

PANDEMIC FLU: PREPAREDNESS IN A CHANGING WORLD

Prologue Series



WHAT IS PAST
IS PROLOGUE

Michael O. Leavitt

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Prologue Series

I have come to understand that public service is a generational relay. Many of the most profound problems are not ours to solve in finality, but rather to incrementally improve during our temporary stewardship.

Three foundation goals thus form the basis for my public service: to leave things better than I found them; to plant seeds for the next generation; and to conclude my work knowing I have given my all.

For nearly sixteen years, my life has evolved in four year terms. I was elected three times as Governor of Utah. Some of what I consider our accomplishments were initiated in my first term, but fully matured in my third. Likewise, some seeds planted in my third term are only now beginning to flower.

Living in four year cycles has taught me the importance of choosing priorities and impressed the need for urgency. Time passes quickly.

I am currently in my fifth year as a member of President George W. Bush's Cabinet. I served first as the Administrator of the Environmental Protection Agency and now as Secretary of Health and Human Services. The constitutional constraints on the President's service imposed limits on what initiatives I might see to completion. However, I view it as my obligation to lead with a longer horizon in mind.

Over time, I have developed a set of tools useful in keeping a long-term vision in mind while managing the day-to-day problems. One such tool is establishing a 5,000 Day Vision, with a 500 Day Plan.

The 5,000 Day Vision is our aspiration for various long-term outcomes. The 500 day plan is more granular, listing what needs to be done now to bring about the larger vision. Both are recalibrated periodically.

As my stewardship comes to a close, it is time to plant seeds for the next generation. I intend to write and deliver a series of formal speeches to convey some of the 5,000 Day Vision and share what I see on our approaching horizon.

I call these speeches *The Prologue Series*. There is a statue behind the National Archives that I look at nearly every day as I drive between HHS and the White House. The statue, the work of Robert Aitken, is called "The Future." It depicts a woman looking up to the horizon from a book as if to ponder what she has just read. At the base of the statue are the words from Shakespeare's *The Tempest* "What is past is prologue."

I have titled this speech in *The Prologue Series*: "Pandemic Flu: Preparedness in a Changing World."

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
Speech given on October 29, 2008
in a PlanFirst Webinar

September 11, 2001, changed America in many ways. It changed HHS as well. Until that time, HHS conducted science, financed health and human services, and regulated certain health matters. Some small elements devoted to emergency response existed, but they were incidental.

In the aftermath of 9/11, HHS began to play a broader role. A significant part of my task as Secretary has been to establish preparedness and response as a major part of our mission. That has required functional changes, but perhaps more importantly, we have been required to make cultural changes.

We are in a race. We are in a race against a fast moving virulent virus with the potential to cause an influenza pandemic.

—Pandemic Planning Update, May 2006

The history of pandemics is not so much the history of health as it is the history of humanity.



During an outbreak of bubonic plague in 1899, the Honolulu Board of Health burned to the ground any building in which a person had contracted the plague.

We have created a new emergency management organization at HHS, led by the Assistant Secretary for Preparedness and Response. It includes the Biomedical Advanced Research and Development Authority, or BARDA, which is a new medical countermeasure enterprise that provides comprehensive and systematic methods of preparing and delivering medical countermeasures.

Because there are so many potential man-made and natural disasters that can occur, we have adopted an all-hazards approach. Our preparation for each strengthens the others. We have identified the 15 types of disasters we think may be the most likely and developed response plans that coordinate federal, state, and local planning, rather than developing separate planning silos.

One of those 15 types of disasters is pandemic influenza, because history teaches us there is a rhythmic certainty that we will have a pandemic at some point in the future.

The history of pandemics is not so much the history of health as it is the history of humanity. When pandemics strike, they cause massive sickness and terrible loss of life. They even reshape nations.

The first great pandemic in recorded history struck Athens at the height of its glory. In 430 B.C., a pestilence—now thought to have perhaps been typhus or typhoid fever—killed about a quarter of Athens' population.

Beginning in the 6th century A.D., Europe was ravaged by the first outbreak of the bubonic plague known as the Plague of Justinian. Amazingly, this plague lasted for about 150 years; and, during that time, Europe's population was cut roughly in half.

Six centuries later, history's well-known pandemic hit: the Black Death of the mid-1300s. This was the return of the bubonic plague. In just six years it carried away about 25 million people, about a third of Europe's population.

