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ARE YOU READY? IMPLEMENTING THE NATIONAL STRATEGY FOR PANDEMIC INFLUENZA

FULL HEARING

BEFORE THE

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HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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ARE WE READY? IMPLEMENTING THE NATIONAL STRATEGY OR PANDEMIC INFLUENZA

Tuesday, May 16, 2006

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The committee met, pursuant to call, at 2:00 p.m., in Room 345, Cannon House Office Building, Hon. John Linder presiding.

Present: Representatives King, Linder, Simmons, Rogers, Dicks, DeFazio, Norton, Christensen, and Etheridge.

Mr. LINDER. The hearing "Are We Ready? Implementing the National Strategy for Pandemic Influenza," will come to order. I would like to thank all of our distinguished panel witnesses for appearing today in this hearing for the Committee on Homeland Security. We are here today to examine the long-awaited implementation plan for the President's national strategy on pandemic influenza and assess our state of readiness should a pandemic become reality.

ABC movies should not be the only source of information on this topic. The leaders we have in the room here today must separate fact from fiction for the American people. Sensational portrayals in the media risk creating unnecessary panic and must be balanced by solid and consistent information from government leaders. We must provide a meaningful guide for all Americans who ask, what should I be doing to prepare for pandemic flu?

In February, the Subcommittee for Prevention of Nuclear and Biological Attack, which I chair, and the Subcommittee on Emergency Preparedness, Science and Technology held a joint hearing examining the nature of the pandemic threat as perceived through the eyes of those on the ground who will be called upon to respond. It was clear that they were looking for more universal guidance from the Federal level. Although the possibility of when the next pandemic may occur is unknown, what is clear is that, based on history, we are overdue for an influenza pandemic.

As the pandemic of 1918 showed, the effects could be dramatic. The United States, like most of the rest of the world, was gripped with a horrific pandemic of Spanish influenza, but that was nearly 90 years ago. Our medical and public health system were rudimentary when compared to today. There was no vaccine for influenza. There were no antibiotics to counter the effects of flu.

Today, we have an advanced medical system and a stronger public health system and pharmacological treatments unimaginable in 1918, but we still have to do more. We need to make sure that

every American can answer the question: I know what to do if and when influenza strikes. We need the government leaders to be able to answer that same question.

Does each government agency know what to do if and when influenza strikes? The Federal Government needs to be able to definitively answer the question, who is in charge? We need to be able to answer questions such as, who will the American people turn to for guidance? Who will get vaccinated first? And the inevitable question, what should I do if I get sick?

The effects of a pandemic could be devastating on our economy. A recent release from HHS stated that up to 40 percent of a business organization's workforce could be out sick or taking care of sick family members. We need to make sure that the Federal Government is providing real world guidance to our business community as well.

The pillars that are laid out in the President's implementation plan are a good start. We need to ensure plans are being made for a potential pandemic everywhere, and what every American should be doing, and how the Federal Government will help them. Communication of rules and responsibility is very important. We need to have the most effective surveillance tools to detect possible outbreaks, and we must be able to quickly respond and hopefully contain the spread of any outbreak.

I look forward to the testimony of our witnesses as they lay out their respective roles for preparing for potential pandemic. We need to be able to separate fact from fiction and make the public more confident that we will be ready in the case of a influenza pandemic. I now turn to my friend from Washington, Mr. Dicks, for the purpose of making an opening statement.

Mr. DICKS. Thank you, Mr. Chairman.

I would like to welcome our witnesses today, and I look forward to hearing their testimony. I am very pleased that the committee is holding a hearing on the important issue of pandemic flu preparedness and response. The witness before us today represents the key Federal agencies that will be involved in responding to a pandemic flu outbreak. In a full-scale pandemic situation, Federal, State, local and private entities will all need to cooperate effectively for a response to be successful. The thousands of State and local health departments are working hard to plan for pandemic flu, but they are struggling with a lack of money and guidance from the Federal Government.

In the President's National Strategy for Pandemic Influenza, the bulk of Federal funding is for vaccine and drug research. The President requested only $100 million for State and local preparedness. While Congress appropriated $350 million in the emergency appropriations this past December, it pales in comparison to the $6 billion that the President requested for vaccines and antivirals.

I believe that the best way to handle the flu is to strengthen our hospitals and other health care facilities, and I don't think enough funding or aid is being offered to State and localities. I am also concerned that the flu response plan that we will discuss today might not complement the National Response Plan, which is supposed to be the plan used to manage domestic emergencies.

We have many questions to answer. Who is in charge of response operations at Federal, State and local levels? Who gets vaccinated first? When should we urge citizens to wear masks or to stay home? When should we close schools? How will hospitals manage the surge of patients?

As I have spoken in recent months to local physicians, hospitals administrators and public health officials and first responders, it has become clear to me that we do not yet have the answers to some of these questions. I hope this hearing will help us begin to answer them.

We cannot be certain how long we have before a full-scale outbreak of avian flu may occur. In that time, we must ensure that a coherent nationwide response is ready, and that it will be properly executed when needed.

Thank you, Mr. Chairman.

Mr. LINDER. Thank you, we are pleased to have before us a distinguished panel of witnesses on this important topic. Let me remind the witnesses that their entire written statement will appear in the record. We would ask, however, that all witnesses make an effort to limit their testimony to no more than 5 minutes.

Mr. LINDER. First up is Dr. Jeff Runge. Dr. Runge is the Acting Undersecretary for Science and Technology and is DHS's Chief Medical Officer. He is a punt person at the DHS for pandemic flu preparedness planning.

Admiral John Agwunobi, Dr. John Agwunobi, is the Assistant Secretary of Health for the Department of Health and Human Services. He is an experienced practitioner in public health and is a former State health officer in Florida.

From the Department of Agriculture, we have Dr. John Clifford. Dr. Clifford is the chief veterinarian for USDA and has extensive experience in the veterinary medicine field, including being the area veterinarian in charge of Ohio, West Virginia, Michigan and Indiana.

Mr. Peter Verga from DOD is the Principal Deputy Assistant Secretary for Homeland Defense. He is a retired U.S. Army officer with 26 years of experience and has held a variety of senior level positions at the Department of Defense.

Dr. Runge, you may begin.

STATEMENT OF HON. JEFFREY W. RUNGE, ACTING UNDERSECRETARY, SCIENCE AND TECHNOLOGY, AND CHIEF MEDICAL OFFICER, DEPARTMENT OF HOMELAND SECURITY

Dr. RUNGE. Thank you, Chairman Linder, Congressman Dicks and members of the committee. My name is Jeff Runge. I serve as Chief Medical Officer for the Department of Homeland Security. I am pleased to be here with my colleagues to discuss the role of DHS as the overall incident manager and coordinator of the Federal response in the event of a influenza pandemic.

We are working closely with our Federal partners, especially at HHS, USDA and the Department of Veterans Affairs and the Department of Defense and the Homeland Security Council to assure that we are fully coordinated in our response to a pandemic. We are all in agreement about our roles in managing an outbreak of

disease, whether it is an outbreak confined to the bird population or in the event of a full-scale human pandemic.

Even though we recognize the need to be ready at the Federal level, preparedness for an incident such as this must be defined at the local level. We have stood shoulder to shoulder with our colleagues from HHS and USDA in nearly 50 State pandemic sessions discussing the need to work together with State and local governments, nongovernmental organizations and the private sector to ensure a condition of readiness.

As you know, the mechanism for coordination of any broad Federal response is the National Response Plan. The NRP supports the concept that incidents are handled at the lowest jurisdictional level, even as it provides the mechanism for a concerted national effort.

In the event we are faced with a pandemic, Secretary Chertoff would activate a national planning element composed of senior officials of Federal relevant agencies who have already been identified to coordinate strategic level national planning and operations. The Secretary would also likely establish as many as five regional joint field offices with a deputy PFO in charge of each regional joint field office to work directly with State and local entities.

Now this framework provides a coordinated response for all levels of government, nongovernment and volunteer organizations and the private sector. It also affords full coordination between the regional joint field offices and any military joint task forces that might be established.

Obviously, a close synchronous working relationship with HHS is essential. Our national public health and medical resources will unquestionably be taxed, probably beyond capacity, and DHS will do everything in its power to support HHS with its mission.

As the DHS Chief Medical Officer, I am and will be the primary point of interface with HHS, as well as being Secretary Chertoff's advisor on all medical issues. The implementation plan contains over 300 action items with very aggressive timelines. DHS has the lead in 58 of those actions and participates with other departments in another 84.

We are currently prioritizing these actions and are searching for the resources that we need to carry them out. As the committee understands, the Department has many competing priorities right now, but we are fully engaged in making sure we are as prepared as we can be for a pandemic.

In addition to our job as the overall incident manager, DHS has some areas of unique responsibility, and in particular, to maintain the function of our nation's critical infrastructures, for border management and for the continuity of DHS operations. We are also working on identifying and managing the economic consequences to our Nation from a pandemic with a special focus on the transportation industry, the flow of trade within and across borders and a supply chain for food and other goods.

Mr. Chairman, with any illness, prevention is by far the most effective method for managing this disease. President Bush and HHS are on the mark in their efforts to improve our domestic vaccine production and to stimulate transformational change in vaccine technology. We also need to reinforce the capacity of State and

local public health organizations and educate the public on good public health practices.

Mr. Chairman, I would also like to make the point that the best way to prepare for a catastrophic event of any nature is to strengthen the institutions that we use every day; namely, public health, medical and emergency services. The collateral benefits that provides will improve our Nation's quality of life as well as our preparedness for what we all fear, a biologic attack of any consequence, of any source.

Mr. Chairman, you have my written remarks for the record. I thank you.

[The statement of Dr. Runge follows:]

PREPARED STATEMENT OF HON. JEFFREY W. RUNGE, MD

Good afternoon Chairman King, Congressman Thompson and Members of the Committee on Homeland Security.n I am pleased to have this opportunity to appear before you today to discuss the current threat from Avian Influenza and how the Department of Homeland Security (DHS) will coordinate the Federal response if an influenza pandemic were to occur in the United States.

Like members of this Committee, the Department of Homeland Security and our Federal partners recognize that an influenza pandemic in the United States could trigger severe public health and economic consequences, catastrophic loss of life, and disrupt our nation's critical infrastructures. DHS is working closely with its Federal partners, especially the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), the Veterans Administration (VA), the Department of Defense (DOD), and the Homeland Security Council to prepare and to ensure that we are coordinated in our response.

The Role of DHS

As we coordinate, we recognize that each Department has responsibilities that are unique as well as some responsibilities that overlap. The DHS responsibilities are clear, pursuant to the Homeland Security Act of 2002 and Homeland Security Presidential Directive-5 (HSPD–5). As the domestic incident manager, the Secretary of DHS will coordinate the overall Federal response to a pandemic in order to ensure the continuity of our government, maintain civil order, preserve the functioning of society and mitigate the consequences of a pandemic. The Secretary of DHS serves as the principal Federal official for overall domestic incident management. In this role, during a pandemic outbreak, the Secretary of Homeland Security is responsible for the coordination of Federal operations and/or resources, establishment of reporting requirements, and conduct of ongoing communications with Federal, State, local, tribal, private sector, and nongovernmental organizations.

Our Federal partners are also quite capable of fulfilling their respective roles in managing outbreaks of avian influenza, from well confined outbreaks in birds to a full-scale pandemic, and we are fully coordinated with them. The USDA, working with its state agriculture counterparts, has ample experience in managing an outbreak in the bird population. HHS has the responsibility and expertise to plan public health and medical preparedness. We all recognize that there is still significant work to be done to ensure the Nation is adequately prepared to respond to an outbreak in humans. As the *National Strategy for Pandemic Influenza* says, "Preparing for a pandemic requires the leveraging of all instruments of national power, and coordinated action by all segments of government and society." This need for coordination of our National instruments is part of the reason that DHS exists. A pandemic could threaten the ability of the health and medical sector to manage all the consequences, which could likewise threaten the functioning of society and the Nation's economy. It is the responsibility of DHS to coordinate the Federal response to manage those risks.

