ISSUE REPORT

Trust for America's Health

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TRUST FOR AMERICA'S HEALTH IS A NON-PROFIT, NON-PARTISAN ORGANIZATION DEDICATED TO SAVING LIVES BY PROTECTING THE HEALTH OF EVERY COMMUNITY AND WORKING TO MAKE DISEASE PREVENTION A NATIONAL PRIORITY.

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PREVENTING EPIDEMICS. PROTECTING PEOPLE.

A Killer Flu?

Scientific Experts Estimate that "Inevitable" Major Epidemic of New Influenza Virus Strain Could Result in Millions of Deaths if Preventive Actions Are Not Taken

The seasonal flu kills approximately 36,000 to 40,000 people and hospitalizes more than 200,000 in the United States each year.[1] Annually, influenza costs the national economy over $10 billion in lost productivity and direct medical expenses.[2] Many view the flu as a relatively predictable and manageable health threat.

Recently, however, health experts worldwide have been sounding the alarm about a different type of flu. They warn of the "inevitable" emergence of a new, severe strain of the flu virus against which people have no immunity to protect them.[3] This could result in a rapidly spreading, worldwide epidemic of this new potentially lethal strain of the disease, which scientists refer to as a "pandemic."[4] New strains of the flu traditionally emerge in animals, often in poultry and pigs, and then as the disease develops over time, it can become transmitted to humans. The severity of an emerging pandemic would be determined by the particular strain of the new form of the virus and how easily contagious it proves to be in humans.

The World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and other health authorities believe that the emergence of a pandemic flu could be devastating to world health and economic stability.

- **In the U.S., projection models predict that a pandemic may cause over a half a million deaths and two million hospitalizations.[5]**
- **The estimated economic impact of a pandemic flu outbreak in the U.S. today, based on projections from the relatively mild 1968 flu epidemic, would be $71.3 to $166.5 billion due to death and lost productivity, excluding other "disruptions to commerce and society."[6]**

The U.S. would be impacted by the global implications as soon as a pandemic outbreak occurred in any part of the world due to the interdependence of economies. Sectors, such as hospitals and the health care system, which rely on supplies manufactured in other parts of the world, including Asia, would feel immediate repercussions and supply shortages. Travel restrictions, possible limitations on public gatherings and events, and other measures taken

In a May 2005 *New England Journal of Medicine* article, Dr. Michael Osterholm, Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, wrote that "even a relatively 'mild' pandemic could kill many millions of people" worldwide.[7]

to limit the spread of disease would also have rapid and far reaching repercussions. Since a pandemic could likely result in political and economic destabilization, particularly in developing countries, it poses serious national security concerns for the U.S.

Based on historical trends and projections, virologists and epidemiologists predict a new flu pandemic will emerge three to four times each century.[8] Health officials around the world are troubled by the severity of the "avian flu" circulating in Asia, which scientists refer to as the H5N1 flu strain. They fear this avian flu could become the next pandemic for humans. The regional director of the WHO for the Western Pacific region stated in February 2005 that the "world is now in the gravest possible danger of a pandemic."[9]

- As of June 17, 2005, this "bird flu" virus has killed 54 individuals and has spread rapidly among bird populations.[10]
- As of April 2005, the strain seems to be exhibiting a mortality rate of over 50 percent in humans. Experts are concerned that when the mortality rate decreases, the virus's transmission rate will increase.
- Health officials are concerned that the avian virus could become more contagious among humans, and that it could remain in a strain against which humans have no natural resistance.
- CLSA Asia-Pacific Markets, the Asian investment banking arm of Crédit Agricole of France, estimates that avian influenza has already cost the impacted region in Asia $8 to $12 billion, mostly from lost revenue from poultry and related industries.[11]

"I am acutely aware of the disaster that a pandemic could cause. Many of us are particularly worried about H5N1 avian influenza virus, and we're right to worry. It has infected at least 89 human beings and killed more than half. There is a chance that this virus could cause the next pandemic[12]"

– U.S. Department of Health and Human Services Secretary Mike Leavitt, May 16, 2005

MAJOR FLU OUTBREAKS OF THE 20TH CENTURY[13]

1918 – The "Spanish" flu pandemic killed 500,000 in the U.S., 50 million worldwide.

1957–58 – An outbreak spread from China across the globe, killing approximately 70,000 in the U.S. In April 2005, a company testing laboratory proficiency mistakenly distributed samples of this pandemic strain to laboratories worldwide, triggering global concern until all samples were accounted for and destroyed.[14]

1968–69 – The "Hong Kong" flu, the most recent pandemic, affected millions worldwide and disrupted world economies.

1997 – The first identification of the avian "bird" flu, which remains active in Asia.[15]

"Since January 2004, events affecting both human and animal health have brought the world closer to an influenza pandemic than at any time since 1968. Whereas past pandemics have consistently announced themselves with an explosion of cases, events during 2004, supported by epidemiological and virological surveillance, have given the world an unprecedented warning that a pandemic may be imminent. They also have opened an unprecedented opportunity to enhance preparedness."

– Report by the WHO Secretariat, April 2005[16]

While experts predict a pandemic flu is "inevitable," subsequent deaths in the United States predicted to be over a half million people are not. Increasing federal leadership, converting national and state pandemic influenza plans into operational blueprints, procuring adequate antiviral medication for treatment, and putting a process in place now for rapid influenza vaccine approval are all steps that should be taken immediately.

Protecting the U.S. and the world against the threat of a pandemic would, at the same time, better prepare countries for threats posed by infectious illnesses, including the intentional spread of disease by terrorists. The threat of a pandemic influenza outbreak was highlighted by the U.S. Department of Homeland Security (DHS) as one of 15 disaster planning scenarios for which the U.S. should be prepared.

In order to help understand the current status of U.S. preparations and highlight ways to improve them, in the following report, Trust for America's Health (TFAH) provides:

- A state-by-state examination of potential deaths and hospitalizations due to a flu pandemic based on model estimates;
- A state-by-state examination of capacity to treat citizens with recommended antivirals based on model estimates;
- A review of U.S. and state pandemic readiness, including a comparison to other nations' progress; and
- Recommendations for improved pandemic readiness.