Today, many people mistakenly think pandemics are a thing of the past. It's true that we no longer have to fear the bubonic plague. We now have a cure for that. The same is true for smallpox.

But we don't have a cure for everything. We don't have a cure for influenza which struck hard in this era of modern medicine—much harder than most people realize. And it will strike again.

Just 90 years ago, the world was struck by an influenza known as the “Spanish Flu” or the “Great Influenza.” Its casualties were mind-boggling. Like World War II, known as the deadliest war in history, the “Great Influenza” killed about 50 million people worldwide.

That's the last time a pandemic has attacked on such a historic scale. But it's not the last time a pandemic has attacked. The influenzas of 1957 and 1968—just 50 and 40 years ago—combined to kill about 100,000 people in the United States alone.

It's not just the old, the very young, or the weak, that die in pandemics. A pandemic killed the vibrant statesman Pericles, called “the first citizen of Athens.” A pandemic killed two Roman emperors, each of whom was the most powerful leader on earth at the time. The 1918 flu was a vicious killer and cruelly seemed to target those in the prime of life. This pandemic killed people in their 20s and 30s at an even greater rate than others and left behind 21,000 orphans in New York City alone.

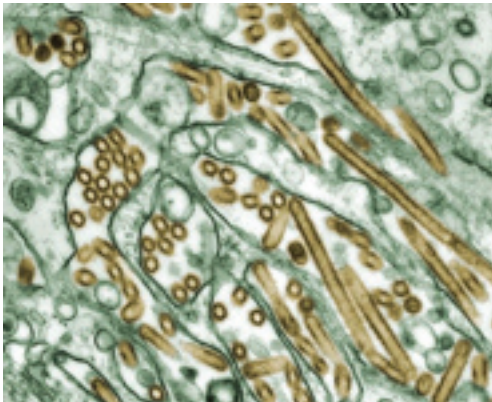
John Barry, author of the “Great Influenza,” a history of the 1918 pandemic, described what happened when the pandemic hit. According to Barry, in one week in October of that year, 4,500 people died from influenza or pneumonia in Philadelphia alone. Let me put that into perspective: In a single week, in a single city, the flu caused almost twice as many deaths as were sustained by all Allied forces combined on D-Day.



Men in front of their hospital beds during the Great Pandemic of 1918.

We don't have a cure for influenza which struck hard in this era of modern medicine—much harder than most people realize. And it will strike again.

Pandemics are hard to talk about. When we discuss them in advance, we sound alarmist. After a pandemic starts, no matter how much preparation has been made, it will be inadequate.



Colorized transmission electron micrograph of avian influenza A H5N1 viruses (seen in gold) grown in MDCK cells (seen in green).

The South Pacific is a continent and an ocean away from Philadelphia. It is some 7,000 miles away and in another hemisphere. Yet in Western Samoa, the same flu killed 22 percent of the population in just a few months. Neighboring American Samoa somehow kept the virus off its island and was spared entirely.

There is no rational reason to believe that in the 21st century, we are invincible to pandemics. It has happened before. And if a pandemic strikes, it will again sweep the globe.

Pandemics are hard to talk about. When we discuss them in advance, we sound alarmist. After a pandemic starts, no matter how much preparation has been made, it will be inadequate. In 2005, two things happened that made it clear we needed to do more than talk about the possibility of a pandemic; we needed to start preparing for it.

The re-emergence of the deadly H5N1 avian influenza strain got my attention. The virus had appeared briefly in Hong Kong a few years earlier, but because of aggressive containment action, the world hoped it had disappeared. When it subsequently began to spread rapidly through bird populations and occasionally to people, scientists became very concerned. The virus had similar genetic properties and identical clinical manifestation to the virus which caused the 1918 pandemic.

The second event was Hurricane Katrina, which I think of as a shakedown of our national response plan. It revealed our weaknesses. I vividly recall walking through medical shelters thinking, “As devastating as this is, a severe pandemic would be far worse because it would be happening in all states at the same time, and it would be ongoing for more than a year.”

We have come a long way since November 2005, when President Bush mobilized the nation to prepare for an influenza pandemic. He called for the deployment of a \$7.1 billion national pandemic plan. Congress responded quickly. As Secretary of HHS, I was given responsibility to implement the plan.

Ultimately, the key to preparing for a pandemic is to develop, stockpile, and prepare to distribute, vaccines and antivirals. We need vaccines to prevent people from becoming infected by a virus, and antivirals to treat them if they are infected.

