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THE NEXT FLU PANDEMIC: EVALUATING U.S.
READINESS

THURSDAY, JUNE 30, 2005

The committee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis (chairman of the committee) presiding.


Staff present: Melissa Wojciak, staff director; David Marin, deputy staff director/communications director; Keith Ausbrook, chief counsel; Robert Borden, counsel/parliamentarian; Rob White, press secretary; Drew Crockett, deputy director of communications; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Sarah D'Orsie, deputy clerk; Kristina Sherry, legislative assistant; Leneal Scott, computer systems manager; Phil Barnett, minority staff director/chief counsel; Karen Lightfoot, minority communications director/senior policy advisor; Naomi Seller, minority counsel; Josh Sharfstein, minority health policy advisor; Earley Green, minority chief clerk; and Jean Gosa, minority assistant clerk.

Chairman Tom Davis. Good morning. The committee will come to order.

I want to welcome everybody to today’s oversight hearing to evaluate the U.S. ability to respond to the threat of a global influenza pandemic. This is the committee’s fifth hearing over the past 2 years on issues surrounding influenza and our public health system’s preparedness levels.

The past few annual influenza seasons, as well as the recent spread of avian flu across Asia, have raised the urgent question of whether the United States is prepared to deal with the threat of a flu pandemic. Today, we will assess our public health system’s response capabilities at the Federal, State and local levels and determine what additional measures are needed in order to improve preparations and reduce the risks imposed by an avian flu outbreak.

The experts tell us the next flu pandemic is a matter of when, not if. No one knows exactly when it might strike or whether the next worldwide pandemic will be a version of the avian flu, which you will hear today referred to as H5N1 or “avian influenza A,” or a different influenza strain.
What is not up for debate is what the stakes are in dollars, resources and human lives. They are enormous. According to experts, the next pandemic would be worse than the Spanish flu, which is estimated to have caused the deaths of 40 million to 50 million people worldwide in 1918 and 1919. Given the global integration of today's economic markets and the capacity for rapid travel from one corner of the globe to another, a pandemic would move around the world in the same amount of time it takes to fly from New York to Tokyo.

This occurred in the case of the SARS outbreak 2 years ago. In the estimation of several international scientists, including U.S. public health officials, a flu pandemic is the largest public health threat facing the world today. Flu pandemics generally occur three to four times per century when novel flu strains emerge and are readily transmitted from person to person. There is a strong feeling among the public health officials that the next one is imminent.

Today, we will examine what actions and planning procedures have been and still need to be taken at Federal, State and local levels to adequately handle a global communicable disease outbreak. Early detection of new strains and the rapid development of effective vaccines are important keys to protecting the public against the flu and anticipating potential outbreaks.

The World Health Organization, the Center for Disease Control Prevention and other public health organizations have been conducting surveillances in Asia, where H5N1 is now circulating and to date has infected and killed more than 50 people in Vietnam, Cambodia and Thailand. The H5N1 flu strain is extremely virulent and most humans lack immunity.

Why is this surveillance so important? As we have heard in previous testimony before this committee, flu vaccines become obsolete following each season and require constant reformulation. Once the next pandemic flu strain has been identified, a vaccine would take at least 4 months to produce. Furthermore, only a few countries have flu vaccine production facilities, and the United States is home to just one of them. Anti-viral medications, which could help alleviate symptoms of those who contract the pandemic flu virus and help reduce mortality levels are considered a strong first line of defense until a vaccine can be produced and administered.

But the United States has only contracted for or stockpiled in its strategic national stockpile enough courses of the anti-viral Tamiflu to cover 5.3 million people, significantly short of the World Health Organization's guideline of 25 percent of the population. So let's do the math. We are about 62 million under the WHO guidelines, and we can cover 5.3 million today.

These statistics are disconcerting and we will be asking our government witnesses today if we should be doing more to protect Americans against the threat of avian flu. I understand some of our witnesses this morning will express concerns about our preparedness levels and Federal funding for States and localities.

I look forward to constructive dialog regarding those concerns. I know we all share the same goal at the end of the day: a public health system that is adequately prepared and equipped to deal with an outbreak of a deadly and contagious disease. We must not
only be preparing for the likely course of events, but we have to be expecting and be able to adjust to the unexpected.

[The prepared statement of Chairman Tom Davis follows:]
Opening Statement of Chairman Tom Davis
Committee on Government Reform
“The Next Flu Pandemic: Evaluating U.S. Readiness”
June 30, 2005

Good morning. I want to welcome everyone to today’s oversight hearing to evaluate the United States’ ability to respond to the threat of a global influenza pandemic. This is the Committee’s fifth hearing over the past two years on issues surrounding influenza and our public health system’s preparedness levels.

