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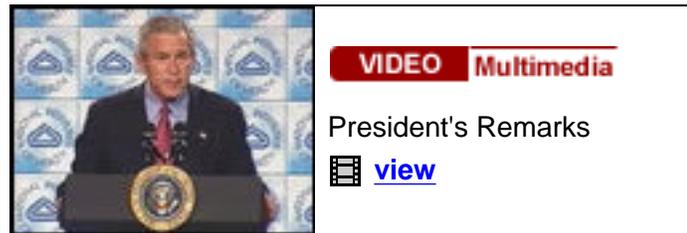
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President Outlines Pandemic Influenza Preparations and Response

William Natcher Center
National Institutes of Health
Bethesda, Maryland

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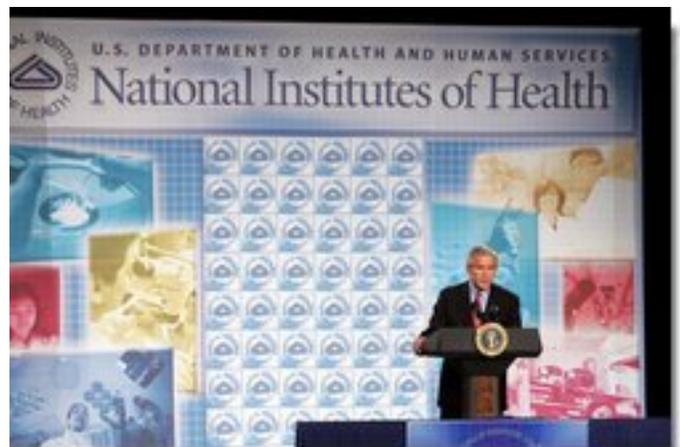


10:04 A.M. EST

THE PRESIDENT: Thank you all. Michael, thank you very much for your introduction. And thanks for the warm reception here at the National Institute of Health. It's good to be back here again.

For more than a century, the NIH has been at the forefront of this country's efforts to prevent, detect and treat disease, and I appreciate the good work you're doing here. This is an important facility, an important complex, and the people who work here are really important to the security of this nation. The scientists who have been supported by the folks who work here have developed and improved vaccines for meningitis and whooping cough and measles and mumps and rubella and chickenpox, and other infectious diseases. Because of the revolutionary advances in medicine pioneered with the help of the NIH, Americans no longer fear these dreaded diseases -- many lives have been saved.

At this moment, the men and women of the NIH are working to protect the American people from another danger -- the risk of avian and pandemic influenza. Today, I have come to talk about our nation's efforts to address this vital issue to the health and the safety of all Americans. I'm here to discuss our strategy to prevent and protect the American people from a possible outbreak.



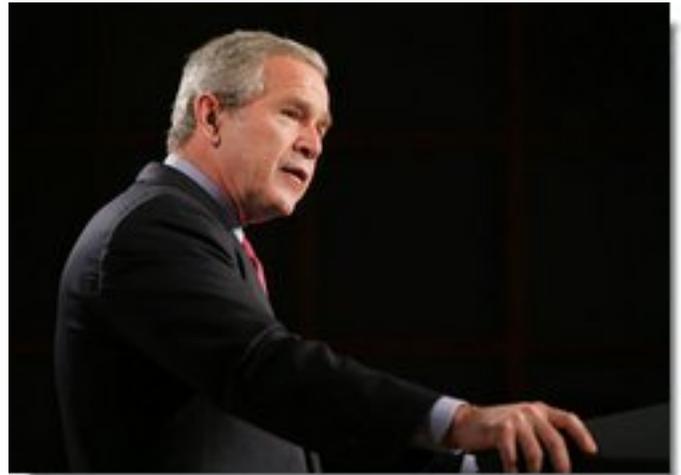
I appreciate members of my Cabinet who are here. More importantly, I appreciate the hard work you've done on this issue. Secretary Rice, Secretary Johanns, Secretary Mineta, Secretary Nicholson, Secretary Chertoff. I appreciate the fact that Dr. J.W. Lee, Director-General of the World Health Organization has joined us. Dr. Lee, thank you for being here.

I want to recognize Dr. David Nabarro, the Senior United Nations System Coordinator for Avian and Human Influenza. Thanks for being here. This is -- you're about to hear me talk about an international scope of response and detection necessary to protect not only our own people, but people around the world. And the fact that these two gentlemen are here is an important signal.

I want to thank Dr. Elias Zerhouni, he's the Director of the NIH; doing a fine job. I want to thank Julie Gerberding, who's the Director of the Centers for Disease Control and Prevention. I appreciate Dr. Rich Carmona, U.S. Surgeon General. Dr. Tony Fauci, Director of the National Institute of Allergy and Infectious Diseases. I want to thank Dr. Bruce Gellin, Director of the National Vaccine Program Office. I want to thank Dr. Andy von Eschenbach, who is the Acting Director of the FDA and the Director of the National Cancer Institute.