Overall, the report finds:

- Despite the health and economic implications of such an event, pandemic planning efforts are lagging in the U.S., especially when compared to the United Kingdom and Canada.
- The U.S. has not assessed or planned for the disruption a flu pandemic could cause both to the economy and society as a whole. This includes daily life considerations, such as potential school and workplace closures, potential travel and mass transit restrictions, and the potential need to close stores resulting in complications in the delivery of food and basic supplies to people. Daily life and economic problems would likely emerge in the U.S. even before the pandemic flu hit the country due to the global interdependence of the world economy.
- Aspects of the planning process, such as ensuring vaccine and antiviral capabilities and surge capacity readiness, are incomplete or fragmented.
- The failure to establish a cohesive, rapid, and transparent U.S. pandemic strategy could prove a major weakness against a virulent and efficient virus -- putting Americans needlessly at risk.

> *"I would like to emphasize that although we cannot be certain exactly when the next influenza pandemic will occur, we can be virtually certain that one will occur and that the resulting morbidity, mortality, and economic disruption would present extraordinary challenges to public health authorities around the world."*
>
> – Dr. Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services [17]

> *"Today, many influenza experts, including those at CDC, consider the threat of a serious influenza pandemic to the United States to be high. Although the timing and impact of an influenza pandemic is unpredictable, the occurrence is inevitable and potentially devastating."*
>
> – Dr. Julie Gerberding, Director, CDC[18]

Model Estimates of the Impact of a Severe-Strain Flu Virus Epidemic

In order to illustrate the potential severity of a pandemic outbreak in the U.S., the chart below uses one model based on assumptions from the current avian flu outbreak. Scientists have used a number of different models to estimate the scope and impact of the emergence of a new strain of the flu. The basic U.S. planning model is based on assumptions from the 1968 "Hong Kong" pandemic flu, which was considered to be relatively mild. Experts also have predicted higher and lower estimates based on different sets of assumptions. The numbers below adapt the model to reflect moderate assumptions for the current avian flu threat.

1. The WHO has estimated that there would be a "contraction" rate of 25 percent for this flu strain. This means they warn that countries should be prepared for approximately 25 percent of their populations to get sick from the pandemic virus. Other scientists have estimated that up to 50 percent of countries' populations could become infected.

2. The current strain of the avian flu is viewed as significantly more lethal than the 1968 pandemic flu strain. A high-level pandemic, such as the 1918 pandemic, is considered to be six times more lethal than the 1968 flu.[19] The projections below reflect a mid-level estimate of a three times higher rate. These numbers are reflected in the "Projected Dead" column in the table below. The range of estimates, from low level to high level severity death rates, can be found in Appendix A.

3. Due to the severity of the avian flu strain, experts also believe that it would result in a much higher hospitalization rate than estimates using the 1968 strain. The estimates below, in the "Projected Hospitalizations" column, reflect a mid-level estimate of a three times higher rate. A more virulent strain of flu, changes in medical care and treatment procedures, and an aged population are all factors behind this projection. The range of estimates, from low level to high level severity hospitalization rates, can be found in Appendix A.

POTENTIAL IMPACT: STATE BY STATE ANALYSIS

To assist state and local health agencies with pandemic readiness, CDC developed a computer model (FluAid 2.0) that generates mortality, hospitalization, and outpatient rates for different age populations on a state-by-state basis.[20] FluAid derives its default numbers from the 1968 Hong Kong pandemic, which had a relatively minor impact on the U.S. According to Dr. Keiji Fukuda, the Chief of Epidemiology and Surveillance Section, Influenza Branch at CDC's National Center for Infectious Diseases, a high severity pandemic, similar to the 1918 pandemic outbreak, may have a mortality rate of six times the 1968 pandemic.[21] To estimate the potential impact from a H5N1 pandemic on the U.S., the following projections multiplied the default FluAid mortality rate for each state and each age group by three (the mid-point between the default numbers and the possible six times mortality rate); hospitalization rates are also three times the default FluAid number.

Projections of deaths and hospitalizations from an H5N1 pandemic are only estimates. Variables including the virulence of the virus, its attack rate, and the success of preventative and controlling measures (including the use of antiviral medication and the development of a vaccine) would influence the actual total. While the mortality estimate provided below -- a U.S. death toll over a half a million persons -- varies from some other experts' forecasts, all projections agree on a critical point: the risk of a pandemic is serious enough to justify urgent steps to improve U.S. ability to fight this virus if it starts to spread.

It is also important to note that planning and accommodating for the surge of sick patients presents a separate, massive challenge to the health care system -- a consideration that the projected death toll should not overshadow. The impact of over two million hospitalized patients would test and possibly overwhelm the surge capacity of hospitals nationwide. For instance, according to the American Hospital Association, in 2003 there are only 965,256 staffed hospital beds in registered hospitals.[22]

TABLE 1: Potential Pandemic Influenza Deaths and Hospitalizations From a Mid-level Pandemic Flu*			
State	**Projected Dead**	**Projected Hospitalized**	**Number of Cases**
Alabama	8,886	38,591	1,079,789
Alaska	886	4,558	152,328
Arizona	9,223	39,675	1,138,742
Arkansas	5,350	22,660	630,705
California	60,875	273,090	8,067,075
Colorado	7,192	32,978	973,161
Connecticut	7,054	29,932	817,465
Delaware	1,507	6,560	182,895
District of Columbia	1,155	4,974	132,241
Florida	35,737	142,386	3,663,486
Georgia	13,655	62,912	1,871,561
Hawaii	2,446	10,571	296,651
Idaho	2,279	10,157	302,558
Illinois	23,720	103,738	2,973,962
Indiana	11,817	51,711	1,466,027
Iowa	6,233	26,090	713,106
Kansas	5,373	22,946	654,335
Kentucky	7,930	34,748	977,031
Louisiana	8,334	37,148	1,087,942
Maine	2,651	11,333	310,513
Maryland	9,958	44,500	1,273,572
Massachusetts	13,136	56,038	1,529,313
Michigan	19,622	86,005	2,443,473
Minnesota	9,304	40,786	1,171,387
Mississippi	5,362	23,531	682,625
Missouri	11,274	48,240	1,350,515
Montana	1,804	7,787	219,703
Nebraska	3,441	14,697	414,218
Nevada	3,243	14,455	419,202
New Hampshire	2,333	10,301	293,177
New Jersey	16,980	72,791	2,013,212
New Mexico	3,244	14,504	432,438
New York	37,701	162,490	4,534,307
North Carolina	14,987	65,637	1,856,296
North Dakota	1,371	5,795	160,221
Ohio	23,197	99,979	2,796,583
Oklahoma	6,833	29,376	829,273
Oregon	6,724	29,047	810,872
Pennsylvania	27,185	112,658	3,004,915
Rhode Island	2,234	9,263	246,857
South Carolina	7,474	32,983	940,045
South Dakota	1,559	6,599	184,493
Tennessee	10,875	47,678	1,342,050
Texas	35,124	160,648	4,859,834
Utah	3,393	15,906	514,787
Vermont	1,185	5,213	147,245
Virginia	13,104	58,872	1,683,499
Washington	10,910	48,610	1,402,591
West Virginia	4,049	17,014	453,947
Wisconsin	10,620	45,842	1,292,419
Wyoming	915	4,086	119,936
U.S. Totals	541,433	2,358,089	66,914,573