The NRP is the primary mechanism for coordination of the U.S. Government response to terrorist attacks, major disasters and other emergencies, and will form the basis of the Federal pandemic response. If a pandemic influenza were to present grave social and economic problems for the United States, the Secretary would—in consultation with other cabinet members and the President—likely declare an Incident of National Significance and ensure implementation of the appropriate NRP coordinating mechanisms to ensure a coordinated Federal response.

The NRP supports the concept that incidents are handled at the lowest jurisdictional level. However, a pandemic will ultimately require a concerted national effort.

Under the National Strategy and the NRP, Federal departments and agencies have assigned roles and responsibilities to support all incidents to include a biological incident.

The Secretary will consider the following four criteria set forth in HSPD–5 when making the determination to declare an Incident of National Significance; however, he will not be limited to these thresholds and may base his decision on other applicable factors:

- A Federal department or agency acting under its own authority has requested the assistance of the Secretary of Homeland Security
- The resources of State and local authorities are overwhelmed and Federal assistance has been requested by the appropriate State and local authorities
- More than one Federal department or agency has become substantially involved in responding to an incident, and
- The Secretary of Homeland Security has been directed to assume responsibility for managing a domestic incident by the President.

DHS will work collectively with the interagency to establish the appropriate multi-agency coordinating structures when the situation warrants, even before a full scale outbreak. The Secretary may consider activating elements of the national response, including designating a Principal Federal Official, standing up the Joint Information Center and Joint Field Offices. The Secretary has already identified a candidate to become the national PFO for pandemic influenza. This individual will be intimately involved in the planning and exercising of our contingency plans.

The Secretary would also set up a national planning element composed of senior officials of relevant Federal agencies to coordinate strategic-level national planning. The Secretary would also likely establish as many as five Regional Joint Field Offices that would be staffed and resourced with a Deputy PFO in charge of each Regional JFO to work directly with state & local entities. This framework provides a coordinated response for all level of government, non-government and volunteer organizations (NGOs), and the private sector. This system also affords full coordination between the regional joint field offices and military joint task forces that may be established. Last month, Secretary Chertoff asked his fellow Cabinet members to identify senior officials to coordinate planning and operations among the Federal departments before a pandemic would strike. The list has been compiled, and we look forward to working with these individuals as we plan and train together with our pre-designated PFO and Deputy PFOs.

In the event of a pandemic, a close, synchronous working relationship with HHS is essential. Our national Public Health and medical resources will unquestionably be taxed, probably beyond capacity, and DHS will do everything in its power to assist HHS with its mission to prevent illness and mitigate the consequences of the anticipated widespread morbidity and mortality. The DHS Chief Medical Officer is the primary point of interface with HHS and is responsible for advising the Secretary of DHS on all medical issues, including avian influenza. The DHS Chief Medical Officer is also responsible for directing and overseeing the planning, policy, training, and operations to protect the health of the DHS workforce in the event of a pandemic in order to maintain critical DHS operations. We are taking advantage of assets across the Department to accomplish this goal, especially the expertise of the U.S. Coast Guard medical officers.

Federal Preparedness for Pandemic Influenza

The National Strategy for Pandemic Influenza, issued by President Bush on November 1, 2005, provides the framework for the Federal government's response to the influenza pandemic threat. It presents a high-level overview of the Federal government's approach to an influenza pandemic, emphasizes the importance of the full participation of State Local, and Tribal Governments, the private sector and critical infrastructure components, the public, and the international community to prepare for, prevent, and contain influenza.

The National Strategy makes it clear that while the Federal government will pursue all avenues available to it to thwart an influenza pandemic, it is essential for the States and communities be fully informed and engaged as well. The resources of the Federal government alone may not be sufficient to prevent the spread of an influenza pandemic across the nation. Preventing, minimizing and mitigating the consequences of an influenza pandemic requires a coordinated and integrated national effort that includes the full participation of all levels of government and all segments of society.

The *Implementation Plan for the National Strategy* announced last week contains over 300 action items with very aggressive implementation timelines. DHS has the lead in 58 of these actions and participates with other departments in 84 additional items. The Department is currently prioritizing these actions and is attempting to

identify resources to carry them out. The department has many competing priorities, but is fully engaged in planning efforts for our own departmental plans as well as fulfilling our responsibilities enumerated in the *Implementation Plan.*

While the Plan directs that departments and agencies undertake a series of action in support of the Strategy, it does not describe the operational details of how the departments will accomplish these objectives. Each department will devise its own planning documents that will operationalize the *Implementation Plan* and will address additional planning considerations that may be unique to each department.

The DHS Pandemic Influenza Implementation Plan

The DHS Pandemic Influenza Plan is structured around the three pillars of the National Strategy: Preparedness and Communication, Surveillance and Detection, Response and Containment. In order to support these pillars, the DHS plan focuses on the overall Federal incident management of a pandemic, as well as our unique responsibilities to manage our borders, protect our Nation's critical infrastructures, ensure the health and safety of the DHS workforce, and find ways to mitigate the overall economic impact tour Nation.

Since December, DHS work groups comprised of representatives from across all components of the Department have been working to accomplish these goals and have been developing contingency planning documents. The DHS Office of Infrastructure Protection has developed plans and exercises to maintain the function of the 17 critical infrastructures, working closely with the private sector and our Federal partners. In conjunction with its interagency partners, the Department will release a Critical Infrastructure and Key Resource Pandemic Influenza Preparedness, Response and Recovery Guide. This guide will assist the private sector in business continuity planning efforts to cope with business disruption and high rates of employee absenteeism that would accompany a pandemic. Our overall incident management workgroup is developing playbooks with the directorates and components of DHS, and has focused efforts on synchronizing operation centers from across Federal and State governments and developing a common operating picture methodology so that real-time communications are optimized. The workgroup on Entry and Exit Policy and Border Management has been working very closely with our Federal partners and the Homeland Security Council to determine the best policy to delay and limit the introduction of a pandemic into the U.S. through effective screening of passengers, travel restrictions and border controls, supporting the CDC's quarantine stations at our major point of entries, and providing training to our front line workforce. The Workforce Assurance workgroup has been working closely with the CDC and the Occupational Safety & Health Administration to devise scientifically sound policies for personal protective equipment and training protocols to minimize disruption to our workforce. They have also been developing contingency planning for Continuity of Government and Continuity of Operations to deal with disruptions in our workforce due to absenteeism or caring for loved ones. The Economic Consequences workgroup has been working with Federal partners and the National Laboratories to identify and inventory the economic modeling capacity in order to drive policy decisions that would minimize economic disruption to our nation during a pandemic. Examples are policies related to transportation industry, the flow of trade within and across borders, and maintenance of the supply chain for food and other goods.

DHS Expenditures: Pandemic Preparedness

As part of the President's supplemental appropriations request to fund the National Strategy for Pandemic Influenza, DHS received $47.3 million to increase the readiness and response capabilities of the department in the event of an influenza pandemic. The Supplemental Funding Plan allocates funds in six key categories that include:

- *Preparedness Planning:* The Plan targets $12 million in funding for preparedness planning. This effort is aimed at preparing for the significant implications that a pandemic influenza would have on the economy, national security and the basic functioning of society. It includes developing the capability to anticipate the impact of the disease on absenteeism across multiple sectors and how this will affect the continuity of essential functions in support of the Federal response. Conducting modeling and simulation to predict the impact of pandemic flu on critical infrastructure; engaging in international negotiations for screening protocols, procedures and quarantine authorities; and participating exercises to test readiness are part of this effort.
- *Training Development and Deployment:* The Plan calls for $10.7 million to be allocated for the protection of border and domestic air and maritime travel. These funds will be used for readiness assessments of high risk airports and ports and training related to the use of quarantine stations and the isolation,

handling, and transportation of potentially infected individuals. The experience of HHS and CDC training exercises will add value to DHS training activities, which will involve personnel of the U.S. Coast Guard, Immigration and Customs Enforcement, Transportation Security Administration, and Customs and Border Protection.

• *Personal Protective Equipment (PPE):* The Plan sets aside $16 million for the acquisition of PPE for approximately 145,000 high risk and mission critical personnel. DHS will develop the requirements to provide these personnel with appropriate PPE and establish respiratory protection programs, which include respiratory fit testing, medical clearance and PPE related training.

• *Rapid Influenza Assay Study:* The Plan provides $1.5 million to support system studies and define operational requirements for a rapid diagnostic tests, working in coordination with HHS. This test could provide more effective screening prior to departure and entry, especially in situations when infected persons may require isolation. This could have broader applications in the transportation sector, the workplace, or for continuity of government purposes.

• *Isolation Systems:* The Plan dedicates $4.4 million to support infrastructure changes and construction of isolation systems at ports of entry or other major transportation hubs. Currently the CDC has only 18 quarantine stations among over 320 ports of entry, few of which have adequate facilities for isolation and containment of infected travelers.

• *Program Support:* The Plan allocates $2.7 million for technical, management, financial, and integration functions relating to the implementation of the Plan. This includes the coordination of requirements from DHS components for workforce protection, environment, training, staffing restrictions and protocols as well as documentation and tracking of requirements and plans.

Conclusion

Since the reorganization of DHS under Secretary Chertoff's 2nd Stage Review and the formation of the Office of the Chief Medical Officer, a tremendous amount of our focus has been on pandemic influenza planning, supplemental budget development and coordination, coordinating with other Federal agencies on policy matters, and participating in the writing of the *Implementation Plan.* DHS senior officials have been present with HHS at nearly every one of the 50 State Pandemic Summits.

The Department of Homeland Security is in the process of making recommendations to further clarify the National Response Plan to better fulfill its incident management role. In collaboration with our international partners, we are developing screening and containment procedures to decrease the likelihood of disease spread should sustained human-to-human transmission occur. We have been working with our federal government and private sector colleagues to provide business continuity guidance and recommendations, especially for critical infrastructure and key resources. Our own plan addresses workforce protection and continuity of operations.

The challenge to complete an effective contingency plan for DHS and realize an appropriate response to such a catastrophic incident is formidable. Carrying out the hundreds of actions in the Implementation Plan will require significant amounts of time, human resources, and budgetary resources. Even with the challenges, this effort will be worth it for the sake of our Nation's biodefense. It has become apparent that the newly found coordination among State, local and tribal governments, HHS, DHS, USDA, VA, and DoD, NGOs and the private sector will put our Nation in much better shape to deal with biological threats, regardless of whether they are natural or man made. The collateral benefits of pandemic planning are undeniable and are worth our department's best efforts and full engagement.

As with any illness, prevention is by far the most cost effective method for dealing with this disease. We fully support the efforts of President Bush and the Department of Health and Human Services to reinvigorate our domestic vaccine production, to stimulate transformational change in vaccine technology, reinforce the capacity of State and Local public health organizations and educate the public on good public health and ways to keep every individual and family safe.

The best way to prepare for and prevent a pandemic or any major catastrophic event is to strengthen the institutions that we use every day, namely public health, medical, and emergency services, as well as the support of medical science for new vaccines and therapeutics. They are also avenues to enhancing the quality of health care and the quality of life in our communities on a daily basis. We look forward to working with Congress as well as our State and local counterparts to ensure that the response is as efficient and effective as it can be.

Mr. LINDER. Thank you, Dr. Runge.

Dr. AGWUNOBI.