I appreciate all the members of the health care community who have joined us today. I want to thank state and local officials who are here. I particularly want to thank Senators Specter and Kennedy for coming, as well as Congressmen Linder, Burgess and Price. I appreciate you all taking time to be here.

Most Americans are familiar with the influenza or the "flu" as a respiratory illness that makes hundreds of thousands of people sick every year. This fall as the flu season approaches, millions of our fellow citizens are once again visiting their doctors for their annual flu shot. I had mine. For most, it's just simply a precautionary measure to avoid the fever or a sore throat or muscle aches that come with the flu. Seasonal flu is extremely dangerous for some -- people whose immune systems have been weakened by age or illness. But it is not usually life-threatening for most healthy people.



Pandemic flu is another matter. Pandemic flu occurs when a new strain of influenza emerges that can be transmitted easily from person to person -- and for which there is little or no natural immunity. Unlike seasonal flu, most people have not built up resistance to it. And unlike seasonal flu, it can kill those who are young and the healthy as well as those who are frail and sick.

At this moment, there is no pandemic influenza in the United States or the world. But if history is our guide, there is reason to be concerned. In the last century, our country and the world have been hit by three influenza pandemics -- and viruses from birds contributed to all of them. The first, which struck in 1918, killed over half-a-million Americans and more than 20 million people across the globe. One-third of the U.S. population was infected, and life expectancy in our country was reduced by 13 years. The 1918 pandemic was followed by pandemics in 1957 and 1968 which killed tens of thousands of Americans, and millions across the world.

Three years ago, the world had a preview of the disruption an influenza pandemic can cause, when a previously unknown virus called SARS appeared in rural China. When an infected doctor carried the

virus out of China, it spread to Vietnam and Singapore and Canada within a month. Before long, the SARS virus had spread to nearly 30 countries on six continents. It infected more than 8,000 people and killed nearly 800. One elderly woman brought the virus from Hong Kong to Toronto, where it quickly spread to her son and then to others. Eventually, four others arrived with the virus and hundreds of Canadians fell ill with SARS, and dozens died.

By one estimate, the SARS outbreak cost the Asian-Pacific region about \$40 billion. The airline industry was hit particularly hard, with air travel to Asia dropping 45 percent in the year after the outbreak. All this was caused by a limited outbreak of a virus that infected thousands and lasted about six months. A global influenza pandemic that infects millions and lasts from one to three years could be far worse.

Scientists and doctors cannot tell us where or when the next pandemic will strike, or how severe it will be, but most agree: at some point, we are likely to face another pandemic. And the scientific community is increasingly concerned by a new influenza virus known as H5N1 -- or avian flu -- that is now spreading through bird populations across Asia, and has recently reached Europe.

This new strain of influenza has infected domesticated birds like ducks and chickens, as well as long-range migratory birds. In 1997, the first recorded outbreak among people took place in Hong Kong, when 18 people became infected and six died from the disease. Public health officials in the region took aggressive action and successfully contained the spread of the virus. Avian flu struck again in late 2003, and has infected over 120 people in Thailand, Cambodia, Vietnam and Indonesia, and killed more than 60 -- that's a fatality rate of about 50 percent.

At this point, we do not have evidence that a pandemic is imminent. Most of the people in Southeast Asia who got sick were handling infected birds. And while the avian flu virus has spread from Asia to Europe, there are no reports of infected birds, animals, or people in the United States. Even if the virus does eventually appear on our shores in birds, that does not mean people in our country will be infected. Avian flu is still primarily an animal disease. And as of now, unless people come into direct, sustained contact with infected birds, it is unlikely they will come down with avian flu.

While avian flu has not yet acquired the ability to spread easily from human to human, there is still cause for vigilance. The virus has developed some characteristics needed to cause a pandemic: It has demonstrated the ability to infect human beings, and it has produced a fatal illness in humans. If the virus were to develop the capacity for sustained human-to-human transmission, it could spread quickly across the globe.

Our country has been given fair warning of this danger to our homeland -- and time to prepare. It's my responsibility as President to take measures now to protect the American people from the possibility that human-to-human transmission may occur. So several months ago, I directed all relevant departments and agencies in the federal government to take steps to address the threat of avian and pandemic flu. Since that time, my administration has developed a comprehensive national strategy, with concrete measures we can take to prepare for an influenza pandemic.

Today, I am announcing key elements of that strategy. Our strategy is designed to meet three critical

goals: First, we must detect outbreaks that occur anywhere in the world; second, we must protect the American people by stockpiling vaccines and antiviral drugs, and improve our ability to rapidly produce new vaccines against a pandemic strain; and, third, we must be ready to respond at the federal, state and local levels in the event that a pandemic reaches our shores.