** Projections are based on CDC's FluAid 2.0 program. The estimated deaths are for a pandemic strain three times more lethal than the 1968 pandemic, on which the default FluAid numbers are based. The hospitalization rate is three times the default 1968 rate. The Dead and Hospitalized numbers represent the most likely FluAid projection at a 25% rate of contraction. The Number of Cases is the projected number of residents contracting the flu, based on a 25% rate of contraction. State population numbers are from FluAid, using U.S. Census data gathered in 1999. Updated population data were not used to ensure consistency with estimated Dead and Hospitalized numbers.*

As of May 2005, the U.S. has stockpiled 2.3 million courses of the antiviral medication Tamiflu, which could be used as a treatment in the event of an outbreak, and intends to order approximately three million more with funds recently appropriated by Congress to total 5.3 million. The WHO is currently estimating that an avian flu epidemic could impact 25 percent of countries' populations. In the U.S., this means it could affect nearly 67 million individuals, based on FluAid projections and population numbers. With the current level of the U.S. Tamiflu order, *over 61.5 million Americans who could be infected would not receive antiviral medication.* If the U.S. orders additional courses of Tamiflu, they would not be available until 2007, unless production capacity significantly changes.

In an actual pandemic, there would likely be geographic concentrations of the disease, especially in the initial stages of an outbreak. U.S. government officials may decide to "front-end" target the limited supply geographically in hopes of containing the initial spread. However, it is likely that the pandemic would still spread to the remainder of the country. As a result of the pandemic's national scope and lacking a prioritized distribution plan, these projections assume that the U.S. would use proportional distribution (based on population) in delivering the remaining Tamiflu courses.

TABLE 2: State-by-State Capacity to Treat Citizens with Recommended Antiviral*

State	Number of Tamiflu Courses Available	Number of Cases	Number of Cases Without Tamiflu
Alabama	85,525	1,079,789	994,263
Alaska	12,065	152,328	140,263
Arizona	90,195	1,138,742	1,048,547
Arkansas	49,955	630,705	580,749
California	638,956	8,067,075	7,428,119
Colorado	77,080	973,161	896,081
Connecticut	64,748	817,465	752,717
Delaware	14,486	182,895	168,409
District of Columbia	10,474	132,241	121,767
Florida	290,168	3,663,486	3,373,318
Georgia	148,238	1,871,561	1,723,323
Hawaii	23,496	296,651	273,154
Idaho	23,964	302,558	278,594
Illinois	235,554	2,973,962	2,738,408
Indiana	116,117	1,466,027	1,349,910
Iowa	56,482	713,106	656,624
Kansas	51,827	654,335	602,508
Kentucky	77,386	977,031	899,645
Louisiana	86,171	1,087,942	1,001,771
Maine	24,594	310,513	285,918
Maryland	100,874	1,273,572	1,172,698
Massachusetts	121,130	1,529,313	1,408,183
Michigan	193,536	2,443,473	2,249,937
Minnesota	92,780	1,171,387	1,078,607
Mississippi	54,068	682,625	628,558
Missouri	106,968	1,350,515	1,243,546
Montana	17,402	219,703	202,301
Nebraska	32,808	414,218	381,409
Nevada	33,203	419,202	385,999
New Hampshire	23,221	293,177	269,956
New Jersey	159,457	2,013,212	1,853,755
New Mexico	34,251	432,438	398,186
New York	359,142	4,534,307	4,175,165
North Carolina	147,029	1,856,296	1,709,267
North Dakota	12,690	160,221	147,530
Ohio	221,505	2,796,583	2,575,078
Oklahoma	65,683	829,273	763,590
Oregon	64,225	810,872	746,646
Pennsylvania	238,006	3,004,915	2,766,910
Rhode Island	19,552	246,857	227,305
South Carolina	74,457	940,045	865,589
South Dakota	14,613	184,493	169,880
Tennessee	106,298	1,342,050	1,235,752
Texas	384,925	4,859,834	4,474,909
Utah	40,774	514,787	474,013
Vermont	11,663	147,245	135,582
Virginia	133,342	1,683,499	1,550,157
Washington	111,093	1,402,591	1,291,498
West Virginia	35,955	453,947	417,992
Wisconsin	102,367	1,292,419	1,190,053
Wyoming	9,500	119,936	110,436
U.S. Totals	5,300,000	66,914,573	61,614,573

** Tamiflu availability projections are based on state-by-state proportional distribution of the 5.3 million courses of Tamiflu ordered or currently in U.S. federal government possession. For example, California, with approximately 12% of the U.S. population, receives 12% of the Tamiflu in the above projection. The Number of Cases is the projected number of residents contracting the flu, based on a 25% rate of contraction. State population numbers are from FluAid, using U.S. Census data gathered in 1999. Updated population data were not used to ensure consistency with estimated Dead and Hospitalized numbers. The Number of Cases Without Tamiflu is the difference between the other two columns.*

U.S. Department of Health and Human Services Draft Pandemic Plan

> "Beyond research and development, we need a public health approach that includes far more than drafting of general plans, as several countries and states have done. We need a detailed operational blueprint of the best way to get through 12 to 24 months of a pandemic.[23]"
>
> – Dr. Michael Osterholm, Director of the Center for Infectious Disease Research and Policy

In August 2004, the U.S. Department of Health and Human Services (HHS) released a draft plan of U.S. strategy to deal with a flu pandemic. The plan, an updated version of a 1978 plan, outlines proposed collaboration among jurisdictions, as well as preparedness and response guidelines for federal, state, and local health officials. The goals of the plan are to 1) decrease the burden of disease; 2) minimize social disruption; and 3) reduce economic impact.[24] The draft plan is accessible on the HHS Web site at www.dhhs.gov/nvpo/pandemics.[25] Related public comments on the plan were accessible at the site in March 2005.