STATEMENT OF HON. JOHN AGWUNOBI, ASSISTANT SECRETARY FOR HEALTH AND HUMAN SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. AGWUNOBI. Thank you, Mr. Chairman, and members of the committee for this opportunity to speak to you on what is a critically important subject, pandemic influenza preparedness. Pandemics are a fact of life. They have occurred numerous times in the past, and they will likely occur in the future.

Our ultimate goal must therefore be to achieve a constant yet flexible state of national preparedness, an enduring national ethic of readiness for any and all hazards. If the next pandemic is anything like the one that we saw in 1918, I know of no nation that can credibly claim to be ready today. Much work remains to be done.

Fortunately, some recent modeling shows that with aggressive nationwide preparedness, exercised readiness and unhesitant leadership when the alarm sounds, we can manage our way through a pandemic and greatly reduce its negative impact on individuals and our community. We will continue to strengthen our plans as we learn more as science provides us with information into the future.

In November of 2005, the President released the National Strategy for Pandemic Influenza and requested $7.1 billion to fund that strategy; $3.8 billion has already been appropriated, so improvements to our preparedness are well under way. This month, the administration released a detailed implementation plan which delineates 300 specific critical preparedness tasks for government and the private sector. That implementation plan identifies HHS very clearly as lead for public health and medical aspects of preparedness and response in a pandemic. We will work very closely with our colleagues in DHS in that regard.

Our efforts to date include stockpiling vaccines, building additional capacity and researching the vast technology for vaccine development and manufacturing. Similarly, we are stockpiling antiviral drugs and searching for new and improved antiviral alternatives. We are working to further the search for rapid, accurate, yet portable diagnostic tests, and we are stockpiling other necessary medical supplies.

But, Mr. Chairman, vaccines and antiviral countermeasures don't in and of themselves equal preparedness. Our goal to achieve true readiness must include and does include intra– and interagency collaboration across this panel and other agencies, our horizontal and vertical coordination across public health and medical communities around the Nation, and the continued strengthening of search capacity across the Nation.

We are also working to enhance surveillance capabilities, the preparation of families and individuals, the development of clear and open risk communication strategies, the improvement of State and local planning and regular exercising of those plans. At the global level, our efforts include the strengthening of international public health partnerships and cooperation, the strengthening of

global surveillance for pandemics and the enhancement of the international ability to rapidly respond and its capacity.

In conclusion, Mr. Chairman, preparedness is not an accomplishment. It is a constant endeavor. It consists of Federal, State and local leaders working in partnership nationwide. Every sector of society, every individual and every community must do their part for us to stand as a Nation prepared.

Pandemic preparedness makes the Nation better prepared for any and all hazards, it is not just about pandemic influenza. It will help in both manmade and natural events.

We are better prepared today than we were yesterday, that is for sure, and we will be better prepared tomorrow than we are today.

Thank you, Mr. Chairman.

[The statement of Dr. Agwunobi follows:]

PREPARED STATEMENT OF JOHN O. AGWUNOBI, M.D.

Mr. Chairman and members of the Committee, I am honored to be here today to describe for you how the Department of Health and Human Services (HHS) is working to improve the nation's preparedness for a potential human influenza pandemic. Thank you for the invitation to testify on this issue, which is one of our highest priorities at HHS.Strategy and Threat Assessment

On November 1, 2005, President Bush released the *National Strategy for Pandemic Influenza,* which outlines the roles of the Federal government and sets expectations for State, local, and tribal governments, private and international partners, and individual citizens in preparing for and responding to an influenza pandemic. The following day, Secretary Leavitt announced the HHS *Pandemic Influenza Plan*-a blueprint for all HHS pandemic influenza preparedness and response planning. The HHS Plan provides guidance to national, State, and local policy makers and health departments with the goal of achieving national readiness and the ability to respond quickly and effectively to a pandemic. The HHS plan also includes an outline of key HHS roles and responsibilities during a pandemic. In the event of a pandemic, under the National Response Plan, HHS will lead the public health and medical response with the Department of Homeland Security carrying out its responsibility for overall domestic incident management and Federal coordination. However, ultimately, the center of gravity for such a response will be at the state and local level.

As you know, the President requested $7.1 billion in emergency funding for the *National Strategy for Pandemic Influenza,* of which $6.7 billion was requested for HHS. Congress appropriated $3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, $3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to becoming the first generation in history to be prepared for a possible pandemic.

We must also continue to prepare against a possible pandemic influenza outbreak. The President's Budget includes $2.3 billion in funding for the 2007 portion of the emergency funding request to fulfill the next phase of the Strategy. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including producing pandemic influenza vaccine for every American within six months of detection of sustained human-to-human transmission of bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness.

The President's FY 2007 budget also requests more than $350 million for important ongoing pandemic influenza activities at HHS such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs, and diagnostics (NIH).

Pandemics are not new. There were three in the 20th century, the worst of which was the Spanish flu epidemic in 1918-1919 that is estimated to have killed over one half million people in the U.S. and 50 million worldwide. While we are focusing today on the impact of the H5N1 avian flu virus from a strain currently circulating in birds in many parts of Asia and Europe, many of the policy issues and preparedness measures that arise for this strain of influenza apply as well to pandemics of other types of influenza, other emerging infectious disease outbreaks and public health emergencies. For example, pandemic preparedness offers tangible benefits in

the fight against seasonal influenza which causes an average of 36,000 deaths each year.

Scientists cannot accurately predict the severity and impact of an influenza pandemic, whether from the H5N1 virus or the emergence of another influenza virus of pandemic potential. However, it is still useful to model possible scenarios based on analysis of past pandemics. In a report released in December 2005, the Congressional Budget Office presented the results of modeling a severe pandemic scenario similar to the 1918 Spanish flu outbreak and a more moderate outbreak resembling the flu pandemics of 1957 and 1968. In the severe scenario, roughly 90 million people become ill and 2 million die in the United States and the impact on the real Gross Domestic Product [GDP] is about a 5 percent reduction in the year following the outbreak. While there is substantial uncertainty associated with these estimates, they illustrate the enormous public health threat of an influenza pandemic and the need for effective access to vaccines, treatments, and a robust public health infrastructure to meet the challenge.

There are several important points to note about an influenza pandemic:

- A pandemic could occur anytime during the year and is unlikely to behave like a typical seasonal influenza. Rather, past pandemics have occurred in multiple ″waves″ of infection and could persist in the world for over a year.
- In the absence of effective vaccines and antivirals, the capacity to prevent or control transmission of the virus once it gains the ability to be efficiently transmitted from person to person will be limited.
- Right now, the H5N1 avian influenza strain that is circulating in Asia and Europe among birds is a significant concern, but there is no way to know whether this virus will in fact lead to a human pandemic. Whether of not the H5N1 adapts itself to the human host, we know that influenza viruses are constantly evolving, and it is possible that this strain or another influenza virus, which could originate anywhere in the world, could cause the next pandemic. This uncertainty is one of the reasons why we need to maintain year-round surveillance of influenza viruses to be able to determine if there are genetic changes that may signal a potential pandemic, to develop reference viruses that can be used to develop pandemic vaccines, and to assess whether influenza viruses have developed resistance to antiviral drugs. As is the case with the H5N1 that is currently in birds around the world, pandemic influenza viruses often emerge in animals. Like other viruses, they tend to remain within a species. However, as we have seen already in the more than 200 documented cases of human infection of H5N1 confirmed by the World Health Organization, they do have the ability to infect humans who have been exposed to infected birds. Of greatest concern for human health is the question of whether the viruses will develop the ability to readily infect people and whether these viruses will be able to transmit efficiently from person to person as is the case with seasonal flu. For all of these reasons, it is critical to maintain constant surveillance of viruses worldwide affecting animal populations and that can potentially be transmitted to humans.
- We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have been many changes in society since the "great influenza" of 1918, including dramatic changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes may have made us more vulnerable.

HHS Preparations for Pandemic Influenza

As you know, the President announced the *Implementation Plan for the National Strategy for Pandemic Influenza* on May 3, 2006. The purpose of this plan is to ensure that the efforts and resources of the Federal government and State, local and tribal governments and the private sector will be brought to bear in a coordinated manner against the pandemic threat. The *Plan* describes more than 300 critical actions, many of which have already been initiated, to address the threat of pandemic influenza. The Implementation Plan for the National Strategy for Pandemic Influenza confirms HHS' role as the lead federal agency for the public health and medical preparation and planning for and response to a pandemic. The Secretary of HHS will lead the Federal health and medical response efforts, serve as the primary Federal spokesperson for pandemic health issues, and coordinate the actions of other departments and agencies in the overall public health and medical emergency response efforts. The Secretary of the Department of Homeland Security (DHS) will provide broader overall incident management for the Federal response, will ensure necessary support to HHS to coordinate the public health response, and coordinate

with HHS and other Federal, State, and tribal agencies in providing non-medical support.The timing of the release of this Plan does not signal that a pandemic is imminent. The Plan is the result of much work in many Federal Departments and agencies to further prepare the government for a pandemic, whenever it might occur. It is important to note that the H5N1 avian influenza is a disease of birds, the virus has not yet appeared in the U.S., and there is no influenza pandemic in the world at this time.

HHS has been working with many Federal agencies, including the U.S. Department of Agriculture, the Departments of Homeland Security, State and others, in drafting the public health and medical aspects of the *Implementation Plan for the National Strategy*. The Plan spells out over 199 specific tasks that HHS will take the lead in or play a supporting role in to accomplish the human health aspects of the strategy. It is important to note that HHS has already started to make progress on many of the tasks delineated in the plan.

The Department's key tasks outlined in the plan include:

- Building stockpiles of pre-pandemic vaccine adequate to immunize 20 million persons against influenza strains that present a pandemic threat;
- Expanding domestic influenza vaccine manufacturing surge capacity for the production of pandemic vaccines for the entire U.S. population within 6 months of a pandemic declaration;
- Building stockpiles of antivirals adequate to treat 25% of the U.S. population, divided between Federal and State stockpiles;
- Building a Federal stockpile of 6 million treatment courses reserved for domestic containment efforts.
- Developing clear guidelines and decision criteria to assist State, local, and tribal governments and the private sector in defining groups that should receive priority access to existing limited supplies of vaccine and antiviral medications and other critical medical care.
- Working with State and tribal entities to develop and exercise influenza countermeasure distribution plans and to include the necessary logistical support of such plans, including security provisions.
- Establishing a strategy for deploying Federal medical providers from across the USG, including expanding and enhancing programs such as the Medical Reserve Corps and supporting the transformation of the Commissioned Corps of the Public Health Service.
- Creating plans to rapidly credential, organize, and incorporate volunteer health and medical providers as part of the medical response in areas that are facing workforce shortages.
- Supporting local and national efforts to:
  - establish "real-time" clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories;
  - link hospital and acute care health information systems with local public health departments; and
  - advance the development of the analytical tools necessary to interpret and act upon these data streams in real time.
- Establishing a single interagency hub for infectious disease modeling efforts, and ensuring that this effort integrates related modeling efforts for transportation decisions, border interventions, economic impact, etc. HHS will also work to ensure that this modeling can be used in real time as information about the characteristics of a pandemic virus and its impact become available.
- Providing guidance to all levels of government on a range of options for infection control and containment, including those circumstances where social distancing measures, limitations on gatherings, or quarantine authority may be an appropriate public health intervention.

Current HHS Progress

In December 2005, Congress appropriated $3.8 billion to help the Nation prepare for pandemic influenza preparedness activities. Of that total, Congress allocated $3.3 billion to HHS for the first year of funding of the HHS Pandemic Influenza Plan. HHS will use these emergency funds to help achieve five primary objectives:

1. Monitoring disease spread to support rapid response;
2. Developing vaccines and vaccine production capacity;
3. Stockpiling antivirals and other countermeasures;
4. Coordinating Federal, State and local preparation; and
5. Enhancing outreach and communications planning.