The past few annual influenza seasons, as well as recent spread of avian flu across Asia, have raised the urgent question of whether the U.S. is prepared to deal with the threat of a flu pandemic. Today, we will assess our public health system’s response capabilities at the federal, state, and local levels, and determine what additional measures are needed in order to improve preparations and reduce the risks posed by an avian flu outbreak.

The experts tell us the next flu pandemic is a matter of when, not if. No one knows exactly when it might strike, or whether the next worldwide pandemic will be a version of the avian flu—which you will hear today referred to as H5N1, or “avian influenza A”– or a different influenza strain.

What is not up for debate is that the stakes—in dollars, resources, and in human lives—are enormous. According to experts, the next pandemic could be worse than the Spanish Flu, which is estimated to have caused the deaths of 40-50 million people worldwide from 1918-1919. Given the global integration of today’s economic markets, and the capacity for rapid travel from one corner of the globe to another, a pandemic could move around the world in the same amount of time it takes to fly from New York to Tokyo. This occurred in the case of the SARS outbreak two years ago.

In the estimation of several international scientists, including U.S. public health officials, a flu pandemic is the largest public health threat facing the world today. Flu pandemics generally occur three to four times per century, when novel flu strains emerge and are readily transmitted from person to person. There is a strong feeling among public health officials that the next one is imminent.

Today we will examine what actions and planning procedures have been, and still need to be, taken at federal, state, and local levels to adequately handle a global communicable disease outbreak. Early detection of new strains and the rapid development of effective vaccines are important keys to defending the public against the flu, and anticipating potential outbreaks.

The World Health Organization (WHO), the Centers for Disease Control Prevention (CDC) and other public health organizations have been conducting surveillance in Asia where H5N1 is now circulating, and to date has infected and killed more than 50 people in Vietnam, Cambodia and Thailand. The H5N1 flu strain is extremely virulent, and most humans lack immunity.
Why is this surveillance so important? As we have heard in previous testimony before this Committee, flu vaccines become obsolete following each season and require constant reformulation. Once the next pandemic flu strain has been identified, a vaccine would take at least four months to produce. Furthermore, only a few countries have flu vaccine production facilities, and the U.S. is home to just one of them.

Antiviral medications, which could help alleviate symptoms of those who contract the pandemic flu virus and help reduce mortality levels, are considered a strong first line of defense until a vaccine can be produced and administered. But the United States has only contracted for, or stockpiled (in its “Strategic National Stockpile”), enough courses of the antiviral Tamiflu to cover 5.3 million Americans, significantly short of the WHO’s guideline of 25 percent of the population. Let me do the math for you: We’re about 62 million people under the WHO guidelines.

These statistics are disconcerting, and we will be asking our government witnesses today if we should be doing more to protect Americans against the threat of avian flu.

I understand some of our witnesses this morning will express concerns about our preparedness levels and federal funding for states and localities. I look forward to a constructive dialogue regarding those concerns. I know we all share the same goal at the end of the day: A public health system that is adequately prepared and equipped to deal with an outbreak of a deadly and contagious disease. And we must not only be preparing for the likely course of events, but we have to be expecting, and be able to adjust to, the unexpected.

We have a great selection of witnesses to provide testimony this morning. Dr. James LeDuc, Dr. Anthony Fauci, and Dr. Bruce Gellin from the Department of Health and Human Services will discuss efforts being taken at the federal level to plan and prepare for a flu pandemic. They will also describe preparedness coordination efforts with state and local authorities.

Joining us on our second panel will be Dr. Marcia Crosse of GAO who will discuss lessons learned from previous annual flu seasons that can be applied to pandemic preparedness. Ms. Mary Selecky, Washington State Secretary of Health, will be testifying today on behalf of the Association of State and Territorial Health Officials to provide an assessment of state and local public health departments’ ability to respond adequately to a flu pandemic. Dr. Shelley Hearne, Executive Director of Trust for America’s Health, which recently produced a noteworthy report that provided an assessment of improvements to the public health system and remaining vulnerabilities. We also invited the two companies who partnered together to research and develop the antiviral Tamiflu, Gilead Sciences, Inc. and Hoffman-La Roche, Inc. to discuss antiviral production capacities and pandemic planning. Dr. John Milligan, Executive Vice President and CFO of Gilead, and Mr. George Abercrombie, President and CEO of Hoffman La-Roche will be joining us to discuss a recent dispute over the Tamiflu license and what impact, if any, it might have on pandemic preparedness. We welcome all the witnesses and their testimony today.
Chairman TOM DAVIS. We have a great selection of witnesses to provide testimony this morning. Dr. James LeDuc, Dr. Anthony Fauci, and Dr. Bruce Gellin from the Department of Health and Human Services will discuss the efforts being taken at the Federal level to plan and prepare for a flu pandemic. They will also describe preparedness coordination efforts with State and local authorities.