Questions for U.S. Pandemic Planning Efforts

- **Is There Coordination Among Government, Health, and Economic Infrastructures?** State, federal, and international efforts must be coordinated, with instructions for specific implementation. Sufficient resources must be allocated to match what is needed to carry out the plan.
- **Does the National Strategic Stockpile Include ALL Necessary Medical Supplies That Will Be Necessary to Respond to a Pandemic?** In addition to stockpiling antivirals and vaccines, when they are available, the U.S. must also stockpile critical medical supplies such as masks, gloves, gowns, bed linens, and all other equipment needed to assure that hospitals and other health care providers are properly protected when the usual supply chain is disrupted either abroad or in the U.S.
- **Are There Sufficient Surge Capacity Capabilities?** A pandemic or other mass-emergency scenario would overwhelm the normal operations of hospitals and the health care system. Readiness efforts must account for massive demand triggered by a pandemic. Local health officials and first responders must be included in planning efforts to maximize the on-the-ground ability to "scale up" capability in a rapid manner.
- **Is There a Prioritization of Who Would Receive Antivirals and Vaccines Based on a Limited Supply?** Specific national guidance must be established on vaccine prioritization, including developing guidelines on the use of antiviral drugs and lists of priority groups for vaccine receipt and distribution, given that there is likely to be insufficient supplies during a pandemic.
- **Is There a Rapid Response Plan to Develop, Test, and Produce a Vaccine?** It will take an estimated six to nine months after a pandemic emerges to develop a vaccine. Questions of how to rapidly review and test the vaccine once it is created remain, including concerns about speeding the approval process by the Food and Drug Administration (FDA), liability protection for vaccine manufacturers, and what type of preservative will be used in the vaccine. In addition, industry representatives have suggested that current production capacity is insufficient to meet the demand for a pandemic influenza vaccine, and that it could take 12-18 months to meet appropriate production levels.[26]

- **Is There Clear Assignment of Who in the Government Would Control and Distribute Vaccine and Treatments?** Do plans exist to stockpile stopgap antiviral medications and vaccines, based on the small supplies of drugs that will be available versus the expected need and demand? As was evident in the 2004 flu season in the U.S. when there was a shortage of available vaccine for the annual flu, there is no centralized infrastructure to control and monitor vaccine distribution.

- **Are There Clear Plans to Communicate and Inform the Public?** Effective response to a pandemic would require a clear action plan for what information would be made available to the public and on what time frame.

- **Are There Coordinated Plans for Monitoring Outbreak and Managing Containment?** Coordinating containment efforts requires sufficient surveillance and tracking systems to monitor and detect outbreaks, infected persons, and the vaccine supply, as well as the ability to examine the readiness of infected survivors to re-enter the workplace. Survivors as a volunteer workforce would prove essential to helping combat the pandemic, because they will have developed immunity to the virus.

RECENTLY, THE U.S. GOVERNMENT HAS TAKEN SEVERAL NOTABLE STEPS TO BEGIN TO PREPARE FOR A POTENTIAL PANDEMIC.

- Congress has been increasingly concerned about the nation's readiness to respond to pandemic and annual influenza. Since convening in January, the 109th Congress has held a series of hearings on issues related to influenza, including:
  - May 26, 2005, *"The Threat of and Planning for Pandemic Flu,"* House Committee on Energy and Commerce, Health Subcommittee.
  - May 4, 2005, *"The State of Readiness for the 2005-2006 Flu Season,"* House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.
  - April 12, 2005, *"Pandemic Preparedness and Influenza Vaccine Supply -- CDC, NIAID and the Office of the Secretary of HHS,"* House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.
  - February 10, 2005, *"The Perplexing Shift from Shortage to Surplus: Managing This Season's Flu Shot Supply and Preparing for the Future,"* House Committee on Government Reform.
- In May 2005, Congress passed supplemental appropriations legislation that made available $25 million "for a coordinated program to prevent and control the spread of the avian influenza virus."[27] In addition, $58 million was appropriated for the purchase of influenza countermeasures for the Strategic National Stockpile. These funds are expected, in part, to be used to order an additional three million courses of Tamiflu, to bring the U.S. stockpile order up to 5.3 million courses of treatment.
- In April 2005, U.S. Senator Barack Obama (D-IL) introduced the AVIAN Act of 2005, proposed legislation that includes a mandate for the federal government to stockpile the antiviral medication oseltamivir, commonly known as Tamiflu.[28]
- In April 2005, U.S. President George W. Bush approved use of quarantine in the event of an outbreak of "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic," which includes, but is not limited to the H5N1 strain of avian flu currently in Southeast Asia.[29]
- In April 2005, the U.S. Department of State issued an advisory statement about the avian flu and announced it is taking measures to support the World Health Organization's (WHO) efforts to contain the outbreak.[30]
- In March 2005, in the U.S. Department of State authorization bill (S.600), the U.S. Senate proposed including $25 million for International Famine and Disaster Assistance to prevent and respond to a possible outbreak of the avian flu and called for a task force to coordinate U.S. policy.[31]

> "'We remain very vulnerable,' summarized Energy and Commerce Committee Chairman Joe L. Barton [(R-Texas)]. 'Think of it like this -- a bad flu outbreak could kill more Americans than either or both of the last century's world wars.'[32]"

State Pandemic Readiness

Similar questions can be asked about the level of preparedness of state and local governments for a pandemic. America's public health system relies on a loosely affiliated network of approximately 3,000 federal, state, and local health agencies often working with private sector and professional health organizations. State governments have primary responsibility for the health of their citizens under U.S. law. Therefore, a federal plan without ready-to-implement state plans would be insufficient.

Most states have developed draft pandemic response plans, but they are in widely different phases of readiness. A recent examination found that only between 25-30 states have made their plans publicly available.[33] Making the plans publicly available is considered by many experts as an essential feature of pandemic readiness in order to improve integration with other jurisdictions as well as to add a level of accountability. In fact, in commenting on the draft U.S. pandemic influenza preparedness plan, the WHO stated, "We feel that in order to ensure broad commitment for the plan, it is essential to involve the community in the planning process."[34]

CITY AND LOCAL PLANNING: ON-THE-GROUND AND FACING UNIQUE PROBLEMS

Pandemic planning efforts must incorporate local health departments and first responders in plan development.