HHS is working both domestically and internationally to monitor the spread of H5N1 and other possible pandemic viruses. On the international front, HHS is spending $125 million of its FY 06 allowance to promote international pandemic

preparedness and planning and augment existing capabilities in areas such as international surveillance, epidemiological investigation, and diagnosis of illness. Through collaborations with the World Health Organization (WHO), the United Nations Food and Agriculture Organization, the World Organization for Animal Health, and numerous national governments, HHS is working to build capacity in other countries to detect outbreaks early and to contain the spread of the virus. HHS has signed Memoranda of Understanding (MOUs) on influenza and other emerging infectious diseases with Institute Pasteur (IP); the Gorgas Institute and the Ministry of Health of Panama; and most recently, the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B). HHS experts have participated in WHO-led investigations into human cases of avian influenza in Indonesia, China, and Turkey and are providing substantial technical assistance for influenza containment activities to many other countries on an as needed basis. Overall, HHS is supporting influenza activities in approximately 40 countries and has assigned influenza staff to the World Health Organization (WHO) Secretariat, Regional, and country offices in Europe and Southeast Asia.

On the domestic front, CDC is devoting $50 million to strengthen local laboratory capacity and capability and $35 million to accelerate the implementation of the national BioSense program to enhance our ability to detect an outbreak early. On January 1, 2006, BioSense RT (Real-Time) was launched in 10 select cities and 32 healthcare institutions across the country. Real-time transmission of existing clinical diagnostic and health information is being sent to CDC and analyzed. In April 2006, CDC launched a new data visualization and analysis tool for the use of all jurisdictional levels of public health (hospital, city, county, state, national). The BioSense implementation timeline is to link up to several hundred hospitals in over 30 cities by the end of 2006.

In the event of a pandemic, infection control practices and social distancing measures (such as school closures, cancellation of public gatherings, etc), and antiviral drugs will be the first line of defense before a vaccine is available and could limit and delay the spread of the pandemic. Currently, the Strategic National Stockpile (SNS) has over 5 million treatment courses of antiviral drugs on hand. On March 22, Secretary Leavitt announced the purchase of additional antiviral drugs that could be used in the event of a potential influenza pandemic. With these purchases, the SNS will have 26 million treatment courses of antiviral drugs that will be available to the States when an influenza pandemic is imminent. HHS' strategy is to federally procure an additional 24 million treatment courses of antiviral drugs through FY 07 and FY 08 funds and to offer a 25 percent federal subsidy for state purchase of another 31 million treatments courses. Thus, additional money will be needed to meet our goal to have enough antivirals for 25 percent of the population during a pandemic. Congressional support of $2.3 billion for the second year of the President's Pandemic Influenza plan will be critical to meet this goal.

The cornerstone of the HHS Pandemic Influenza Plan is to create domestic manufacturing capacity sufficient to produce 300 million vaccine courses within 6 months of the onset of a pandemic outbreak, and to maintain a stockpile of pre-pandemic vaccine. We currently have approximately 4 million courses of pre-pandemic vaccine against a clade 1 H5N1 avian influenza strain. Plans and procedures are also underway to manufacture pre-pandemic vaccine against a clade 2 H5N1 avian influenza strain that is currently circulating the globe.

On May 4, 2006 Secretary Leavitt announced the award of $1 billion for five contracts to support the development of advanced techniques using a new cell-based, rather than an egg-based, approach to producing influenza vaccines. Using a cell culture approach to producing influenza vaccine is a promising technology and offers a number of benefits. Vaccine manufacturers can bypass the step needed to adapt the virus strains to grow in eggs. In addition, cell culture-based influenza vaccines will help meet surge capacity needs in the event of a shortage or pandemic, since cells may be frozen in advance and large volumes grown quickly. U.S. licensure and manufacture of influenza vaccines produced in cell culture also will provide security against risks associated with egg-based production, such as the potential for egg supplies to be contaminated by various poultry-based diseases, including pandemic influenza strains. Finally, the new cell-based influenza vaccines will provide an option for people who are allergic to eggs and therefore unable to receive the currently licensed vaccines.

A total of $1.7 billion in FY 2006 funding is allocated for vaccine development to increase vaccine production capacity by accelerating cell-based manufacturing technology, increasing egg-based vaccine production capacity, and supporting the advanced development for antigen sparing technologies that could extend the vaccine supply by decreasing the amount of antigen needed to protect each individual.

Progress has also been made in the SNS purchase of medical supplies and equipment essential to pandemic readiness. HHS has purchased over 150 million N95 respirators and surgical masks with approximately $50 million of FY06 funds. Other planned procurements include personal protective equipment (PPE), ventilators, IV antibiotics, and other medical supplies. Advanced development for rapid diagnostic tests also continues through the use of FY06 funds. A request for information (RFI) was issued for a point-of-care diagnostic on March 30, 2006 and a request for proposal (RFP) will be issued soon.

State and Local Preparedness

Pandemic influenza preparedness requires the active planning and participation of States and local communities. If a pandemic were to occur in the U.S., it would likely affect thousands of communities at the same time over the course of many weeks. The Federal Government is working to provide guidance regarding how state, local, and tribal governments can develop pandemic preparedness plans and respond in the event of a pandemic. As part of the Administration's effort to enhance State and local pandemic preparedness, HHS has held pandemic influenza summits in 47 States and the District of Columbia so far. These summits have brought together State and local officials, public health, schools, businesses, and other stakeholders to discuss pandemic preparedness. With the FY 2006 emergency funding, HHS has awarded $100 million of the $350 million allocated for State preparedness for pandemic influenza preparedness planning activities. The remaining portion of these funds will be awarded based on benchmarks that will measure States' progress.

It is important to note that HHS funding to enhance State and local preparedness for public health emergencies, including pandemic influenza, has existed since 2001. Principally through CDC and HRSA funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting.

First, CDC provides preparedness funding annually to public health departments of all the States, certain major metropolitan areas, and other eligible entities through cooperative agreements. Second, HRSA employs complementary cooperative agreements to provide preparedness funding annually within States for investment primarily in hospitals and other healthcare entities. HHS collaborates with DHS toward ensuring that the guidance associated with the CDC and HRSA awards is coordinated with the guidance associated with those DHS awards that address other aspects of State and local preparedness, such as emergency management and law enforcement. Including the funding we have requested for FY07, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost $8 billion.

In addition, the ability to quickly increase the number of health care workers available is a critical component of State and local public health emergency response capacity. HRSA has supported efforts to improve personnel surge capacity. Funds are used to allow jurisdictions to develop or enhance Emergency Systems for Advance Registration of Volunteer Health Professionals (ESAR–VHP), authorized under the Public Health Security and Bioterrorism Preparedness and Response Act. ESAR–VHP is designed to help States develop registries of volunteer health professionals whose credentials have been verified in advance of an emergency so that they can be quickly called on and utilized in an emergency. In addition to the FY07 budget request of $8 million to continue HRSA's registration system, the budget also proposes development of a web-based portal that would create the means for integrating the state ESAR–VHP systems into a National system, thereby promoting a more coordinated national deployment of personnel. The portal is intended to not only integrate existing state ESAR–VHP systems, but to also provide a credentialing service that could assist states with the development of their ESAR–VHP databases. The budget also proposes to fund a Mass Casualty Initiative, including the Medical Reserve Corps and Healthcare Provider Credentialing and the Commissioned Corps Transformation initiatives.

Lastly, effective communications and outreach are essential to pandemic preparedness at the Federal, State and local levels. President Bush called for the development of a single, comprehensive web site to be the official Federal source of pandemic and avian influenza information. This web site, *www.PandemicFlu.gov,* includes a wide range of information on pandemic influenza and preparedness activities. In addition, HHS has developed a series of checklists intended to aid preparation for a pandemic in a coordinated and consistent manner across all segments of

society. Thus far, ten checklists have been released and are aimed at State and local governments, the business community, the education sector, the health sector, community organizations, and individuals and families.

Conclusion

Thank you for the opportunity to share this information with you. Although much has been accomplished, continued vigilance and preparation are needed for us to be ready for a pandemic. I am happy to answer any questions at this time.

Mr. LINDER. Thank, Dr. Agwunobi.

Dr. CLIFFORD.

STATEMENT OF HON. JOHN CLIFFORD, DEPUTY ADMINISTRATOR FOR VETERINARY SERVICES, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

Dr. CLIFFORD. Chairman Linder, Congressman Dicks, members of the committee, thank you for the opportunity to testify before the committee today. The implementation plan for the National Strategy for Pandemic Influenza takes major components of the President's National Strategy for Pandemic Influenza and breaks them down into more than 300 critical actions.

As the primary agency for dealing with the disease in poultry, the implementation plan directs USDA to play either a leadership or coordinating role in 98 critical actions. Examples include continuing our support of efforts overseas to slow the spread of the disease in poultry, expanding our domestic surveillance and early warning systems, and ensuring we have a strong plan in place to respond to protection of high pathogenic H5N1 in U.S. poultry.

The last department emergency supplemental bill for pandemic influenza preparedness included $91.35 million for USDA. We have since been working to ensure that our plans for using these funds are strategically sound and coordinated with our many cooperators. We are using approximately $20 million to help affected countries overseas in collaboration with international organizations such as the FAO, the World Health Organization and the OIE, which is the World Organization for Animal Health.

Domestically, we are using approximately $72 million for a variety of efforts, including antismuggling programs, continued research, strengthening wild bird and domestic poultry surveillance efforts and increases to the current animal vaccine stockpile.

I would like to focus my remaining time on APHIS's newly drafted avian influenza response plan. This draft response plan supports one of USDA's major mandates in the President's implementation plan, the control and eradication and the introduction into the United States of highly pathogenic avian influenza. This plan would guide the steps taken by the USDA and our State and industry partners following the detection of high path H5N1 in domestic poultry.

USDA has in place a robust emergency response program designed to complement all of our surveillance efforts. In conjunction with our colleagues, APHIS maintains State level emergency response teams. These teams would typically be on site within 24 hours of the initial examination and diagnosis or presumptive diagnosis of avian influenza or any other significant foreign animal disease.

Destruction of the affected flocks would be our primary concern and course of action. The response plan also provides guidelines as to how APHIS would work with States to quarantine affected premises and clean and disinfect those premises after birds have been depopulated and disposed.

Surveillance testing would also be conducted in the quarantine zone and surrounding area to be sure that the virus is completely eradicated. The response plan focuses on quickly containing and eradicating the virus before it has a chance to spread further in poultry population. It draws on our real world experience in handling avian influenza viruses, as well as our ongoing partnerships with Federal agencies, State agricultural departments, State veterinarians, the poultry industry and the conservation and wildlife communities. The plan is designed to be flexible and does not supersede any State response plans. The response plan will be an evolving document and takes into consideration the latest scientific information and approaches to emergency preparedness and response.

I would like to close by offering a few important thoughts.

First, just like in people, there are many strains of influenza that affect birds with varying degrees of impact and importance.

Second, the detection of high path H5N1 virus circulating overseas in birds found here in the U.S. would not indicate a start of a human pandemic.

Third, a detection in wild birds does not mean the virus will reach a commercial poultry operation. We are certainly preparing as if it will. But the U.S. poultry industry employs a very sophisticated program of firewalls to protect the safety of their product.

Fourth, even if a virus reaches a commercial poultry operation, there is no reason for consumers to be concerned about the safety of poultry that they purchase and eat.

Finally, when it comes to food safety, consumers have the power to protect themselves. Proper handling and cooking of poultry kills a virus as well as other foodborne pathogens. Properly prepared poultry is safe.

Thank you again for the opportunity to testify before the committee today.