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Dr. Shelley Hearne, executive director of Trust for America’s Health, which recently produced a noteworthy report, will provide an assessment of improvements to the public health system’s remaining vulnerabilities. We have also invited the two companies who partnered together to research and develop the anti-viral Tamiflu, Gilead Sciences, Inc. and Hoffman-La Roche, to discuss anti-viral production and capacities and pandemic planning.

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We welcome all the witnesses today and their testimony.

I would now recognize the distinguished ranking member, Mr. Waxman, for his opening statement.

Mr. WAXMAN. Thank you, Mr. Chairman.

Today’s hearing comes at a time of high alert for the public health system. Eight years ago, a lethal strain of influenza skipped from chickens to humans and led to multiple deaths in Hong Kong. The virus has continued to mutate and has become arguably the most serious imminent threat to human health in the world.

From chickens in Hong Kong, the avian flu virus now infects waterfowl species in 10 Asian countries. It infects ducks, domestic cats and even wild tigers. Increasingly, it has skipped the species barriers into humans. Over the last 18 months, more than 100 people have been diagnosed with avian flu in Vietnam, Thailand and Cambodia. Over half have died.

According to experts in infectious disease, this virus may be only a few mutations away from becoming highly contagious and triggering a global public health crisis. This hearing asks a simple question: Are we ready? Unfortunately, we are going to hear the answer: We are not. Our pandemic flu plan is still in draft form. A vaccine against pandemic flu will take months to produce and the global capacity to make such a vaccine falls far short of what is needed. We have a fraction of the anti-viral medication we will need to respond to a pandemic, and our public health system is underfunded and straining.

Last year’s flu vaccine shortage exposed confusion and inefficiency in the delivery of key drugs. We have no stockpile of routinely recommended childhood vaccines. There are major shortages
of qualified personnel around the country. If a global pandemic were to start tomorrow, our country and the world would be in serious danger. According to experts, as many as 500,000 Americans could die.

It is unlikely the pandemic will start tomorrow. We are now in the window between the sounding of the alarm bells and the start of an outbreak, so we need to act quickly. A key priority is to finish the pandemic plan. This plan needs to be specific enough so that the Federal Government, States, localities, businesses and private citizens are ready to step into their roles immediately.

A second priority is to mend the gaps in our public health system. We must ensure that our local and State public health departments have the resources to conduct surveillance, organize a local response, and distribute scarce vaccines and anti-viral medications. It is appalling that the administration is proposing to cut support for these activities by $130 million this next year. We must ensure that key vaccines for children are stockpiled so we are prepared if production lines are needed to make a pandemic flu vaccine. We must invest in public health training and infrastructure.

A third priority is to develop the vaccine to make a vaccine quickly and in large amounts. This is a major scientific challenge that will require significant resources. So far, we have spent $4 billion to prepare for a smallpox attack, which is very unlikely, and an anthrax attack which would likely be contained geographically. We have not yet made this type of investment in effort to counter an imminent and catastrophic strain of influenza.

A fourth priority is to stockpile anti-viral medications. Today, we will hear from two companies responsible for the drug Tamiflu, which is the only therapy that is believed to be effective against avian flu. These companies are fighting about who has the right to make the drug. I expect that they will hear a bipartisan message today not to let their dispute interfere with the drug's supply.

The biggest obstacle we have is complacency. For years, public health experts warned the Department of Health and Human Services that it needed a better plan to address the fragility of our vaccine supply, and for years we have heard reassuring platitudes from officials about how everything possible was being done. Yet when we had an actual flu vaccine shortage last year, we learned the truth. The executive branch was caught flat-footed because warning after warning had been ignored.

We need to have a zero tolerance policy for complacency. We need to demand action, not empty promises. Being prepared for pandemic flu is not a Republican or Democratic issue. We need to join together to direct both more attention and more financial resources to this serious threat.

I thank the witnesses for coming and I look forward to their testimony.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]
Statement of
Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
The Next Flu Pandemic: Evaluating U.S. Readiness
June 30, 2005

Today’s hearing comes at a time of high alert for the public health system. Eight years ago, a lethal strain of influenza skipped from chickens to humans and led to multiple deaths in Hong Kong. The virus has continued to mutate and has become arguably the most serious, imminent threat to human health in the world.