While states have legal jurisdiction to oversee much of a pandemic plan's contents, local responders will be responsible for the related operational, on-the-ground implementation. Surge capacity, antiviral prioritization, and outbreak tracking are among the areas especially critical to plan for in the local context. Additionally, a highly-dense urban area poses a particular danger because of the possibility of massive virus transmission.

Local areas, in coordination with state and federal officials, need to prioritize pandemic preparations to ensure that implementation and first response is as seamless and effective as possible.

> "We have to plan for the worst-case event"
>
> – Dr. Jean Taylor, head of Maryland pandemic-planning efforts, Maryland Department of Health and Mental Hygiene.[35]

Vaccine and Antiviral Medication Issues

National planners must focus on questions surrounding stockpiling antivirals and stabilizing vaccine development to protect people in the event of an outbreak. This is problematic given the limited production capacity for antivirals and vaccines in the U.S. and throughout the world.[36]

THE SHRINKING VACCINE MANUFACTURING MARKET

In 1976, 37 U.S. companies manufactured vaccines. In 2002, there were only three. Reasons given for the decline are mostly economic:

- Vaccine production can take decades of research and development and, according to industry estimates, costs about $800 million per licensed vaccine.
- Concerns about liability impact manufacturers' decisions to avoid vaccine production, especially after the significant compensation claims that followed the swine flu immunization program in the mid-1970s.
- Some companies also cite insufficient market size as reason to stay out of the vaccine market, due to the current low incidence of many diseases in the U.S., such as tuberculosis. The flu vaccine demand is particularly seen as unstable due to the unpredictability of the size and scope of the market each year.
- There are only two manufacturers currently licensed to produce influenza vaccines in the U.S., and a third overseas manufacturer who supplies vaccine to the U.S. One of the U.S.-licensed manufacturers produces inactivated influenza vaccine and one manufacturer produces the live, attenuated vaccine administered through nasal spray.[37]

Flu Vaccine Crisis of 2004

The October 2004 announcement that approximately half of the expected flu vaccine for the U.S. would not be available heightened public awareness about the fragility of the public health system's vaccine development system and national readiness for a fast-moving influenza epidemic.

In early October, Chiron Corporation announced it would not be able to meet demand for its flu vaccine after problems at a British plant halted production of millions of doses. The dose shortage highlighted the fact that the U.S. relies on very few manufacturers to deliver the country's "projected need of 100 million doses."[38] As a result, CDC officials were forced to encourage changes in the nation's distribution procedures for the flu vaccine supply, reserving doses only for the populations most in need. This illustrates the lack of coordination for the prioritization and distribution of vaccines, particularly in a crisis.

The shortage resulted in a focus of media and public attention on the issue, long lines at health clinics around the country, and calls for incentives, liability reforms, and other measures to encourage a broader range of vaccine producers.

OUTDATED TECHNOLOGY FOR DEVELOPING FLU VACCINE

Flu vaccines similar to those currently in use were first introduced during the 1940s. Since then, scientists have improved the standardization and purity of the process. However, the world remains dependent on the same basic technology that relies on inoculating the current influenza virus strains into embryonated hens' eggs for vaccine production.[39]

The influenza vaccine available each year is carefully engineered to respond to particular strains of the flu judged most likely to emerge based on projections and the genetic composition of prior outbreaks. However, the creation of a vaccine to combat a particular flu season is an annual "best guess" by virologists. It takes approximately six to nine months to develop yearly seasonal flu vaccines or vaccines for new strains of the disease. Therefore, employing the currently used technology, there will be a lag time of at least six to nine months before a vaccine will be available after a pandemic outbreak strikes.

There are new technologies being developed to produce flu vaccine, which involve cell cultures, recombinant protein, and DNA-based approaches. They may help produce influenza vaccine more efficiently and provide more adaptability to unexpected problems or losses in production. The U.S. government has invested approximately $150 million over the last two years to stimulate development of these new technologies.[40] However, this technology will not be available for use in the immediate future, including within the timeframe that most experts predict a pandemic outbreak will occur.

In the meantime, the federal government has invested $41 million to expand and maintain the chicken flocks used by Sanofi Pasteur, the only company that has a U.S.-based influenza vaccine production facility. The goal of the investment is to ensure that flocks can produce eggs year-round.

STOPGAP ANTIVIRAL MEASURES ARE POSSIBLE TO PROTECT PEOPLE IN THE SIX TO NINE MONTHS OR MORE IT WOULD TAKE TO DEVELOP A VACCINE FOR A NEW, LETHAL FLU VIRUS STRAIN

In February 2005, WHO released a report recommending that nations around the world stockpile antiviral medication to protect against the current lethal avian strain of the flu. The WHO has recommended this as a "stopgap" measure, since it would likely take a minimum of six months to develop a vaccine after a widespread outbreak. Therefore, antiviral stockpiling would be an essential interim step to have a way to protect people if a pandemic outbreak spread before a vaccine was developed. While health experts expect a pandemic will occur soon, there is no way to forecast the exact timing. The quantities of both the antiviral medication and a vaccine, once one becomes available, would be limited and countries around the world would all be seeking supplies.

An antiviral medication, oseltamivir, commonly known as Tamiflu, exists that could help alleviate symptoms of those who contract the pandemic flu and reduce mortality levels. It can also be used as prophylaxis, or preventive treatment, to help protect emergency first-responders and front-line health care workers.

The WHO estimates that a pandemic flu outbreak could impact approximately 25 percent of the population in nations worldwide. Unfortunately, there is limited production capacity for this vital medication.

The U.S. federal government reportedly has ordered 5.3 million courses of Tamiflu for the Strategic National Stockpile, however it would require approximately 70 million courses to cover 25 percent of the U.S. population.[41]

Several other countries have already ordered enough Tamiflu to protect between 20-25 percent of their populations in case of an outbreak. The U.S. is already behind in the queue to place an order for the medication, for which there is a single manufacturer worldwide -- Roche Pharmaceutical, which is located in Switzerland. In testimony before the U.S. House of Representatives Health Subcommittee of the Energy and Commerce Committee, the medical director for Tamiflu of the Roche company explained that historically they have not produced the levels of Tamiflu required for global stockpiling. To help accommodate the growing concerns and orders, they have increased production of the antiviral nearly eight-fold since 2003.[42]

On March 1, 2005, the British government announced that it was taking steps to procure 14.6 million courses of Tamiflu.[43] This procurement would cover 25 percent of the British population, the rate WHO has recommended.