[The statement of Dr. Clifford follows:]

PREPARED STATEMENT OF DR. JOHN CLIFFORD

Chairman King, Ranking Member Thompson, thank you for the opportunity to testify before the Committee this afternoon. My name is Dr. John Clifford and I am the Deputy Administrator for Veterinary Services with the Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). In this position, I also serve as USDA's Chief Veterinary Officer.

USDA appreciates your interest in our efforts to ensure that preparedness for a potential introduction of highly pathogenic H5N1 avian influenza virus into the U.S. poultry population remains high. I also welcome the opportunity to provide you with information on our roles and responsibilities under the *Implementation Plan for the National Strategy for Pandemic Influenza.*

National Implementation Plan for Pandemic Influenza

On May 3, 2006, President Bush announced his *Implementation Plan for the National Strategy for Pandemic Influenza. The focus of the Implementation Plan* is to ensure that the efforts and resources of the Federal government are being brought to bear in a coordinated manner against the pandemic threat.

The *Implementation Plan* takes the major components of the President's *National Strategy for Pandemic Influenza* and breaks them down into more than 300 critical

actions—many of which have already been initiated. The Plan directs involved Federal agencies to carry out these critical actions within prescribed amounts of time. The Plan is helping to ensure that the Federal government, along with our State and local partners and industry, continues to take appropriate steps in preparation for a possible influenza pandemic in the country.

I want to stress that this disease, first and foremost, continues to affect birds. However, we know it has caused acute illness in people who have had direct contact with sick or infected birds, with about half of these human cases resulting in death. We know that the virus, through mutation, could present a much greater risk to human health worldwide. So, there are both animal health and human health aspects of the Federal government?s preparations.

As the President's *Implementation Plan* makes clear, these preparations are being closely coordinated among several departments, as well as with State and local governments and industry. USDA is the primary agency in terms of dealing with the disease in poultry. The *Implementation Plan* directs USDA to play either a leadership or coordinating role in 98 critical actions. These include initiatives such as continuing our support of the coordinated efforts overseas to slow the spread of the disease in poultry and expanding our domestic surveillance and early warning systems while ensuring we have a strong plan in place to guide, along with our partners, the swift, decisive response to any eventual detection of highly pathogenic H5N1 avian influenza in poultry here in our country.

A few examples of USDA's critical actions under the *Implementation Plan include:*

- Supporting the testing of all broiler flocks in the United States for avian influenza and, more broadly, strengthening surveillance across the board for the disease in other segments of the poultry industry, as well as migratory birds.
- USDA's National Veterinary Stockpile is strategically storing "strike packs" containing personal protective equipment supplies designed to protect response personnel from influenza viruses. These strike packs can be deployed within 24 hours to the site of an outbreak in the United States.
- USDA recently posted to its avian influenza website a draft summary of the National Avian Influenza Response Plan. Once finalized, this plan will comprehensively guide the aggressive steps that will be taken by USDA and our State and industry partners following a detection of highly pathogenic H5N1 avian influenza in domestic poultry.
- Providing expertise and funding to assist the United Nation's Food and Agriculture Organization (FAO) with a new Crisis Management Center to enhance the coordinated response to detections of highly pathogenic H5N1 avian influenza worldwide. USDA training has been provided on incident command system structures, communications, and deployment procedures. We expect that the command center will be operational in the very near future.

I will touch more on these and other USDA critical actions in a few moments. But first I would like to stress that as we work to complete these efforts in the coming weeks and months, USDA will continue to use a four-pronged approach to combating avian influenza. First, we are focused on slowing the spread of this disease offshore by supporting other nations affected with this virus through robust support to the International Partnership on Avian and Pandemic Influenza and by adopting a coordinated approach to work with affected countries through the FAO and the World Organization for Animal Health (OIE). Second, we are conducting a proactive messaging campaign designed to educate the American public and poultry owners on this animal disease. We want to inform while not alarming. A third pillar of our doctrine is an aggressive surveillance program that focuses on four key areas: wild bird surveillance; commercial poultry operations; live bird markets; and backyard flocks. The fourth and final pillar of our doctrine is, when necessary, to execute our response and containment plans. USDA has a long and successful history of dealing with foreign animal diseases and, in particular, handling avian influenza. These successful efforts are due in large part to the high degree of cooperation we have undertaken with our State animal health colleagues, industry, and other Federal agencies.

I want to emphasize to the Committee that in taking this multi-faceted approach, we are not waiting for the virus to reach our shores before we begin coordinating our preparedness and response efforts with our partners. We know that the threat is real and that the virus could potentially arrive in our country via migratory birds. Therefore, many important planning and coordination efforts are already well underway. Our strategy, again, is that we are preparing as if the virus will reach U.S. poultry, while taking measures where possible to slow its spread overseas and, where and when we can, prevent its entry through pathways that we can address. I believe this approach is the right one to take, and will pay off greatly in the event

this highly pathogenic H5N1, or another serious avian influenza virus, reaches our country.

Summary of Pandemic Influenza Supplemental Funding for USDA

Last December, Congress approved, and President Bush signed into law, an emergency supplemental funding bill for pandemic influenza preparedness that included $91.35 million for USDA. Since that time, we have been working expeditiously to ensure that our plans for using these funds are strategically sound and fully coordinated with our many international, Federal, State, local, and industry cooperators. We have taken these responsibilities so seriously, in fact, that we have utilized USDA's and APHIS' emergency operations centers to coordinate our efforts. Our animal health officials have also worked under an incident command structure to maximize their communications, planning, and logistical capabilities.

Let me quickly summarize the international and domestic initiatives funded by supplemental appropriations, all of which are also included as critical actions in the *Implementation Plan*.

On the international front, we are using approximately $20 million to help affected countries overseas in collaboration with international organizations. Again, we are participating in a coordinated effort by the various interested U.S. Government agencies, led by the Department of State, to work with affected countries through the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), and the World Organization for Animal Health (OIE).

We have developed a coordinated approach to work with affected countries through the FAO and the OIE. This plan calls for the OIE to lead and coordinate robust, consistent assessments of veterinary service capacity in developing countries reporting cases of the H5N1 virus. This would also entail evaluating H5N1 eradication and control plans in affected and at-risk countries. These assessments will form the basis for carefully planned attempts to improve animal health services capacity, using a range of support mechanisms including international financial assistance and technical and other support from the private and public sectors. Countries, like the United States, with proven expertise in these areas would also provide personnel for assessment teams that will travel to countries and provide on-the-ground recommendations and assistance. Then, ultimately, a prioritized list of needs for specific regions of the world would be produced to further direct program coordination and resources to the most at-risk areas. The FAO will coordinate these infrastructure improvements efforts globally, regionally, and in affected countries with local authorities.

On the domestic front, we are utilizing approximately $72 million from the emergency supplemental appropriation, in part, to:

- Enhance smuggling interdiction and trade compliance ($9 million);
- Continue research and development of improved tools like vaccines, genome sequencing; environmental surveillance and biosecurity measures ($7 million);
- Enhance surveillance of wildlife/bird flyways ($18 million);
- Strengthen other domestic surveillance and diagnostics (about $18 million);
- Increase the current animal vaccine stockpile and stock other response supplies ($10 million);
- Enhance planning, equipment, and preparedness training, and the development of simulation models ($9 million); and
- Improve a variety of other preparedness activities ($1 million)

USDA has been engaged in avian influenza response efforts for decades. We have much real-world experience dealing with the disease—both the low pathogenic and highly pathogenic forms. Based on that experience, we are focusing our resources where they are most needed.

Surveillance and Detection

A 1983 outbreak of highly pathogenic avian influenza was the largest incident of the disease in this country, ultimately resulting in the destruction of 17 million birds in Pennsylvania and Virginia to eradicate the virus. By contrast, a 2004 outbreak in Texas was quickly isolated to a flock of 6,600 birds and eradicated.

The disease detection in Texas underscores just how critical effective biosecurity measures, stringent surveillance, timely reporting, and swift control, eradication, and disinfection are to an effective emergency response. We are striving to bolster all of these capabilities through our plan for using the emergency supplemental funding, as well as by meeting our requirements under the Pandemic Influenza Implementation Plan.

I believe we are in an excellent position to accomplish this goal today because of the partnerships we have forged with State animal health officials and the poultry industry over the years. Several programs are helping to foster close relations with

States and industry. One of them is the longstanding National Poultry Improvement Plan (NPIP), a cooperative Federal-State-industry program designed to enhance the health and marketability of commercial U.S. poultry. The other is our new low-pathogenic avian influenza program, designed to increase surveillance efforts for the low-pathogenic H5 and H7 strains of the disease in commercial flocks and the live bird marketing system. These strains, if left unaddressed, have the potential to mutate into a more virulent disease. Both of these programs are serving as springboards as we enhance surveillance efforts, enter into additional cooperative agreements with States, and tighten our emergency response plans.

We are using approximately $5.9 million for the NPIP cooperative effort to enhance the testing of commercial flocks—broilers, layers, turkeys, and their respective breeding flocks—for avian influenza viruses of concern. The supplemental also includes $2.9 million for surveillance by USDA's National Veterinary Services Laboratories (NVSL). This funding will allow NVSL to provide support to approved laboratories for the processing of samples. This includes all segments of the surveillance program for H5N1, including samples collected from wildlife, commercial poultry, and the live bird marketing system in the United States.

This funding will also allow NVSL to develop and contract out the production of agar gel immunodiffusion (AGID) testing reagents to be distributed at no charge to laboratories approved to participate in the surveillance effort. In this way, we will meet the poultry industry's desire to test all broiler flocks in the United States for avian influenza and, more broadly, surveillance across the board will be strengthened.

Migratory Bird Surveillance

Another area where we have taken steps to obtain better information regarding any potential disease threat to U.S. poultry is migratory bird surveillance. Wild birds, in particular certain species of waterfowl and shorebirds, are considered to be the natural reservoirs for many common, relatively harmless strains of avian influenza. We also know that migratory birds have been implicated, to some degree, in the spread of the disease overseas.

On March 20, 2006, the Departments of Agriculture, the Interior, and Health and Human Services released an inter-agency strategic plan that expands the monitoring of migratory birds in the United States for the highly pathogenic H5N1 virus and establishes common protocols for testing birds and tracking the data.

"An Early Detection System for H5N1 Highly Pathogenic Avian Influenza in Wild Migratory Birds—U.S. Interagency Strategic Plan" reflects the best possible scientific information on the highly pathogenic H5N1 virus and the migratory patterns of wild birds. In addition, the plan draws on ongoing partnerships with State and private wildlife experts, animal health experts, as well as public health officials.

The plan targets bird species in North America that have the highest risk of being exposed to, or infected with, highly pathogenic H5N1 because of their migratory movement patterns. Key species of interest include ducks, geese, and shorebirds.

Personnel from USDA, Department of the Interior, State wildlife agencies, and other cooperators will work closely to obtain samples and test them for avian influenza viruses of concern.

Under the new enhanced surveillance program for migratory birds, APHIS officials began sampling efforts in Alaska in late April. I would note here that between 1998 and 2005, USDA's Agricultural Research Service and the University of Alaska partnered to test some 12,000 samples taken from wild migratory birds in Alaska for avian influenza viruses of concern. All these samples were negative for these viruses of concern to us.

In other areas under the enhanced migratory bird surveillance plan, APHIS has also begun sampling Eastern wild turkeys in collaboration with the Vermont Fish and Wildlife Department. And just last week, our National Wildlife Research Center began processing environmental water and fecal samples collected from areas of Alaska that harbor high-risk waterfowl and shorebirds. Other states will begin collecting similar high-risk environmental samples in June based on migration patterns.

Import Restrictions and Anti-Smuggling Efforts

There are other important efforts USDA has employed to keep the H5N1 virus and others out of the United States. As a primary safeguard, APHIS maintains trade restrictions on the importation of live poultry, birds, and unprocessed poultry products from all affected countries. Heat-treated poultry meat and eggs from countries with highly pathogenic avian influenza are considered eligible for importation from countries with equivalent meat inspection systems. Imports of live birds, poultry and unprocessed poultry products may resume after APHIS has completed a regionalization analysis that identifies the entire country or zone within the affected-

country as disease-free. Import permits must accompany properly sanitized products, such as feathers.