From chickens in Hong Kong, the avian flu virus now infects waterfowl species in ten Asian countries. It infects ducks, domestic cats, and even wild tigers. And, increasingly, it has skipped the species barrier into humans. Over the last 18 months, more than 100 people have been diagnosed with avian flu in Vietnam, Thailand, and Cambodia. Over half have died.

According to experts in infectious disease, this virus may be only a few mutations away from becoming highly contagious and triggering a global public health crisis.
This hearing asks a simple question: Are we ready?

Unfortunately, we’re going to hear this answer: We aren’t.

Our pandemic flu plan is still in draft form.

A vaccine against pandemic flu will take months to produce, and the global capacity to make such a vaccine falls far short of what is needed.

We have a fraction of the antiviral medication we will need to respond to a pandemic.

And our public health system is underfunded and straining.

Last year’s flu vaccine shortage exposed confusion and inefficiency in the delivery of key drugs. We have no stockpile of routinely recommended childhood vaccines. There are major shortages of qualified personnel around the country.

If a global pandemic were to start tomorrow, our country and the world would be in serious danger. According to experts, as many as 500,000 Americans could die.
It is unlikely the pandemic will start tomorrow. We are now in the window between the sounding of the alarm bells … and the start of an outbreak. So we need to act quickly.

A key priority is to finish the pandemic plan. This plan needs to be specific enough so that the federal government, states, localities, businesses, and private citizens are ready to step into their roles immediately.

A second priority is to mend the gaps in our public health system. We must ensure that our local and state public health departments have the resources to conduct surveillance, organize a local response, and distribute scarce vaccines and antiviral medications. It is appalling that the Administration is proposing to cut support for these activities by $130 million this year.

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A fourth priority is to stockpile antiviral medications. Today, we will hear from two companies responsible for the drug Tamiflu, which is the only therapy that is believed to be effective against avian flu. These companies are fighting about who has the right to make the drug. I expect that they will hear a bipartisan message today not to let their dispute interfere with the drug’s supply.

The biggest obstacle we face is complacency. For years, public health experts warned the Department of Health and Human Services that it needed a better plan to address the fragility of our vaccine supply. And for years, we heard reassuring platitudes from officials about how everything possible was being done. Yet when we had an actual flu vaccine shortage last fall, we learned the truth: the executive branch was caught flat-footed because warning after warning had been ignored.
We need to have a zero-tolerance policy for complacency. We need to demand action, not empty promises.

Being prepared for pandemic flu is not a Republican or Democratic issue. We need to join together to direct both more attention and more financial resources to this serious threat.

I thank the witnesses for coming and I look forward to their testimony.
Chairman Tom Davis. Thank you very much, Mr. Waxman.

Mr. Shays.

Mr. Shays. Thank you, Mr. Chairman. Mr. Chairman, thank you for holding this hearing.

I would just say to our witnesses that we are very grateful for the work that they do. I have had a number of visits to the World Health Organization. I think it is one of the world’s treasures. They are unbelievable. I just appreciate as well the work that we do in this country.

I would just end by saying that flu is a tremendous practice for biological terror. If we are ready for the flu, we are practically ready for anything. Mother nature gives us this practice, and we should take advantage of it on that level, but obviously most importantly to save lives.

So it is great that we are doing this hearing, and I thank you.

Chairman Tom Davis. Thank you very much.

Any other opening statements? Mr. Gutknecht.

Mr. Gutknecht. Just real briefly. Again, thank you, Mr. Chairman, for holding this hearing. I think on behalf of all Americans who are learning more about the potential of this pandemic, we want to make certain that we at the Federal level and NIH and others are doing all we can to not only prevent it, but to come up with potential solutions.

So again thanks for this hearing.

Chairman Tom Davis. Thank you very much.

Mr. Cummings.

Mr. Cummings. Thank you very much, Mr. Chairman. I thank you for holding this critically important hearing to evaluate our Nation’s preparedness to respond to pandemic influenza.

The Chiron Corp.’s inability to supply the United States with the flu vaccine we anticipated for the 2004–2005 flu season exposed the fragility of our Nation’s vaccine supply. This colossal failure to get it right last flu season raised some serious questions about our Nation’s preparedness to lessen the impact of a more destructive strain of the flu that could trigger a global pandemic.