But the rub is how to achieve this. The goal of developing and stockpiling vaccines is simply stated, yet not easily achieved. Developing and stockpiling vaccines is not a job for any one government. It is not even a job for any one nation.

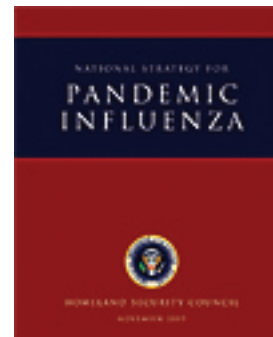
Rather, it requires cooperation between nations, cooperation between different government entities within nations, and cooperation between governments and the private sector. Pandemic preparedness requires that all of these different elements work together. The better they do so, the better prepared we will be.

Every nation should develop comprehensive strategies and contingency plans for a global pandemic. These plans should be coordinated regionally and globally. The opportunity to contain an initial outbreak can only be realized through the development of a sophisticated global strategy.

Every nation should develop plans at all levels of government and in all sectors outside of government. These plans should detail how health departments and agencies of local governments will prevent, mitigate, and respond to an influenza pandemic.

Local preparedness is the foundation of pandemic readiness. In addition to state governors, leadership must come from mayors, county commissioners, school principals, church pastors, college presidents, corporate planners, and the entire medical community.

Any community that fails to prepare because it expects that the federal government can come to the rescue will be tragically wrong—not because we lack the will or the



National Pandemic Influenza Plan

“The point of preparing for pandemic is it’s much more than the health sector, it’s much more than emergency room, it’s all society.”

—Dr. Bruce Gellin,
Director, HHS National Vaccine Program
Office

Community-level direction is the best in dealing with public health and medical issues... who knows the behavior, the culture, the desire, the priorities of the community better than the people who actually live in that community?

—Rear Admiral Craig Vanderwagen, Assistant Secretary for Preparedness and Response



Eggs are used to grow viruses, both for testing and for vaccine production.

wallet, but because there is no way to be everywhere at once. A pandemic is unique in that it happens in nearly every community simultaneously.

One of our highest priorities is to enhance and expand U.S.-based production capacity to the point that it can generate enough pandemic influenza vaccine for every American within six months of the time that the actual pandemic virus is identified.

When we started this initiative, we didn't have a vaccine for the H5N1 virus. Even if we had, there was insufficient manufacturing capacity to produce the amount we would need. Most of the production capacity was outside the United States. This would be a serious problem in a global pandemic, when other nations would need their own production for themselves.

Another challenge was that the traditional egg-based methods of manufacturing vaccine are limited by the number of chickens and facilities. We decided to face both problems head-on. We partnered with the private sector to develop new cell-based methods of production, along with sophisticated adjuvant or dose-sparing technology, that will radically reduce production constraints and dramatically lower the price of vaccines.

Today, with over \$1 billion of HHS funding supporting them, six companies are in various stages of implementing commercial-scale production of cell-based methods and/or expanding their capacity for conventional manufacturing using chicken eggs. We will reach our goal of having the needed capacity by 2011.

Partly as a result of these efforts, we have now procured 26 million doses of H5N1 pre-pandemic influenza vaccine. If the virus mutates to where it has pandemic properties, a new vaccine will have to be developed, but this one will provide some protection.

This stockpile is also available to support clinical trials and to protect physicians and other first-responders in the early stages of a pandemic. We plan to buy additional doses of pre-pandemic vaccine. We have reached our goal of stockpiling enough pandemic influenza antivirals to cover 50 million people.

Meanwhile, state governments have taken advantage of a chance to purchase up to 31 million treatment-courses of antiviral drugs while receiving a 25 percent federal subsidy and while making use of federal “best price” contracts. Some states have decided to purchase additional antiviral drugs under these federal contracts, but with funds not subsidized by the federal government.

To date, the states have purchased 22 million treatment-courses of Tamiflu and Relenza for pandemic stockpiles.

We have awarded a total of \$576 million for state and local preparedness. Through these grants, HHS has assisted in building response-elements in local communities and has supported expanded interoperability. This means states can help each other on an almost interchangeable basis.

We have been working with states and local communities to update their pandemic influenza plans and to ensure that they evaluate their plans by conducting exercises.

To make sure that states knew the importance of this effort, we conducted a pandemic influenza summit in each of the 50 states and every one of the U.S. territories. I personally attended about three-quarters of the state summits. These summits brought together health care professionals, schools, and the private sector to advance state and community preparedness.

