.ca/eic/site/spp-psp.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>

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