Avian flu is considered increasingly likely to cause a pandemic. Experts estimate that a pandemic will result in the deaths of over 500,000 Americans and infect 25 percent of the world’s population. The Baltimore Sun on June 12, 2004 reported in an article entitled Fears of Flu Pandemic Spearheading Preparations, “The threat of an avian flu pandemic from Asia could cause 12,000 deaths in the State of Maryland early on, with the possibility of many more later.”

The article continues by noting that, “More conservative estimates from the U.S. Centers for Disease Control and Prevention suggest 1,600 to 3,700 Maryland deaths and 16,000 hospitalizations.” Mr. Chairman, I ask that this article be included into the record.

[The information referred to follows:]
Fears of flu pandemic spurring preparations

The threat of global influenza prompts research, but critics say the efforts fall short.

By Frank D. Roylance
Sun Staff

June 12, 2005

They gathered around a hotel conference table in Howard County, planning for what might be Maryland's worst public health crisis.

The public health and safety experts spun a shocking scenario arising from the threat of an avian flu pandemic from Asia: 12,000 deaths in the state early on, with the possibility of many more later.

More conservative estimates from the U.S. Centers for Disease Control and Prevention suggest 1,600 to 3,700 Maryland deaths and 16,000 hospitalizations. But public health leaders can't be optimists.

"We have to plan for the worst-case event," said Dr. Jean Taylor, who heads Maryland's pandemic-planning efforts at the state Department of Health and Mental Hygiene.

To safeguard Americans against a pandemic that scientists generally agree is inevitable, federal, state and local officials are developing extensive plans encompassing needs such as hospital and mortuary capacity and production of antiviral medication and vaccines. Local health departments have begun identifying locations such as school gyms and community centers that could accommodate temporary hospitals -- space that might be needed for months.

This month, President Bush signed an executive order authorizing use of quarantines for avian flu cases.

Despite the enormous efforts, critics are warning that the federal government hasn't done enough. Among them are Andrew Pavia, chairman of the Infectious Diseases Society of America's task force on pandemic influenza. He told Congress late last month that "the United States is woefully unprepared for a pandemic that might occur in the next few years."

Essential tools
Much of the concern focuses on the nation’s capacity to provide antiviral medications and vaccines.

Antiviral drugs like Tamiflu are essential tools in slowing the spread of disease until a vaccine can be developed to immunize people -- a process that can take six to eight months from the time a killer virus is identified. The United States has enough Tamiflu on hand to care for 2.3 million people, significantly less than some other nations.

But federal authorities said substantial progress is being made:

- The Centers for Disease Control and Prevention have paid $13.9 million for the manufacture and stockpiling of 2 million doses of an experimental vaccine for the H5N1 virus, which has killed millions of chickens and a small number of people in Asia. The vaccine is being tested at the University of Maryland School of Medicine in Baltimore and two other sites. It is intended for research, shelf-life studies and, if approved, possibly for limited human inoculations.

- To beef up the capacity of the only flu vaccine plant left in the United States, authorities invested $41 million last fall to expand and maintain the chicken flocks used by the company Sanofi Pasteur in Swiftwater, Pa. By September, that will allow year-round production of the millions of fertile eggs vital to vaccine production.

- Sanofi Pasteur has also won a $97 million contract to develop a technology for vaccine production in a line of human cells, which could reduce by months the time needed to produce a new vaccine.

- A Swiss maker of antiviral medication has committed to producing it in a new U.S. plant next year.

This summer, the National Vaccine Program Office will finalize a Pandemic Influenza Preparedness and Response Plan. State health departments are expected to have their plans ready by September.

But there’s only so much the government can do to prepare.

Despite years of worry about an avian flu outbreak in Asia, virologists don’t know for sure which virus they would face in a pandemic, where it would evolve, how deadly it will be or how easily it would be passed from person to person.

Pharmaceutical manufacturers can’t begin making vaccines until that new virus emerges. Even then, they’ll need months, while the disease is spreading, to grow the vaccine proteins in fertilized chicken eggs.

Also, public health authorities, elected officials, hospital managers and health care providers can’t be sure that what they’ll face will amount to a very bad flu season -- or a public health calamity that exhausts medical supplies, overwhelms mortuaries and brings the economy to a crawl.
But scientists and public health officials are in substantial agreement on this much:
Sooner or later, the world will face a severe influenza pandemic, borne by a newly
evolved virus against which humanity has little or no natural immunity.

All that's needed to touch it off, scientists said, is a chance exchange of viral DNA inside
a single pig or human victim. That could produce a virus with the virulence of H5N1 and
the easy communicability of an ordinary flu bug.

If it ever happens, said Dr. John Bartlett, chief of infectious diseases at the Johns Hopkins
School of Medicine, "it's going to be awful."