We have purchased more than 150 million masks and respirators. We have also obligated \$100 million for the purchase of ventilators, syringes, and intravenous antibiotics for potential distribution in case of an influenza pandemic.



Antivirals Tamiflu and Relenza.

To date, the states have purchased 22 million treatment-courses of Tamiflu and Relenza for pandemic stockpiles.

We have supported pandemic influenza preparedness activities in approximately 40 countries around the world.



Testing a chicken for avian flu in Bangladesh.

We have developed a highly sensitive and specific five-target polymerase chain reaction rapid-diagnostic test for avian and seasonal influenza. This will serve as the gold-standard test worldwide for confirming the first cases of avian or potentially pandemic influenza.

We have awarded funds to developers of new point-of-care influenza rapid-test devices. These will enable doctors and other health care professionals to diagnose avian influenza rapidly and easily in a clinical office or other outpatient setting. FDA approval and clinical trials are anticipated by the end of 2009.

We have supported pandemic influenza preparedness activities in approximately 40 countries around the world. Since 2005, HHS has committed over \$350 million to international pandemic preparedness. This assistance is helping other countries improve their laboratory capacities, develop and strengthen disease-surveillance systems, develop preparedness plans, and train health-workers to respond rapidly to outbreaks.

We have deployed teams of experts to help investigate suspected cases of human transmission of influenza A in 12 countries in Asia, Africa, and Europe. We have led workshops to provide country-level rapid-response training in 112 countries, from all six WHO regions.

In summary, we are much better prepared today than we were in the spring of 2005. But there is much that still needs to be done. As I turn over this responsibility to the next Secretary of HHS, there are four priorities I would suggest be considered.

First, follow through with the vaccine facilities. By the end of 2008, we plan to award \$500 million in contracts to companies that will build cell-based vaccine-production facilities in the United States. It's all planned, the money's in the budget, but some of the contracts might need to be finalized in 2009.

Second, strongly defend the global sample-sharing network against short-term opportunism. For 56 years, nations have openly and freely shared virus samples. It is one of the most important global health success stories, and it is being threatened by a few nations who want to hold samples hostage for compensation. These countries would like to have a virus that is first identified in their nation treated as their own intellectual property; they would insist that they benefit in royalties if a vaccine is made to combat the virus identified in their country. I have often asked if the virus spreads from country to country, as they all inevitably do, who owns it then? Owning a virus fails the logic test, but if the world community succumbs to it, all nations will ultimately suffer.

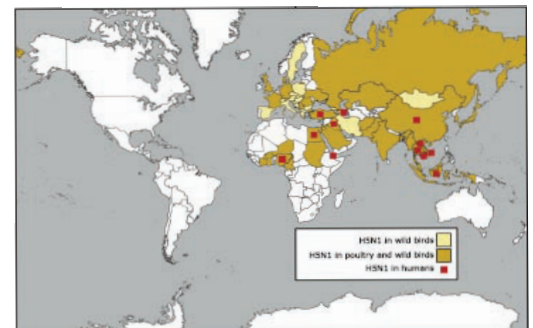
If these nations persist in pursuing compensation for viruses, we should accept the short-term risk their behavior presents. Meeting their demands will result in the downfall of global sample-sharing. Once compensation is paid, there will be no end to demands, and the system will fail, subjecting everyone in the world to even more danger.

The foundation of a global policy of compensating for viruses represents a scarcity mentality. We must pursue an abundance mentality strategy. The collective effort of nations to develop cell-based influenza technology is the perfect example. If the world is dependent on egg-based technology to produce a pandemic influenza vaccine, nearly all of us will be without a vaccine. There just aren't enough chickens to get the job done in the short-time allowed in a pandemic. However, by using new cell-based technology, we have a solution.

Third, concentrate on countermeasure distribution. We have developed an impressive stockpiling system. Within 12 hours, massive amounts of medical countermeasures, and medical supplies can be moved to any location within the United States. However, getting pills into the palms of people's hands fast is critical, and not every state has adequate plans to carry that out.