APHIS' Smuggling, Interdiction, and Trade Compliance (SITC) teams, as well as our colleagues with the Department of Homeland Security's Customs and Border Protection, have been alerted and are vigilantly on the lookout for any poultry or poultry products that might be smuggled into the United States from any of the affected countries. In the coming weeks, APHIS port veterinarians will make presentations to CBP officials at numerous high-traffic U.S. ports of entry to ensure that inspectors are reminded of the protocols for handling live birds they intercept, as well as have accurate contact information for any related questions or concerns. Additionally, USDA quarantines and tests imported live birds from countries (excluding Canada) not known to have cases of infection to make sure that pet birds and other fowl do not inadvertently introduce disease into the United States.

I'd like to point out that APHIS' SITC program is responsible for intelligence gathering and other anti-smuggling activities, such as secondary market and warehouse inspections, that help prevent animal and plant pests and diseases from entering the United States. As I said, SITC has increased its targeting of illegal shipments of birds or bird products that could potentially carry the highly pathogenic H5N1 avian influenza virus, as well as its partnering with other Federal agencies and law enforcement personnel. Thus far in fiscal year 2006, SITC has already contributed to 63 separate seizures of prohibited products from countries reporting detections of the highly pathogenic H5N1 virus. These seizures total more than 135,000 pounds of prohibited poultry products that, again, could pose a risk of harboring the H5N1 virus, or other serious poultry diseases.

The Draft National Avian Influenza Response Plan

Now that I have touched on our plans to slow the spread of the highly pathogenic H5N1 virus overseas, exclude its entry into the United States through trade restrictions and anti-smuggling programs, and bolster domestic surveillance, I'd like to update you on our plans for responding to a detection of any highly pathogenic avian influenza in commercial poultry.

Again, our ability to respond swiftly is linked directly to the strong cooperative efforts APHIS is engaged in with States and industry relative to avian influenza. The U.S. Poultry and Egg Association convened an industry-wide meeting in Atlanta, Georgia, on April 27, to facilitate dialogue with State and USDA officials regarding the many operational, policy, and communications issues related to our cooperative avian influenza preparedness efforts. Many of APHIS' senior animal health staff attended the meeting, which was, I believe, extremely beneficial to all who attended.

Prior to the poultry industry meeting in Atlanta, APHIS posted to its website a draft summary of the National Avian Influenza Response Plan. This draft response plan supports one of USDA's major mandates in the President's *Implementation Plan*—the control and eradication of an introduction into the United States of highly pathogenic avian influenza.

The draft response plan would guide the steps taken by USDA and our State and industry partners following a detection of highly pathogenic H5N1 avian influenza in domestic poultry. It reflects USDA's scientific expertise on highly pathogenic avian influenza viruses, as well as our real world experience in planning for, and responding to, incursions of significant animal diseases into the United States.

In addition, the plan draws on our ongoing partnerships with other Federal agencies, State Agriculture Departments, State Veterinarians, the poultry industry, and the conservation and wildlife communities. In this way, the plan is designed to be flexible and does not supersede any State response plans. Rather, it complements such plans already in existence, or under development.

As a result of tabletop exercises and numerous meetings and discussions with our partners, the response plan incorporates much positive feedback. In releasing a summary of the draft document and posting it online, we fully expect further review and comment by stakeholders. In this way, we intend for the response plan to be an evolving document that takes into account the latest scientific information and approaches to emergency preparedness and response.

Let me elaborate a bit further on the Response Plan. USDA has in place a robust emergency response program designed to complement all of our surveillance efforts. When we have unexpected poultry, or for that matter livestock, illnesses or deaths on a farm, we immediately conduct a foreign animal disease investigation. We have a cadre of specially trained veterinarians who can be on site within four hours to conduct an initial examination and submit samples for additional laboratory testing. Also, the Departments of Health and Human Services and Labor are providing occupational health guidance on the use of personal protective equipment and antiviral

prophylaxis treatments to USDA and other departments that have personnel in direct contact with live infected or dead poultry.

In conjunction with our State colleagues, APHIS maintains State-level emergency response teams on standby. These teams will typically be on site within 24 hours of the initial examination and diagnosis of a presumptive diagnosis of avian influenza or any other significant foreign animal disease. Destruction of the affected flocks would be our primary concern and course of action. We would also work with States or tribes to possibly impose State-level quarantines and movement restrictions.

For highly pathogenic avian influenza as well as for low pathogenic H5 and H7 subtypes, the Response Plan provides guidelines as to how APHIS would work with States to quarantine affected premises and clean and disinfect those premises after the birds have been depopulated and disposed. Surveillance testing would also be conducted in the quarantine zone and surrounding area to ensure that the virus has been completely eradicated.

I would like to note here that APHIS also maintains a bank of avian influenza vaccines for animals in the event that the vaccine would be a potential course of action in any outbreak situation. Funding included in the emergency request will augment the current animal vaccine bank by an additional 40 million doses. This expansion of the animal vaccine bank to approximately 100 million doses of avian influenza vaccine will be critical in the event of a large-scale avian influenza situation in the United States.

I need to stress here, however, that wide-scale vaccination of poultry is not our primary strategy against avian influenza. Rather, poultry vaccination could be used in response to widespread detection of the disease in the United States to create barriers against further spread and assist with our overall control and eradication measures.

The Response Plan's focus, first and foremost, is on quickly containing and eradicating this virus before it has the chance to spread further in the poultry population.

Communications

I also want to emphasize that for the last several years APHIS has conducted a major outreach campaign called "Biosecurity for the Birds." The campaign places informational materials directly into the hands of commercial poultry producers, as well as those raising poultry in their backyards. All of the brochures and fact sheets are available in several languages and emphasize the need for good biosecurity and disease surveillance programs to reduce the possibility of bringing any disease, not just avian influenza, on the farm or into their backyard. The campaign also encourages producers to report sick birds, thereby increasing surveillance opportunities for avian influenza.

We also recognize that an essential part of a successful emergency response program is effective communication with the media and the public. This is especially important given the concern right now regarding avian influenza and potential risks to human health. To be prepared in the event of a detection, USDA has been coordinating closely with its counterparts at other Federal agencies, State Agriculture Departments, and industry organizations to ensure, when the time comes, consistent messages regarding the strain of the disease found, the steps being taken in response, and the potential effects to poultry and, if appropriate, human health. USDA officials have also participated in numerous government-wide tabletop exercises with a focus on avian influenza. Coordination will be vital to our ability to deliver important information, while maintaining public confidence in, among other things, the food supply and public health system. Our draft National Avian Influenza Response Plan includes a detailed communications plan that will guide our efforts in these areas.

Conclusion

Allow me to close by offering a couple of thoughts that I believe are absolutely central to our discussion today. These points are also a critical part of understanding the broader context in which I believe avian influenza should be viewed.

First, just like in people, there are many strains of influenza that affect birds, with varying degrees of impact and importance.

Second, a detection of the highly pathogenic H5N1 avian influenza virus circulating overseas in birds here in the United States does not signal the start of a human pandemic. This virus is not easily transmitted from person to person. As I said, almost all of the human illnesses overseas were the result of direct contact with sick or dead birds.

Third, a detection in wild birds does not mean the virus will reach a commercial poultry operation. We are certainly preparing as if it will, but the U.S. poultry in-

dustry employs a very sophisticated system of firewalls to protect the safety of their product. In addition, the wild migratory bird surveillance plan is serving as an early warning system for commercial poultry operations.

Fourth, even if the virus reaches a commercial poultry operation, there is no reason for consumers to be concerned about the safety of the poultry that they purchase and eat, as long as the poultry is properly handled and cooked. Again, I believe that our state of readiness for a detection in commercial poultry is high, and our Response Plan would guide a swift, comprehensive response designed to minimize further spread of the disease.

Finally, I want to stress again that when it comes to food safety, consumers have the power to protect themselves. Proper handling and cooking of poultry, quite simply, kills this virus and other food-borne pathogens. Properly prepared poultry is safe. To reinforce this message in the event of an outbreak in domestic poultry, the Federal government will provide supplemental guidance on food preparation and public health protection through a robust communications plan.

Thank you again for the opportunity to testify before the Committee today. I will be happy to answer your questions.

Mr. LINDER. Thank you, Dr. Clifford.

Mr. Verga.

STATEMENT OF HON. PETER F. VERGA, DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HOMELAND DEFENSE, DEPARTMENT OF DEFENSE.

Mr. VERGA. Mr. Chairman, distinguished members of the committee. I will also thank you for the opportunity to address you today regarding Department of Defense's role in preparing for and responding to a possible outbreak of a pandemic influenza. I am joined today by Ms. Ellen Embry, who is our Deputy Assistant Secretary of Defense for Force Health Protection and Lieutenant Colonel Antonio Aragon of the Joint Staff.

On Monday, March 11, 1918, as the United States continued to mobilize for the war in Europe, an Army private named Albert Gitchell reported to the camp hospital at Fort Riley, Kansas complaining of a fever, sore throat and a headache. By noon that same day, the camp's hospital had seen well over 100 soldiers with similar symptoms, and by week's end, the number had jumped to 500. The pandemic influenza of 1918, which killed some 675,000 people in the United States and over 40 million worldwide, had begun.

The effects of the 1918 influenza pandemic on the U.S. military were devastating. Of all the U.S. servicemen who died in Europe during World War I, approximately half of them, about 43,000, fell to the influenza virus and not the enemy. As the servicemen gathered together to train for war, they unknowingly spread the virus that would eventually take so many lives.

Entire units already shipping out to Europe were already showing the effects of the virus, while servicemen on the front became too sick to fight. The flu eventually devastated both sides of the conflict, and some believe that the virus killed more servicemen than weapons of war.

The lessons of the 1918 worldwide influenza pandemic figure predominantly in global planning efforts made in preparation for the potential threat from an avian influenza pandemic.

As noted, the National Strategy for Pandemic Influenza was published, and additionally, on May 3, 2006, the Federal Government published an implementation plan for that national strategy which details Federal Government preparedness and response efforts.

These documents provide a blueprint for a coordinated national response to an influenza pandemic.

Today I will focus on the Department of Defense's preparations for and response to a potential outbreak, which could have consequences similar to those of the catastrophic 1918 pandemic. I will also address ongoing preparations within DOD to respond more broadly to a pandemic outbreak and not just the threat of an H5N1 strain.

That national strategy was developed to guide our preparedness and response to a pandemic with the intent of stopping, slowing or otherwise limiting the spread, limiting the spread of the pandemic and mitigating disease, suffering and death, and sustaining infrastructure and mitigating impact of the economy and the functioning of society.

The strategy has three pillars, preparedness and communication activities that should be undertaken before a pandemic; surveillance and detection of domestic and international systems to provide continuous situational awareness; and response and containment, actions to limit the spread of the outbreak among humans and to mitigate the health, national security, social and economic impacts.

Preparing for and responding to pandemic influenza or any other threat, requires an active layered defense to integrate seamlessly U.S. government capabilities in the forward regions of the world, the approaches to U.S. territory, and within the United States. The effort will also include assisting partner countries to prepare for and detect an outbreak, respond should an outbreak occur, and manage the key second order of effects.

There are four planning priorities in the implementation plan: protection of the health and safety of personnel; determination of essential functions and services and maintenance of those; support of the Federal response to a pandemic; and effective communications. The DOD implementation plan addresses each of these planning priorities in alignment with the pillars of the national strategy.