Bartlett said the United States needs to get ready now even if the H5N1 avian flu proves
to be a dud. Influenza pandemics have occurred with regularity, and new ones will arise
as new viruses evolve.

The "Spanish flu" pandemic in 1918-1919 caused more than 500,000 deaths in the United
States and more than 20 million worldwide. The "Asian flu" of 1957 killed 70,000
Americans, and the "Hong Kong" flu in 1968 left 34,000 dead.

Conservative CDC estimates of the toll from a future pandemic in the United States
predict up to 207,000 deaths and 734,000 hospitalizations. A virus as nasty as the 1918
flu bug would be expected to kill as many as 1.7 million Americans.

About 100 humans are known to have contracted the H5N1 virus from animals since
December 2003, with 54 deaths. Thai authorities reported one "probable" case of human-
to-human transmission within a family last year.

The Asian outbreak has focused the attention of public health officials worldwide on
finding an effective vaccine.

The University of Maryland and two other universities are testing 8,000 doses of H5N1
vaccine on 450 volunteers to see if it is safe and effective. The vaccine was produced by
Sanofi Pasteur under a contract awarded by the National Institutes of Health in March
2004.

Even if it proves effective, experts said there's no guarantee the vaccine will work should
a pandemic occur. All influenza viruses are constantly mutating, a process known as
"antigenic drift."

"Even one or two changes, if they occur in the right spot, can affect whether the virus
would be recognized by the immune system," said John Treanor, a professor of medicine
at the University of Rochester and the principal investigator for the NIH trials.

An old technology
Vaccine production still relies on a 30-year-old technology based on millions of fertile chicken eggs.

Sanofi Pasteur maintains flocks of millions of chickens. They produce eggs nine to 10 months a year -- all that's needed to make the vaccines to tackle the routine flu viruses we face every winter.

But that would not be enough to take on an influenza pandemic. The new five-year, $41 million federal contract will help Sanofi expand and maintain its flocks to produce eggs year-round.

The government is investing millions in Sanofi because it is the only remaining manufacturer of influenza vaccines in the United States. Low and inconsistent demand for the annual flu vaccines drove everyone else in the United States out of the business.

FluMist, a flu vaccine that is inhaled, is made in bulk in Britain and finished in the United States. But it is based on a live, weakened virus that might not be safe for patients with weak immune systems.

And in a global pandemic, officials said, the United States would probably not be able to turn to other countries for vaccine supplies. They will be facing their own public health crises.

Several European countries, as well as Japan, Australia, Taiwan, Korea and Brazil, are also developing H5N1 vaccines or building manufacturing capacity.

"The biggest concern I have globally is Africa," said James T. Matthews, director of external research and development at Sanofi. There is no vaccine in development on that continent, and "they are very vulnerable."

Expanding capacity

U.S. health authorities are planning campaigns to encourage more Americans to get annual flu shots, hoping that will increase demand, attract more drug manufacturers and expand the nation's domestic vaccine capacity.

In a pandemic outbreak -- an epidemic over a wide geographic area -- vaccines would arrive late and slowly, officials said. Vaccination priority would go to critical services personnel and to the most vulnerable populations. As more supplies arrived, distribution would broaden to the wider population.

Scientists are also working to determine whether and how a flu vaccine could be formulated or administered differently -- perhaps under the skin rather than into the muscle -- to stretch limited supplies.

Meanwhile, Sanofi is trying to develop a new technology for vaccines that would grow in
human cell lines instead of chicken eggs. The hope is that cell cultures would produce vaccine in as little as a month after a novel influenza vaccine is isolated.

For now, the world is stuck with egg technology, and with the fact that, for months at the start of a pandemic, most of the population will not have been vaccinated.

"If we assume that people will need two doses to be protected," said Dr. Benjamin Schwartz, senior science adviser to the National Vaccine Program Office, "a substantial proportion of the population would not have access to vaccine during that first year" of a pandemic that is likely to last two.

During that period, the United States would have to rely largely on antiviral medicines and infection control to stem or slow the tide of illness.

Stopping it in Asia, or wherever it emerges, would be the first goal. If that fails, antivirals and infection control would be used at home to protect as many vulnerable people as possible until vaccines arrive.

Antiviral medicines can be used to prevent infection. They are also valuable as therapy. Taken within 48 hours of the first symptoms of flu, they can limit the severity and duration of the illness. That helps to slow the spread of an epidemic.

There are two types of antiviral drugs. But the H5N1 virus has developed a resistance to one of them, called adamantines.