To meet these three goals, our strategy will require the combined efforts of government officials in public health, medical, veterinary and law enforcement communities and the private sector. It will require the active participation of the American people. And it will require the immediate attention of the United States Congress so we can have the resources in place to begin implementing this strategy right away.

The first part of our strategy is to detect outbreaks before they spread across the world. In the fight against avian and pandemic flu, early detection is our first line of defense. A pandemic is a lot like a forest fire: if caught early, it might be extinguished with limited damage; if allowed to smolder undetected, it can grow to an inferno that spreads quickly beyond our ability to control it. So we're taking immediate steps to ensure early warning of an avian or pandemic flu outbreak among animals or humans anywhere in the world.

In September at the United Nations, I announced a new International Partnership on Avian and Pandemic Influenza -- a global network of surveillance and preparedness that will help us to detect and respond quickly to any outbreaks of disease. The partnership requires participating countries that face an outbreak to immediately share information and provide samples to the World Health Organization. By requiring transparency, we can respond more rapidly to dangerous outbreaks.

Since we announced this global initiative, the response from across the world has been very positive. Already, 88 countries and nine international organizations have joined the effort. Senior officials from participating governments recently convened the partnership's first meeting here in Washington.

Together, we're working to control and monitor avian flu in Asia, and to ensure that all nations have structures in place to recognize and report outbreaks before they spread beyond human control. I've requested \$251 million from Congress to help our foreign partners train local medical personnel, expand their surveillance and testing capacity, draw up preparedness plans, and take other vital actions to detect and contain outbreaks.

A flu pandemic would have global consequences, so no nation can afford to ignore this threat, and every nation has responsibilities to detect and stop its spread.

Here in the United States, we're doing our part. To strengthen domestic surveillance, my administration is launching the National Bio-surveillance Initiative. This initiative will help us rapidly detect, quantify and respond to outbreaks of disease in humans and animals, and deliver information quickly to state, and local, and national and international public health officials. By creating systems that provide continuous situational awareness, we're more likely to be able to stop, slow, or limit the spread of the pandemic and save American lives.

The second part of our strategy is to protect the American people by stockpiling vaccines and antiviral

drugs, and accelerating development of new vaccine technologies. One of the challenges presented by a pandemic is that scientists need a sample of the new strain before they can produce a vaccine against it. This means it is difficult to produce a pandemic vaccine before the pandemic actually appears -- and so there may not be a vaccine capable of fully immunizing our citizens from the new influenza virus during the first several months of a pandemic.

To help protect our citizens during these early months when a fully effective vaccine would not be available, we're taking a number of immediate steps. Researchers here at the NIH have developed a vaccine based on the current strain of the avian flu virus; the vaccine is already in clinical trials. And I am asking that the Congress fund \$1.2 billion for the Department of Health and Human Services to purchase enough doses of this vaccine from manufacturers to vaccinate 20 million people.

This vaccine would not be a perfect match to pandemic flu because the pandemic strain would probably differ somewhat from the avian flu virus it grew from. But a vaccine against the current avian flu virus would likely offer some protection against a pandemic strain, and possibly save many lives in the first critical months of an outbreak.

We're also increasing stockpiles of antiviral drugs such as Tamiflu and Relenza. Antiviral drugs cannot prevent people from contracting the flu. It can -- but they can reduce the severity of the illness when taken within 48 hours of getting sick. So in addition to vaccines, which are the foundation of our pandemic response, I am asking Congress for a billion dollars to stockpile additional antiviral medications, so that we have enough on hand to help treat first responders and those on the front lines, as well as populations most at risk in the first stages of a pandemic.

To protect the greatest possible number of Americans during a pandemic, the cornerstone of our strategy is to develop new technologies that will allow us to produce new vaccines rapidly. If a pandemic strikes our country -- if a pandemic strikes, our country must have a surge capacity in place that will allow us to bring a new vaccine online quickly and manufacture enough to immunize every American against the pandemic strain.

I recently met with leaders of the vaccine industry. They assured me that they will work with the federal government to expand the vaccine industry, so that our country is better prepared for any pandemic. Today, the NIH is working with vaccine makers to develop new cell-culture techniques that will help us bring a pandemic flu vaccine to the American people faster in the event of an outbreak. Right now, most vaccines are still produced with 1950's technology using chicken eggs that are infected with the influenza virus and then used to develop and produce vaccines. In the event of a pandemic, this antiquated process would take many, many months to produce a vaccine, and it would not allow us to produce enough vaccine for every American in time.

Since American lives depend on rapid advances in vaccine production technology, we must fund a crash program to help our best scientists bring the next generation of technology online rapidly. I'm asking Congress for \$2.8 billion to accelerate development of cell-culture technology. By bringing cell-culture technology from the research laboratory into the production line, we should be able to produce enough vaccine for every American within six months of the start of a pandemic.