Given the current and projected production capacity, if the U.S. did place a large order for Tamiflu, Roche has testified before Congress that it could be the end of 2007 before they could deliver enough to the national stockpile for 25 percent of the population. Thus, antiviral treatment will only be an effective part of the U.S. response if a pandemic does not occur for several years and, of course, if the pandemic strain is responsive to antiviral medications.

"Roche has received and is filing on schedule, pandemic stockpile order for Tamiflu from 25 countries worldwide. Discussions are underway for the U.S. government to purchase significantly greater amounts of Tamiflu. However, HHS stockpile purchases to date are sufficient to treat less than one percent of the U.S. population. We have also received a non-binding letter of intent for HHS to purchase additional treatments to cover under 2 percent of the population.

In contrast, countries such as the United Kingdom, France, Finland, Norway, Switzerland, and New Zealand are ordering enough Tamiflu to cover between 20 and 40 percent of their populations. Unfortunately, given the complexities I have described and the increasing global demand, any government that does not stockpile sufficient quantities of Tamiflu in advance cannot be assured of an adequate supply at the outbreak of an influenza pandemic."[44]

– Dr. Dominick Iacuzio, Medical Director for Tamiflu at Roche in testimony before the U.S. House of Representatives Health Subcommittee of the Energy and Commerce Committee on May 26, 2005.

STRATEGIC NATIONAL STOCKPILE AND ONGOING ANTIVIRAL CONCERNS

Tamiflu and other antiviral medications have shelf life considerations. The FDA has currently approved a five year shelf life for Tamiflu. In the event that a pandemic does not occur within the five year window for use of the stockpiled reserve of the drug, the U.S. and other countries can still make use of the Tamiflu they have ordered for use against annual regular flu concerns before it expires.

Shelf life concerns of antiviral medications, that are part of the Strategic National Stockpile, however, need to be taken into consideration. Budgeting to replace the reserve of medications that have been determined to be essential to protecting Americans in the event of emergencies need to be factored into ongoing homeland and health security discussions.

> "The next pandemic is imminent ... (and we) ... are not prepared. Vaccine availability is not secured. Antiviral stocks do not exist and will not be under the current market forces. In the event of a pandemic millions of people could die, economies could be affected and medical and civil services could collapse. Members of the public will not excuse authorities, who will be held responsible for not having put in place up-to-date preparedness."[45]
>
> – The European Commission, November 27, 2001

New Concern: Birds to Pigs to Humans?

According to a May 2005 edition of Nature Magazine, *scientists are increasingly concerned that a "dangerous strain" of the avian flu virus may be growing in pigs in Indonesia.[46] Pigs are known to serve as a "mixing vessel" that incubate strains of disease that become more easily transmissible to humans.[47]*

Southeast Asia's Containment Capacity

Southeast Asia, the epicenter of the avian influenza outbreak, has a poor capacity to contain a pandemic if one should emerge. A pandemic would overwhelm the capabilities of local Asian health departments. With their insufficient capacity and technology, much of Southeast Asia's ability to detect and monitor the outbreak is severely limited. As a result, the U.S. must also decide how it will assist the world community in responding to the threat -- and prepare for the worst.

U.S. Versus the World?

U.S. planning and preparedness for a pandemic lags behind a number of other countries. Below is a comparison of the U.S. versus the U.K. and Canadian efforts across a number of dimensions. While the preparations in the U.K. and Canada compare favorably to the U.S., some public health experts still raise concerns about the degree of implementation-readiness in their efforts.

	US	UK	Canada
Leadership	No government-wide coordination mechanism in place; Secretary of HHS receives daily briefings; within HHS divided authority between pandemic preparedness (Office of the Assistant Secretary for Health) and pandemic response (Office of the Assistant Secretary for Emergency Preparedness). Guidance provided to states for planning purposes; no release or systematic review of local plans.	Cabinet-level office coordinates government-wide and "civil society" efforts. Department of Health leads public health and National Health Service response. Similar plans adopted and coordinated with Scotland, Wales, and Northern Ireland.	Pandemic Influenza Committee co-chaired by federal government and provincial representative to coordinate national efforts.
Planning	Draft plan released August 2004 for public comment; no timeline for finalized plan.	Plan effective March 2005	Plan effective February 2004
Vaccine Development	NIH-funded research on pandemic vaccine; initial contracts for building potential vaccine stockpile. Significant portion of US vaccine supply manufactured abroad.	Research being conducted on potential vaccines. Prototype "dossier" for regulatory approval of pandemic vaccine in development. Discussions with manufacturers regarding optimizing capacity. Most UK vaccine production occurs in the UK.	Canadian government has contracted for reserve production capacity for a pandemic vaccine with a Canadian manufacturing facility.
Vaccine Planning	HHS soliciting public comment on prioritization for receipt of limited supply of vaccine.	Priority groups for vaccination identified in plan.	Priority groups for vaccination identified in plan.
Antiviral Planning	5.3 million courses of antiviral ordered for stockpile (two percent of population). HHS soliciting public comment on prioritization for distribution of limited supply.	Courses to cover 25 percent of the U.K. population have been ordered. Priority groups for antiviral treatment identified.	Courses ordered to cover three percent of the Canadian population. Priority groups for antiviral treatment identified.
Health Care System Surge Capacity Planning	Planning guidance provided for health care system.	U.K. has integrated health care system through National Health Service and local Primary Care Trusts, under direct leadership of U.K. Department of Health	Checklist of activities issued for surge capacity preparation.
Communications Planning	Outline of steps to prepare communications tools and mechanisms.	Specific professional (provider), public and media communications messages and activities identified by stage of pandemic.	Checklist of activities by stage of pandemic issued.

Recommendations

> "U.S. PANDEMIC READINESS WILL DEPEND ON IMMEDIATE AND LONG-TERM STRATEGIES AS WELL AS DEDICATED, INFORMED FEDERAL LEADERSHIP."
>
> – Congressman Jerry Lewis (R-CA), Chairman of the Appropriations Committee of the U.S. House of Representatives

> "THERE IS A TIME IN THE LIFE OF EVERY PROBLEM WHEN IT IS BIG ENOUGH TO SEE AND SMALL ENOUGH TO SOLVE. FOR FLU PREPAREDNESS, THAT TIME IS NOW.[48]"
>
> – U.S. Department of Health and Human Services Secretary Mike Leavitt, May 16, 2005

Overall, U.S. pandemic preparedness is inadequate. Both the federal pandemic plan and various state pandemic plans are insufficient blueprints for an effective national response to a pandemic influenza.