That leaves the neuraminidase inhibitors such as Tamiflu, made by the Swiss firm Roche. But there are problems there, too, health officials said: Tamiflu is made in Switzerland, it takes almost a year to produce, and supplies might be restricted in a global pandemic.

Britain and France have set about buying enough antiviral medicine to treat 25 percent and 21 percent of their populations, respectively.

The U.S. government has set no such target. But it has gotten Roche to commit to building a production plant in the United States. "They're anticipating that next year they would begin making the drug here," Schwartz said.

**Other remedies**

Public health officials said they won't be able to rely on drug remedies alone. In their pandemic plans, experts are looking closely at how best to control the spread of infection in the face of shortages of antivirals and vaccines.

Drawing on bioterrorism and disaster plans, and on their experience with severe acute respiratory syndrome (SARS) and similar recent disease scares, federal and state agencies have begun to work out their pandemic plans.
They include procedures for screening airline passengers arriving from places with pandemic flu outbreaks, educating health professionals to be alert for signs of flu and to ask patients about their travels.

Plans are in the works for isolating sick people and placing people exposed to the virus in quarantine -- at home or in public facilities.

In August, Maryland health officials will conduct a "table top" simulation with state and local school officials to figure out when and how to close schools -- a decision that would have enormous impact on the economy as working parents are forced to stay home with their kids.

Hospitals, too, are hammering out plans for coping with high absenteeism and shortages of empty beds, medical supplies and equipment. Of particular concern are mechanical ventilators, vital for keeping alive flu victims with secondary lung infections.

The list of potential disruptions seems endless -- absenteeism among prison guards and ambulance crews; shortages of blood donors and refrigerated storage as mortuaries are overwhelmed by the dead; a scarcity of volunteers needed to deliver meals and medicines to people isolated at home.

Dr. Peter L. Beilenson, who announced last week his resignation as Baltimore's health commissioner, said the city is better prepared to respond to a bioterrorism attack than a flu pandemic. There are stockpiles of medicines for anthrax and smallpox, he said, but Baltimore lacks the weapons for flu.

"There just aren't the vaccines and pharmaceuticals that we probably need," said Beilenson.

**Disturbing prospect**

While many public officials have been working on the issue for years, some got their wake-up to these kinds of issues at last year's exercise in Howard County.

"For the few participants who, for the very first time, heard about pandemic flu and what it's implications were, it was stunning," said Jean Taylor, at the state health department.

Seated at the table were representatives from the governor's office, state and local agencies for public health, transportation, public safety and emergency management, as well as leaders representing hospitals, nurses, morticians and academia.

It wasn't just the deaths in the scenario that disturbed them. Medical supplies were in short supply. Absenteeism was soaring. Police, firefighters, medical workers and air traffic controllers were among the thousands of sick, dead or terrified. Hospitals and mortuaries were overwhelmed.
The first small batches of vaccine were arriving, but they were reserved for health care and public safety workers. Crowds gathered, demanding vaccination, and small riots were breaking out.

Planning for such events is valuable even if the H5N1 avian flu bug never mutates into a pandemic virus.

"It's not a question of if, it's when," Bartlett said. "If we know how to respond to avian influenza in terms of building a vaccine and being able to have antiviral agents fast and have all the machinery in place, we'll be ready."

Sun staff writers Jonathan Bor and Michael Stroh contributed to this article.
Mr. CUMMINGS. One need not be an expert to comprehend the magnitude of this loss of life and the disastrous impact a flu pandemic would cause to our economy and to our society. With this in mind, we must agree to move forward in the best interests of the Nation and achieve our ultimate objective of ensuring that our Nation is capable of effectively and efficiently addressing a flu pandemic. This begins with having a plan, one that covers intergovernmental coordination, the use of the strategic national stockpile, and a process for distributing anti-virals and vaccines.

While the administration took a step in the right direction when it released the draft pandemic flu plan, this plan is unfortunately silent on critical details and is not yet finalized. How the vaccines will be distributed, purchased, prioritized, and what information will be conveyed to the public remain unresolved.

In light of the fact that State and local health departments will function on the frontlines of a flu pandemic, I am deeply troubled that the administration proposed undermining State and local preparedness by cutting $130 million in Federal support of those efforts in fiscal year 2006, with the World Health Organization stating: “Everything suggests that the situation we are in now, there is a greater risk for a pandemic than for many decades.” We should increase Federal funding of our public health infrastructure instead of attempting to restore fiscal sanity to the detriment of public health and safety.