I'm also asking Congress to remove one of the greatest obstacles to domestic vaccine production: the growing burden of litigation. In the past three decades, the number of vaccine manufacturers in America has plummeted, as the industry has been flooded with lawsuits. Today, there is only one manufacturer in the United States that can produce influenza vaccine. That leaves our nation vulnerable in the event of a pandemic. We must increase the number of vaccine manufacturers in our country, and improve our domestic production capacity. So Congress must pass liability protection for the makers of life-saving vaccines.

By making wise investments in technology and breaking down barriers to vaccine production, we're working toward a clear goal: In the event of a pandemic, we must have enough vaccine for every American.

The third part of our strategy is to ensure that we are ready to respond to a pandemic outbreak. A pandemic is unlike other natural disasters; outbreaks can happen simultaneously in hundreds, or even thousands, of locations at the same time. And unlike storms or floods, which strike in an instant and then recede, a pandemic can continue spreading destruction in repeated waves that can last for a year or more.

To respond to a pandemic, we must have emergency plans in place in all 50 states and every local community. We must ensure that all levels of government are ready to act to contain an outbreak. We must be able to deliver vaccines and other treatments to frontline responders and at-risk populations.

So my administration is working with public health officials in the medical community to develop -- to develop effective pandemic emergency plans. We're working at the federal level. We're looking at ways and options to coordinate our response with state and local leaders. I've asked Mike Leavitt -- Secretary Leavitt -- to bring together state and local public health officials from across the nation to discuss their plans for a pandemic, and to help them improve pandemic planning at the community level. I'm asking Congress to provide \$583 million for pandemic preparedness, including \$100 million to help states complete and exercise their pandemic plans now, before a pandemic strikes.

If an influenza pandemic strikes, every nation, every state in this Union, and every community in these states, must be ready.

To respond to a pandemic, we need medical personnel and adequate supplies of equipment. In a pandemic, everything from syringes to hospital beds, respirators, masks and protective equipment would be in short supply. So the federal government is stockpiling critical supplies in locations across America as part of the Strategic National Stockpile. The Department of Health and Human Services is helping states create rosters of medical personnel who are willing to help alleviate local shortfalls during a pandemic. And every federal department involved in health care is expanding plans to ensure that all federal medical facilities, personnel, and response capabilities are available to support local communities in the event of a pandemic crisis.

To respond to a pandemic, the American people need to have information to protect themselves and others. In a pandemic, an infection carried by one person can be transmitted to many other people, and so every American must take personal responsibility for stopping the spread of the virus. To

provide Americans with more information about pandemics, we're launching a new website, pandemicflu.gov. That ought to be easy for people to remember: pandemicflu.gov. The website will keep our citizens informed about the preparations underway, steps they can take now to prepare for a pandemic, and what every American can do to decrease their risk of contracting and spreading the disease in the event of an outbreak.

To respond to a pandemic, members of the international community will continue to work together. An influenza pandemic would be an event with global consequences, and therefore we're continuing to meet to develop a global response. We've called nations together in the past, and will continue to call nations together to work with public health experts to better coordinate our efforts to deal with a disaster.

Now, all the steps I've outlined today require immediate resources. Because a pandemic could strike at any time, we can't waste time in preparing. So to meet all our goals, I'm requesting a total of \$7.1 billion in emergency funding from the United States Congress. By making critical investments today, we'll strengthen our ability to safeguard the American people in the awful event of a devastating global pandemic, and at the same time will bring our nation's public health and medical infrastructure more squarely in the 21st century.

The steps I have outlined will also help our nation in other critical ways. By perfecting cell-based technologies now, we will be able to produce vaccines for a range of illnesses and save countless lives. By strengthening our domestic vaccine industry, we can help ensure that our nation will never again have a shortage of vaccine for seasonal -- seasonal flu. And by putting in place and exercising pandemic emergency plans across the nation, we can help our nation prepare for other dangers -- such as a terrorist attack using chemical or biological weapons.

Leaders at every level of government have a responsibility to confront dangers before they appear, and engage the American people on the best course of action. It is vital that our nation discuss and address the threat of pandemic flu now. There is no pandemic flu in our country or in the world at this time -- but if we wait for a pandemic to appear, it will be too late to prepare, and one day many lives could be needlessly lost because we failed to act today.

By preparing now, we can give our citizens some peace of mind knowing that our nation is ready to act at the first sign of danger, and that we have the plans in place to prevent and, if necessary, withstand an influenza pandemic.

Thank you for coming today to let me outline my strategy. Thank the United States Congress for considering this measure. May God bless you all. (Applause.)

END 10:30 A.M. EST

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