How prepared the U.S. and the rest of the world are to respond to and control a pandemic will be determined by how much time remains until an outbreak occurs. Preparations must be considered without knowing this exact timeframe. Scientists predict it could happen as soon as this year, or it could take several years. Therefore, planning and policies must consider what would need to be done if an outbreak occurred very soon or with longer lead time to prepare.

- **Crucial immediate steps** that must be taken to minimize loss if a pandemic occurs in the near term include outbreak tracking, stockpiling medical supplies, and communications plans.
- **Intermediate steps** that must be considered if a pandemic occurs with several years to prepare include stockpiling antivirals and developing additional surge capacity plans for hospitals and other medical providers.
- **Longer-range steps** that should be undertaken if there are a number of years to prepare include increasing vaccine production and the development of new technologies for vaccines.

Whether a pandemic emerges from the H5N1 virus or a different strain, the challenge remains constant. Responding quickly and effectively to a pandemic requires a comprehensive national plan integrated with state and local-based emergency planning efforts. Though wider national attention and a general acknowledgement of the virus's danger are important developments, specific U.S. pandemic planning efforts are in need of immediate attention. A review of both the federal pandemic plan and state pandemic plans found that many important planning topics remain under-addressed. Shoring up these weaknesses should be the highest of government priorities. In the interim, every effort should be made by the federal government to procure the antivirals as a stopgap measure.

To move towards operational plans capable of wider integration and implementation, and as a first step towards a strong, cohesive, and rapid-preparation U.S. pandemic flu strategy, TFAH recommends the following activities be addressed in federal, state, and local preparedness efforts:

Define Roles and Responsibilities

A clearly-defined organizational structure and chain of command is essential for rapid and efficient control and response, both in the federal government and at the state level. At the federal level, the President should designate a single senior official whose primary responsibility is to assure Cabinet-level coordination of the federal government's response to a pandemic and also to ensure coordination between civil society (non-governmental economic infrastructure) and government during a pandemic. Immediate planning should be occurring at the federal level to minimize disruption of the health care system and the overall economy. CDC must review and approve of state pandemic plans to ensure nationwide preparedness standards and regional coordination. States must define and agree upon leadership roles and responsibilities with respect to who is in charge of a state's public health and health care decisions. Plans must also designate liaisons to work with other jurisdictions and federal officials.

Outbreak Tracking

Plans should ensure adequate laboratory surveillance of influenza, including the ability to isolate and subtype influenza viruses year-round. Following federal guidelines outlined by HHS, states should report all necessary data and information to federal and other health officials as soon as it becomes available. Congress should provide additional support for CDC's global surveillance activities, and the U.S. should support the WHO's surveillance program to assure as early a warning as possible for U.S. preparedness purposes.

Vaccine Research, Development, and Production

The U.S. should continue to support and expand research into new technologies for influenza vaccine and clinical trials for potential avian flu and other pandemic vaccines. While the U.S. has issued limited contracts for stockpiling a potential pandemic vaccine, the federal government should also explore the Canadian approach of contracting for a reserve production capacity located in the U.S. A vaccine stockpiling approach is successful if public health authorities have guessed correctly on what the pandemic strain will be. A reserve production capacity can assure quick turnaround for production of a vaccine for the actual pandemic strain.

Prior to production, the U.S. Food and Drug Administration (FDA) must approve a new vaccine. Other nations are putting protocols in place now with respect to creating a rapid review process for a pandemic flu vaccine. With clear advance notice of the scientific data that will be required for approval from regulatory agencies, vaccine manufactures can better anticipate how to comply. For example, regulators in the U.K. are already working with vaccine manufactures to develop a model application for approval of a pandemic vaccine, which they estimate could reduce production time by as much as two months. The U.S. FDA should adopt a similar strategy.

Procure Additional Antivirals for Treatment

Even during a pandemic, when efforts to contain transmission may seem futile, there exists a capacity to treat infected individuals. While the ultimate effectiveness of treatment depends on the particular strain, Tamiflu may be an effective treatment option while scientists work on the development of a vaccine. Furthermore, Tamiflu can be used prophylactically to protect hospital and health care workers on the front lines.

The recently enacted emergency supplemental appropriations legislation made available $58 million for the purchase of influenza countermeasures for the Strategic National Stockpile, including, but not limited to, antiviral medications and vaccines. These funds are most welcome, but TFAH believes that Congress should provide additional funds during the FY 2006 appropriations cycle to continue to build the nation's antiviral stockpiles from the current level of two percent of the U.S. population to cover a higher percentage of the population.

Mass Vaccination and Treatment Systems

The federal government, in coordination with the states, must develop systems for tracking and distributing antiviral medication and vaccines. A national system is needed to assure targeted and/or equitable distribution of supply, so we do not have a repeat of the 2004-2005 flu season distribution problems. State-level systems also are needed to assure similar availability across a state. One of the best ways to improve vaccination preparations for a pandemic outbreak may be to enhance annual flu vaccination coverage for non-traditional high-risk groups (e.g. individuals with chronic diseases or compromised immune systems) to facilitate access to these populations during a pandemic.

Prioritize Who Would Receive Antivirals and Vaccines Based on Limited Supplies

It is important to determine a protocol for allocation among high priority populations, such as health care workers, prior to an outbreak. The federal government should provide specific guidance to states as to which sectors of the population should receive antiviral medications and vaccines, and in what order, particularly since the amount of available pharmaceuticals will be limited.

Public Information Campaigns and Materials

Communicating with the public in a clear and efficient manner is essential during a high-anxiety time. The federal government, in conjunction with the states, should develop coordinated messages for various audiences (media, public, providers, etc.) for each stage of a potential pandemic. States must identify and train spokespersons in multiple languages and educate public health officials, politicians, community leaders, partners, and the media about what information will and will not be available during a pandemic. States should ensure clear and consistent messaging by creating information templates in multiple languages ready for customization and distribution during a pandemic.

Stockpile Medical and Safety Equipment for Health Care Workers and First Responders

Efforts must be undertaken to ensure that basic medical and safety equipment will be available for health care workers and emergency responders in the event of a major outbreak. Currently, most health providers order and stock supplies on a "just-in-time" basis. This means they often only have a few days of reserve supplies, equipment, and medicines, including many basic protective items, such as masks, gloves, gowns, and clean hospital linens. In order to prepare for a mass event, steps must be taken immediately to stockpile additional supplies, particularly since during an outbreak, many production and delivery systems for supplies will likely be stalled or even stopped.