It is also critically important to our Nation’s readiness that we have adequate supplies of vaccines and anti-virals. While vaccines are considered effective, they are difficult and slow to produce. Regrettably, apparent global capacity to make a flu vaccine will potentially leave billions of people in need during a pandemic.

Equally disturbing is the fact that the United States is particularly vulnerable to a shortage due to limited vaccine manufacturing facilities in the United States. While the Federal Government works to improve our Nation’s access to a safe, affordable and effective flu vaccine, it seems prudent that we also obtain anti-viral drugs deemed effective against pandemic flu. It should be noted while the World Health Organization recommends that countries purchase enough of an anti-viral drug called Tamiflu to treat 25 percent of their population, the United States only has enough of this drug to treat 2 percent of the population.

With last year’s flu season fresh in mind, we must ensure that no Americans needlessly suffer or die due to poor preparedness. Our Nation must be ready to safeguard our citizens by providing them with either the proper treatment or means to prevent infection in the event of an outbreak. Any less would be a gross abdication of our responsibility to protect citizens from threats both seen and unseen.

I yield the balance of my time and I thank you.

[The prepared statement of Hon. Elijah E. Cummings follows:]
Opening Statement

Representative Elijah E. Cummings, D-Maryland


Committee on Government Reform
U.S. House of Representatives
109th Congress

June 30, 2005

Mr. Chairman,

Thank you for holding this critically important hearing to evaluate our nation’s preparedness to respond to pandemic influenza.

The Chiron Corporation’s inability to supply the United States with the flu vaccine we anticipated for the 2004-2005 flu season exposed the fragility of our nation’s vaccine supply. This colossal failure to get it “right” last flu season raised some serious questions about our nation’s preparedness to lessen the impact of a more destructive strain of the flu that could trigger a global pandemic.

The Avian flu is considered increasingly likely to cause a pandemic. Experts estimate that a pandemic would result in the deaths of over 500,000 Americans and infect 25% of the world’s population. The Baltimore Sun on June 12, 2005 reported in an
article entitled, *Fears of Flu Pandemic Spurring Preparations*, that “the threat of an avian flu pandemic from Asia...[could cause] 12,000 deaths in the state [of Maryland] early on, with the possibility of many more later.” The article continues by noting that “[m]ore conservative estimates from the U.S. Centers for Disease Control and Prevention suggest 1,600 to 3,700 Maryland deaths and 16,000 hospitalizations.”

Mr. Chairman, I ask that this article be included into the record.

One need not be an expert to comprehend the magnitude of this loss of life and the disastrous impact a flu pandemic would cause to our economy and society. With this in mind we must agree to move forward in the best interest of the nation and achieve our ultimate objective of ensuring that our nation is capable of effectively and efficiently addressing a flu pandemic.

This begins with having a plan, one that covers intergovernmental coordination, the use of the strategic national stockpile, and a process for distributing antivirals and vaccines. While the Administration took a step in the right direction when it released a draft pandemic flu plan, this plan is unfortunately silent
on critical details and is not yet finalized. How the vaccines will be distributed, purchased, and prioritized, and what information will be conveyed to the public remain unresolved.

In light of the fact that state and local health departments will function on the front lines of a flu pandemic, I am deeply troubled that the Administration proposed undermining state and local preparedness by cutting $130 million in federal support of those efforts in FY 2006.

With the World Health Organization stating, “Everything suggests, that the situation we are in now, there is a greater risk for a pandemic than for many decades” we should be increasing federal funding of our public health infrastructure instead of attempting to restore fiscal sanity to the detriment of public health and safety.

It is also critically important to our nation’s readiness that we have adequate supplies of vaccines and antivirals. While vaccines are considered effective, they are difficult and slow to produce. Regrettably, current global capacity to make a flu vaccine would potentially leave billions of people in need during a pandemic. Equally disturbing is the fact that the United States is particularity
vulnerable to a shortage due to limited vaccine manufacturing facilities in the United States.

While the federal government works to improve our nation’s access to a safe, affordable, and effective flu vaccine, it seems prudent that we also obtain antiviral drugs deemed effective against pandemic flu. It should be noted, while the World Health Organization recommends that countries purchase enough of an antiviral drug called Tamiflu to treat 25% of their population, the U.S. only has enough of this drug to treat 2% of the population.

With last year’s flu season fresh in my mind, we must ensure that no Americans needlessly suffer or die due to poor preparedness. Our nation must be ready to safeguard our citizens by providing them with either the proper treatment or a means to prevent infection in the event of an outbreak. Any less would be a gross abdication of our responsibility to protect citizens from threats both seen and unseen.

I yield the balance of my time and look forward to the testimony of today’s witnesses.