The top priority within the Department is maintaining operational capability by protecting DOD forces. We must do this in order to execute our primary mission of defense of the homeland. In addition, DOD has a large supporting role in the national and international response to a pandemic influenza. The national strategy directs the Department, along with other departments and agencies, to examine ways to support the government-wide response.

DOD has identified 19 critical tasks that the Department will perform to provide protection of personnel, mission assurance and the support to civil authorities, both foreign and domestic. These tasks include, among others, biosurveillance, disease detection, interagency planning support, communications support, the maintenance of civil order, continuity of operations in government and the support of international allies and nongovernmental organizations. Our five geographic combatant commanders around the world are also developing more detailed plans in their areas of responsibilities.

In a very unique and tragic way, Army Private Albert Gitchell continues to significantly influence DOD's efforts to respond to pandemic influenza. By understanding the effect of the 1918 influenza pandemic on the U.S. military, we can better forecast the potential effects on our current operations and take prudent steps to minimize the potential impact on our fighting force as well as our Nation.

Mr. Chairman, the efforts that are under way to prevent an outbreak of pandemic influenza are a testament to the leadership at the Federal level and superb coordination and cooperation among Federal, State, local, tribal and nongovernmental organizations and international organizations, including our allies.

The Department of Defense is prepared to both combat the spread of a potentially catastrophic flu pandemic within the United States military and provide support to national and international organizations in their efforts to fight this disease.

I thank you for your leadership on this issue and for the opportunity to appear before you today. I welcome any questions you may have.

[The statement of Mr. Verga follows:]

PREPARED STATEMENT OF PETER F. VERGA

Introduction

Chairman King, Ranking Member Thompson, and distinguished members of the subcommittee: thank you for the opportunity to address you today regarding the Department of Defense's role in preparing for, and responding to, a possible outbreak of pandemic influenza.

On Monday, March 11, 1918, as the United States continued to mobilize for war in Europe, Army Private Albert Gitchell reported to the camp hospital at Fort Riley, Kansas, complaining of fever, sore throat, and a headache. By noon that same day, the camp's hospital had seen well over 100 soldiers with similar symptoms. By week's end, that number had jumped to 500. The influenza pandemic of 1918, which killed 675,000 people in the United States and 40 million people worldwide, had begun.

The effects of the 1918 influenza pandemic on the U.S. military were devastating. Of all the U.S. servicemen who died in Europe during World War I, approximately half of them, an estimated 43,000 servicemen, fell to the influenza virus and not to the enemy. As the servicemen gathered together to train for war, they unknowingly spread the virus that would eventually take so many lives. Entire units shipping out to Europe were already showing the effects of the virus while servicemen on the front became too sick to fight. The flu eventually devastated both sides of the conflict—some believe the virus killed more servicemen than the weapons of war.

The lessons from the 1918 worldwide influenza pandemic figure prominently in the extraordinary global planning efforts made in preparation for the potential threat from an avian influenza pandemic. On November 1, 2005, President Bush announced the publication of the *National Strategy for Pandemic Influenza.* Additionally, on May 3, 2006, the Federal government published the *Implementation Plan for the National Strategy for Pandemic Influenza,* which details the Federal government's preparedness and response efforts for a pandemic influenza scenario. These documents provide a blueprint for a coordinated national response to an influenza pandemic.

My testimony today will focus on the Department of Defense's preparations for and response to a potential outbreak of avian influenza, which could have consequences similar to those of the catastrophic 1918 pandemic. I will also address ongoing preparations within DoD to respond more broadly to a pandemic influenza outbreak, and not just the current threat posed by the H5N1 strain of the avian influenza.

National Strategy for Pandemic Influenza and the Implementation Plan for the National Strategy for Pandemic Influenza

The *National Strategy for Pandemic Influenza* was developed to "guide our preparedness and response to an influenza pandemic with the intent of (1) stopping,

slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the spread of a pandemic and mitigating disease, suffering, and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society." The *National Strategy* uses three pillars to guide and enhance preparedness and further directs the development of Federal implementation plans in order to support the tenets of the *National Strategy.*

The three pillars of the *National Strategy* are:

- *Pillar #1: Preparedness and Communication*—These are activities that should be undertaken before a pandemic to ensure preparedness and the communication of roles and responsibilities to all levels of government, segments of society, and individuals.
- *Pillar #2: Surveillance and Detection*— These are the domestic and international systems that provide continuous "situational awareness" to ensure the earliest warning possible of outbreaks among animals and humans to protect the population.
- *Pillar #3: Response and Containment*—These are the actions to limit the spread of the outbreak among humans and to mitigate the health, national security, social, and economic impacts of a pandemic.

In addition to the National Strategy, the Federal Government recently released the *Implementation Plan for the National Strategy for Pandemic Influenza.* This document provides a framework to the *National Strategy,* assigns preparedness and response tasks to Federal departments and agencies, and describes U.S. Government expectations of non-Federal entities, including State, local, and tribal governments, the private sector, international partners, and individuals. The *Implementation Plan* translates the *National Strategy* into over 300 tasks to achieve the goals of the *National Strategy.*

DoD's Implementation of the National Strategy for Pandemic Influenza

Preparing for and responding to a pandemic or pandemic influenza, or any other threat, requires an active, layered defense. This posture is global in scope and seeks to integrate seamlessly U.S. government capabilities in the forward regions of the world, in the approaches to the U.S. territory, and within the United States. This effort will also include assisting partner countries to prepare for and detect an outbreak, to respond should an outbreak occur, and to manage the key second-order effects that could lead to an array of challenges.

Under the *Implementation Plan,* Federal departments and agencies, including DoD, focus on four Federal planning priorities: (1) protection of the health and safety of personnel and resources; (2) determination of essential functions and services and the maintenance of each; (3) support the Federal Response to a Pandemic; and (4) effective communications. DoD's Implementation Plan addresses each of the planning priorities, in alignment with the three pillars of the *National Strategy.*

The top priority within DoD is the protection of DoD forces, which are composed of the uniformed military, DoD civilians, and contractors performing critical roles, as well as the associated resources necessary to maintain the readiness of the Total Force. Of equal importance is our ability to execute our primary mission of the defense of our homeland. Priority consideration is also given to protecting the health of DoD beneficiaries and family members, who rely upon military treatment facilities and on private health care providers.

In addition to the protection of DoD forces, DoD has a supporting role in the national and international response to a pandemic influenza. The *National Strategy* directs DoD, along with all other Federal departments and agencies, to examine ways to support a government-wide response to a pandemic. DoD is developing plans to utilize its medical surveillance and laboratory testing facilities abroad to provide early warning and tracking of a pandemic influenza. Potentially, the military could provide transportation of essential resources with its air and ground transportation assets. National Guard units and members—to whom the *Posse Comitatus* Act does not apply when in State Active Duty or Title 32 status—could provide security for the protection and distribution of pharmaceuticals. Another potential support role for DoD could be the provision of surge medical capability such as health and medical care providers.

DoD has identified 19 critical tasks that the Department will perform to provide protection for its personnel, mission assurance, and support to civil authorities, both foreign and domestic, in response to a pandemic influenza outbreak. These tasks are already driving the shape and content of joint training, military exercises, and coordination with interagency partners. These tasks include:

- Medical intelligence
- Force Protection (including Force Health Protection)
- Biosurveillance, disease detection, and information sharing

- Interagency planning support
- Surge medical capability to assist civil authorities
- Medical care to U.S. forces
- Patient transport and strategic airlift
- Installation support to civilian agencies
- Bulk transport of pharmaceutical/vaccines/commodities
- Security in support of pharmaceutical/vaccine production and distribution
- Protect defense critical infrastructure
- Communications support to civil authorities
- Quarantine assistance to civil authorities
- Military assistance for civil disturbances
- Mission assurance: Defense Industrial Base
- Mortuary affairs
- Continuity of operations/government
- Support to international allies and non-governmental organizations
- Public affairs support to civil authorities

Additionally, the five geographic combatant commanders (U.S. Northern Command, U.S. Southern Command, U.S. Pacific Command, U.S. Central Command, and U.S. European Command) are developing more detailed plans to protect DoD personnel, ensure mission continuity, support local or host-nation authorities, and interagency partners. These commanders are synchronizing their plans at the regional level with our international partners, as well as with other Federal, State, and local authorities.

DoD's Pandemic Influenza Task Force

To better prepare for a potential pandemic, in November 2005, the Deputy Secretary of Defense directed that a pandemic task force be established within DoD. The Assistant Secretary of Defense for Homeland Defense (ASD(HD)) was named as the lead for the Pandemic Influenza Task Force (PITF). The Assistant Secretary of Defense for Health Affairs (ASD(HA)) has supported the effort as the Department's lead for force heath protection and health and medical response. Additionally, the Office of the Assistant Secretary of Defense for Special Operations and Low Intensity Conflict (ASD(SO/LIC)) has provided policy oversight of the DoD pandemic influenza bilateral and multilateral international partnership capacity building program.

The ASD(HD) serves as the principal civilian advisor to the Deputy Secretary of Defense for all matters concerning pandemic influenza preparedness and response, as well as the official who coordinates all efforts of the Task force. These efforts include coordination of pandemic influenza preparedness, mitigation, and response policy within DoD and among appropriate interagency, international, governmental and non-government agencies and host nation partners.

The Task Force is charged with the coordination and implementation of policies and plans that will (1) prepare, prevent, and contain the effects of a pandemic on military forces, DoD civilians, contractors, family members, and beneficiaries; (2) ensure the Department protects American interests at home and abroad; and (3) render appropriate assistance to civilian authorities in the United States.

Conclusion

In a very unique and tragic way, Army Private Albert Gitchell continues to significantly influence DoD's efforts to respond to pandemic influenza. By understanding the effect of the 1918 influenza pandemic on the U.S. military, we can forecast the potential effects on our current operations and take prudent steps to minimize the potential impact on our fighting force, as well as our Nation.

Mr. Chairman, the extraordinary efforts that are underway to prevent an outbreak of pandemic influenza are a testament to superb coordination and cooperation that is ongoing among Federal, State, local, tribal, non-governmental organizations, international organizations, and our allies. The Department of Defense is prepared to both combat the spread of a potentially catastrophic influenza pandemic within the U.S. military establishment, and to provide support to national and international organizations in their efforts to fight this disease.

Thank you once again for this opportunity to testify before you today. I welcome any questions you may have.

Mr. LINDER. Dr. Runge, at what point does a public health event, such as the spreading of influenza, become an incident of national significance and DHS takes over from HHS coordinating the response?

Dr. RUNGE. Mr. Chairman, we anticipate that in the event that this disease escapes simply the public health and medical response role, which we think will happen very shortly after human-to-human transmission is sufficient and sustained in the U.S., it would escape the confines of public health and medical and enter into severe economic consequences as well as the need for possible security issues. I think the Secretary would be very forward leaning in declaring such an incidence of significance.

Just to remind the committee, the work of HHS goes on. The work of HHS is one of coordination and support for the public health and medical as well as our other medical responsibilities.

Mr. LINDER. Dr. Agwunobi, is HHS taking the responsibilities for finding surge capacity for hospital beds, sufficient numbers of ventilators and things such as that?

Dr. AGWUNOBI. HHS recognize that an important part of pandemic preparedness is facilitating the development of adequate surge capacity in communities. But we see it as primarily a responsibility of local and State governments to look to their specific needs and to build those needs into their plans. We are stockpiling beds and ventilators within the Federal national stockpile, in case that is needed. Ultimately, we are also working with States and local governments to help them develop the capacity and the strategies to manage through the increase in surge that can be expected in a pandemic.

Mr. LINDER. Mr. Verga, does the DOD consider itself part of the surge problem?

Mr. VERGA. Yes, sir, as far as the surge capability, absolutely. Both National Guard and active duty medical response personnel would be available for medical surge. That is one of those 19 tasks that we identified.