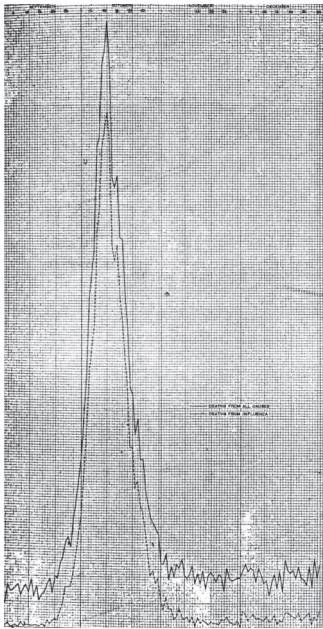
For 56 years, the World Health Organization's Global Influenza Surveillance Network has been providing the world with early warnings of evolving flu viruses. Sample-sharing is essential to its efforts. All nations therefore have a responsibility to share data and virus samples.

—Speech, Anjou, France,
September 8, 2008



According to WHO, as of December 2008, there are 393 confirmed human cases of H5N1 and 248 deaths.

State legislatures are simply failing to adequately fund public health and preparedness. As a former Governor, I completely understand the challenges.



The massive mortality due to the influenza epidemic in October of 1918 in Kansas. This is representative of what happened in every state in the nation.

This is a serious problem because, in the case of anthrax and other biologic attacks, the survival-rates decline dramatically after 48 hours. In such cases, speed truly is life, and the failure of a local government to adequately prepare is potentially catastrophic.

We have been pursuing a series of tools at the federal level that can be immensely helpful on a local level. These include the use of postal workers for house-to-house delivery, or making home med-kits available for first responders and others who wish to have them. Distribution is the Achilles' heel of our countermeasure strategy. It needs continued work.

My last suggestion is directly related: continually remind states, communities, businesses and families about their responsibility to be prepared. This is a never-ending task. The media buzz has died down, but the "bird flu" virus has not. The threat of terrorism has not diminished. Nor is it any less likely that citizens will be subject to life-threatening natural disasters.

We have to resist the tendency that exists right now for local and state governments to use budget limitations as a means of upwardly delegating responsibility for preparedness. Public health is a state and local responsibility, and nobody defends that principle more fervently than state and local officials—until it is time to pay for it.

State legislatures are simply failing to adequately fund public health and preparedness. As a former Governor, I completely understand the challenges. Frankly, public health is one of many important functions being crowded off the budget table by the relentless and unconstrained growth of Medicaid.

The combination of Medicaid eating up state budgets and a cultural change that happened with Katrina, has begun to drive a change toward nationalization of public

health. It has become commonplace to assume that if the federal government doesn't fund it, then local and state governments aren't responsible either.

I'm sympathetic to the challenge of balancing state budgets right now, but there is a reason public health is a local responsibility. Local governments are better able to accomplish the mission.

The federal government has an indispensable role to do things that no individual state can do on its own, and to provide added capacity and coordination. Frankly, in the last three years, there has been tremendous progress in the federal government's capacity to meet this important challenge. However, local and state governments know their communities; they understand their unique needs. States and local governments need to do their duty, and most do.

The key to success in preparing for a pandemic, or any potential disaster is collaboration. We need to continually promote transparency, surveillance, and communication—the essential components of collaboration in the pandemic-preparedness realm.

When it comes to a pandemic or any other emergency—natural or man-made—there is a role for everyone to play. For the world to be prepared, every nation, every city, every business, every school, every hospital, every clinic, every church, and every household needs a plan. And we need to exercise and practice these plans.

Preparation is a continuum. Each day that we prepare brings us closer to being ready. We are better prepared today than we were yesterday. And we will be better prepared tomorrow than we are today.

I'll leave you with this thought: The word "pandemic" comes from the Greeks, the first people known to have



Pandemicflu.gov is the central source of federal flu pandemic information.

Pandemic planning is a shared responsibility. Even families and individuals have a role in preparing for a pandemic.

—Pandemic Planning Update March 2008

A pandemic, at its very essence—in its very name—is something that involves all people, something that concerns everyone.

suffered from a great pandemic. It's composed of "pan," meaning "all" and "demos," meaning "people." Put it together, and you have "all people."

Therefore, a pandemic, at its very essence—in its very name—is something that involves all people, something that concerns everyone.

I believe we can prepare successfully for a pandemic. But it will require determination. It will require change.

There are three ways to approach change. You can fight it and fail; you can accept it and survive; or you can lead it and prosper. We are the United States of America. Let us lead.

In a global market there are three ways to approach change. You can fight it and fail; you can accept it and survive, or you can lead it and prosper.

We are the United States of America; let us lead.

What is past is prologue...