Surge Capacity Capabilities

Plans must account for the likelihood that hospitals will be quickly overwhelmed during a pandemic, by developing auxiliary sites such as shelters, schools, nursing homes, hotels, and daycare centers for surge capacity treatment and for treatment of the "walking well." States should be conducting surveys of potential sites and obtaining agreements. Cooperation and integration with local health officials and first responders is essential.

Secure a Backup Workforce

States should conduct and maintain an inventory of healthcare professional residents, including current and retired doctors, nurses, veterinarians, emergency medical staff, and other potential volunteers. These workers could be an essential expanded workforce during a pandemic. Pandemic survivors are also a population of potential workers. States should plan for tracking and soliciting volunteer support from this population, which is presumably immune to the virus. Planning efforts should also incorporate private sector support whenever possible, especially in infrastructure and non-health service provider capacities.

Ensure Availability of Food, Water, and Other Supplies

States must account for high demand for food, water, and other basic supplies, and plan for distribution to general and hard-to-reach populations. Plans should factor in potential complications of infected food and delivery workers, possible infected store facilities, and limitations on public interaction both for those infected and the general population at risk of exposure. Planners must also weigh the issue of "just-in-time" manufacturing of food and supplies, since reserves of supplies will not be available. Additionally, planners must address the limitations of medical equipment manufacturing, much of which Asia exports to the world.

Quarantine Measures and Authority to Close Public Places

States must establish clear legal authority and emergency measures to effectively contain the spread of disease. States must have powers to prohibit public gatherings, close public facilities and schools, and restrict travel, if necessary.

Measures to Manage Mass Death

Planning for worst-case scenarios is a critical component of effective planning. States must conduct and maintain an inventory of facilities with sufficient refrigerated storage to serve as temporary morgues in the event of a pandemic.

As indicated, there are several concrete steps that the U.S. can take to better prepare against an influenza pandemic. Such policies and investments will help stabilize the nation's health and economy in the event of a pandemic while ensuring that pandemic readiness preparations are "commensurate with the scale of the threat we face."[49]

Report Authors

Margaret A. Hamburg, MD
Vice President for Biological Programs
NTI

Shelley A. Hearne, DrPH
Executive Director
Trust for America's Health

Jeffrey Levi, PhD
Senior Policy Advisor
Trust for America's Health

Kim Elliott, MA
Deputy Director
Trust for America's Health

Laura M. Segal, MA
Director of Public Affairs
Trust for America's Health

Michael J. Earls
Public Affairs Associate
Trust for America's Health

Peer Reviewers

The opinions expressed in this report do not necessarily reflect the views of the peer reviewers. TFAH greatly appreciates the reviewers' time and insights.

Michael Osterholm, PhD, MPH
Director, Center for Infectious Disease Research and Policy, and Professor, School of Public Health
University of Minnesota

Alonzo Plough, PhD, MPH
Vice President, Program, Planning, and Evaluation
The California Endowment
(Effective July 18, 2005)

Appendix A: State-by-State Range of Potential Pandemic Influenza Deaths and Hospitalizations*

State	Projected Dead		Projected Hospitalized	
	25% contraction, lower severity flu deaths	25% contraction, high severity flu deaths	25% contraction, lower severity hospitalizations	25% contraction, high severity hospitalizations
Alabama	2,962	17,771	12,863	77,178
Alaska	295	1,771	1,519	9,114
Arizona	3,074	18,446	13,225	79,350
Arkansas	1,783	10,700	7,553	45,318
California	20,292	121,750	91,030	546,180
Colorado	2,397	14,383	10,993	65,958
Connecticut	2,351	14,107	9,978	59,868
Delaware	502	3,014	2,187	13,122
District of Columbia	385	2,310	1,658	9,948
Florida	11,912	71,474	47,462	284,772
Georgia	4,552	27,309	20,970	125,820
Hawaii	815	4,892	3,524	21,144
Idaho	760	4,558	3,385	20,310
Illinois	7,907	47,439	34,579	207,474
Indiana	3,939	23,634	17,237	103,422
Iowa	2,078	12,465	8,697	52,182
Kansas	1,791	10,746	7,648	45,888
Kentucky	2,643	15,859	11,583	69,498
Louisiana	2,778	16,668	12,383	74,298
Maine	884	5,302	3,778	22,668
Maryland	3,319	19,916	14,833	88,998
Massachusetts	4,379	26,271	18,679	112,074
Michigan	6,541	39,244	28,668	172,008
Minnesota	3,101	18,608	13,596	81,576
Mississippi	1,787	10,723	7,844	47,064
Missouri	3,758	22,548	16,080	96,480
Montana	601	3,608	2,595	15,570
Nebraska	1,147	6,882	4,899	29,394
Nevada	1,081	6,486	4,819	28,914
New Hampshire	778	4,665	3,434	20,604
New Jersey	5,660	33,960	24,264	145,584
New Mexico	1,081	6,488	4,835	29,010
New York	12,567	75,401	54,163	324,978
North Carolina	4,996	29,973	21,880	131,280
North Dakota	457	2,742	1,931	11,586
Ohio	7,732	46,393	33,326	199,956
Oklahoma	2,278	13,666	9,792	58,752
Oregon	2,241	13,447	9,682	58,092
Pennsylvania	9,062	54,369	37,553	225,318
Rhode Island	745	4,467	3,087	18,522
South Carolina	2,491	14,947	10,995	65,970
South Dakota	520	3,118	2,199	13,194
Tennessee	3,625	21,750	15,893	95,358
Texas	11,708	70,247	53,550	321,300
Utah	1,131	6,786	5,302	31,812
Vermont	395	2,369	1,738	10,428
Virginia	4,368	26,207	19,624	117,744
Washington	3,637	21,820	16,204	97,224
West Virginia	1,350	8,097	5,671	34,026
Wisconsin	3,540	21,240	15,281	91,686
Wyoming	305	1,830	1,363	8,178
TOTALS	180,478	1,082,866	786,032	4,716,192

* Projections based on CDC's FluAid 2.0 program. The estimated deaths and hospitalizations assume the following: The projections range from the most likely number of deaths and hospitalizations at a 25% rate of contraction for a relatively mild pandemic, similar to the 1968 pandemic, to the most likely number of deaths and hospitalizations for a more severe pandemic, similar to the 1918 pandemic.

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