Mr. LINDER. Do you see your role in the United States, after concerning yourself with the health of your troops and the protection of the mission, do you see a role in the United States more in terms of law and order or medical delivery or what?

Mr. VERGA. Sir, I think it is a combination, depending on the situation. As I said, we identified those 19 tasks, which run the gamut from assisting in the maintenance of public order, which we always have that mission of doing, to providing transportation, for example, the movement of critical, medical equipment or supplies, should the public transportation system not be adequate to handle it.

We see ourselves very much in the role of supporting our Federal interagency partners in doing what they need to do to meet the needs of the American people in this kind of an emergency.

Mr. LINDER. Dr. Clifford, there was a recent story in The New York Times about a week ago that the migrating birds that have returned from South Africa on their way to Europe had no H5N1. What does that make you think about?

Dr. CLIFFORD. Well, I think, from our standpoint, we are enhancing the surveillance activities within the U.S., with regard to migratory bird surveillance. The plans with USDA and Department of Interior include sampling anywhere from 75,000 to 100,000 samples in the four flyways across the U.S., and we have begun that effort in Alaska, as well as 50,000 environmental samples, so as far

as I think we need to monitor the flyways, as well as other potential avenues for introduction, which would also look at the Euro-Asian flyways as well. If we see a decrease of evidence of the virus in those birds, I think that is a positive thing.

Mr. LINDER. What are we doing about the millions of pounds of smuggled chickens into Europe from China?

Dr. CLIFFORD. I am not familiar with the millions of pounds of smuggled product from Europe.

Mr. LINDER. Into Europe.

Dr. CLIFFORD. Into Europe from China. Obviously the European Union or other European countries need to take action with that. With regard to the U.S., we work very closely with the Department of Homeland Security and our Customs and Border Patrol at the major ports of entry, as well as within APHIS. We have smuggling and interdiction teams that play a critical role as a second line of defense for smuggling into the U.S. That has been proven to be very beneficial in confiscation of illegal product into the U.S. from some of these countries.

Mr. LINDER. Are any of you prepared to say we are comfortable with the reporting we are getting out of China.

Dr. Runge.

Dr. RUNGE. I must profess not to be an expert in whether the veracity of their reports are sufficient or not, Mr. Chairman. I do think that the level of transparency has increased significantly, due to the good work of the folk overseas, as well as at WHO. We are seeing improvements in that area.

Mr. LINDER. Dr. Agwunobi.

Dr. AGWUNOBI. I would concur. I think when we compare the degree of openness that we see today with what we saw during the SARS outbreak, it is pretty clear that they have come a long way since then.

Mr. LINDER. Dr. Clifford, do you agree?

Dr. CLIFFORD. I agree that it is improved. I mean, there is always more room for improvement, but it certainly has improved.

Mr. LINDER. Mr. Dicks is recognized for 5 minutes.

Mr. DICKS. There is still some question out here, I think. I think it might be good to discuss this. The President has released his National Strategy for Pandemic Influenza. But some people feel that it is still not a plan, it is actually a plan to develop more plans.

During the press conference announcing the release of the National Strategy for Pandemic Influenza, the White House Homeland Security Advisor Fran Townsend stated the plan contains over 300 specific actions for Federal departments and agencies, because we think it is important to measure and demonstrate the effectiveness of our efforts. Every one of the Federal actions included in the plan included a measure of performance and a timeline for implementation of the actions.

Now, is that a plan, or is it a plan to make a plan? Can you help us with that?

Dr. RUNGE. Congressman Dicks, the answer is yes. It is a plan, and it is also a plan to plan further.

I want to point out that even as this interagency planning document has been produced through a rather exhaustive interagency process, even of writing it, and assigning ourselves actions and

metrics and timelines, the departments themselves are busily engaged in doing their own planning for their areas are of unique responsibility. It is border management. It is workforce protection. It is quick consequences. It is a continuation of government, as well as protection of our critical infrastructures. HHS is busy doing the things that are unique to HHS. This is a means for us to coordinate the things which we must do.

Mr. DICKS. Well, how many actions does Homeland Security have to take?

Dr. RUNGE. We have 58 that we are responsible for.

Mr. DICKS. How many do you have in place that you would consider an operational plan for those 58, any of them?

Dr. RUNGE. We are very close on some, and we are way behind on others.

Mr. DICKS. Well can you give us a little bit of a more definitive answer, how many—one, two—what number have you finished?

Dr. RUNGE. We have not finished any of them.

Mr. DICKS. There are 58 plans in action.

Dr. RUNGE. There are 58 actions and another 84 which we are coordinating—we are coordinating other agencies. We have made great strides in workforce protection issues, for instance. We have made great strides in border management issues. We are still—there are policy issues that have bubbled up as a result of making these policy plans that actually need resolution during the policy process. Fortunately, we still have some time to deal with this.

Mr. DICKS. What about HHS?

Dr. AGWUNOBI. Sir, we have 199 of the action items dictated in the plan. We have a Department-wide plan that is already out, our strategic plan that came out a while ago, late last year. But in addition to that, we are working on the detailed implementation steps required to come through on our commitment to these 199, and that plan will be released shortly.

Mr. DICKS. Are any of them completed now?

Dr. AGWUNOBI. Any of the individual 199.

Mr. DICKS. Yes.

Dr. AGWUNOBI. I think a number are actually marked as being completed.

Mr. DICKS. Could you give us that number for the record?

Dr. AGWUNOBI. I will be sure to submit to you on the record, sir, what we have completed. I do want to leave one point, which is that all of these plans are go to be iteratively improved over time.

Mr. DICKS. Right. We understand spiral development, maybe that is for Mr. Verga—we understand you have a plan, and then you improve on the plan. At least we hope you do.

Dr. Clifford.

Dr. CLIFFORD. With regard to agriculture, I think many of the action items are enhancements to things that we have already been doing, so it is a continuation of those things. I would just like to add—

Mr. DICKS. Are there any brand new ones?

Dr. CLIFFORD. Yes, there are some new ones that we have put in there as additional enhancements, but it is things relatively new from a standpoint, just didn't start with this concept. For example,

the National Veterinary Stockpile. We had already been talking about that and initially were putting those actions into place.

So it is stockpiling those, it is getting strike packs for those ready in case of an actual introduction for this National Veterinary Stockpile. Strike packs are goods that will go to the location to provide the support needed for the personnel there.

Mr. DICKS. Now, in order to do a vaccine, you have to have a strain of the flu; is that correct?

Dr. AGWUNOBI. That is correct, sir.

Mr. DICKS. You can't really start until you have that strain, is that correct? I am not a biologist.

Dr. AGWUNOBI. What we lack today is not only a sample of a pandemic strain, because there is none yet, there is no pandemic around the world, but we also lack the capacity to develop what we plan to do, which is to be able to deliver 300 million doses of pandemic vaccine within 6 months of the pandemic virus rearing its head. Building that capacity requires that we begin now to invest not only in science and development, but also in the industry, trying to get the industry to be able to have the capacity that it takes to deliver on that promise.

Mr. DICKS. Those of us who have been through hearings on bioshield, we haven't seen a great deal of ability for HHS and DHS and the companies to do very much. Is that going to be a problem here as well? I mean, are the companies willing to work on this?

Dr. AGWUNOBI. We have learned a lot over the years. The companies are indeed very willing to work with us on this. They recognize this is a very critically important subject.

Mr. LINDER. Thank you. The gentleman from Alabama is recognized for 5 minutes.

Mr. ROGERS. Thank you, Mr. Chairman.

Specifically, Dr. Agwunobi, what are you doing to make sure that the industrial infrastructure is in place to deal with the pandemic virus once it is identified?

Dr. AGWUNOBI. A number of different steps. Specifically, for example, as recently announced by the Secretary, we have invested $1 billion in the furthering of our ability to use cell-based vaccine technology, new ways of producing vaccine. We are trying to diversify the numbers companies that are in the business of vaccine manufacturing. We are trying to diverse—

Mr. ROGERS. Are they domestic or foreign or both?

Dr. AGWUNOBI. They are actually both, but in our approach, we would have them produce their vaccine right here in the United States. We believe that is an essential part of the strategy. So our investment makes that happen.

But we are also diversifying the different ways that you can make vaccine, egg based, cell based, recombinant. We are investing in technology to try and get all of those options under way and to make sure that the first one that gets there is available to us.

Mr. ROGERS. I understand that. There is a company in Alabama, not in my district, but in Alabama called BioCryst that has produced permavir. I understand an RFP has recently gone out from your Department for an award on an antiviral. My urging to you would be whether it is permavir, or whatever you discern to be the

best vaccine, antiviral vaccine, that you grant that award in a timely manner and not let that languish around.

Dr. AGWUNOBI. I will be sure to take back that message. Whether it be for antivirals or for vaccines, I concur we need to move more quickly, and indeed, we are.

Mr. ROGERS. One of the things you made reference to in your earlier comments was stockpiling. What are you stockpiling since you acknowledge you don't know what the virus would look like?

Dr. AGWUNOBI. Well, I think the strategy is to stand ready with a diverse armamentarium so that regardless of what the eventual virus might look like, its characteristics to drugs, that we might have a number of choices on that day.

So we are stockpiling today, H5N1 vaccine, a vaccine against the virus that we are seeing in birds, the premise being that if the pandemic virus in the future looks very similar, that the vaccine that we have on hand today might be able to offer some abilities to protect.

But we are also stockpiling antivirals, a number of different antivirals. We are stockpiling ventilators. We are stockpiling beds. We are stockpiling other medications, antibiotics others that might be needed, not only in a pandemic but in other hazards. We are stockpiling masks and gloves and other resources that might be required to fight a war against a pandemic. So it is really across the board.

Mr. ROGERS. I represent a very rural district in Alabama. I am curious to know in your action plans how you incorporate rural hospitals and rural clinics into your ability to distribute vaccines.

Dr. AGWUNOBI. Two points. One actually goes to the question by the Chairman related to surge capacity. That is since 2001, we have actually, Congress and the Federal Government has invested $6.7 billion in preparing our Nation for public health emergencies. We have done so through the CDC. We have done so through HRSA, Health Resources and Services Administrations in the Department of Health and Human Services, and that has been focused on, almost 26 percent of that $6.7 billion has been focused on making sure that every hospital in our communities and in our Nation has been better able to take up a public health emergency. Much of that money has gone to rural hospitals specifically.

As we move forward, we are investing pandemic influenza preparedness moneys in preparing states, $350 million, as was mentioned.

Mr. ROGERS. Over what timeline?

Dr. AGWUNOBI. Our timeline for investing in preparedness is a 3-year time line. The $7.1 billion that was requested by the President, $3.8 billion of which has already been delivered, is really mainly dedicated to this 3-year strategy of building preparedness, not just in big cities but across every aspect of our Nation.

Final point, sir, a pandemic is an equal opportunity threat. It will go to rural hospitals, to cities, to every corner of our Nation. Therefore, we can't afford to focus on one area and forget another.

Mr. ROGERS. Which is my point exactly. I want to make sure that we are just not focused on urban areas, and their hospitals and their ability to deliver the vaccine once it is identified—I do want to make sure that your action plans incorporate rural America, be-

cause most of this country is, in fact, rural and dependent on rural clinics and hospitals for delivery of this kind of health care.

Mr. Runge, I would ask the same question to you about rural health care delivery in the area of a pandemic.

Dr. RUNGE. I think it is important to note, Congressman Rogers, that we have gone out to, I think, 49 States now. When we go to these summits, we get representatives from every corner of every State, the public health community officers, as well as the State. We met with the hospital associations, the medical associations, the faith-based groups, the private sector, all together to talk about their role in a pandemic, with the major theme that the Federal Government has its responsibilities, but so do the local communities. In fact, every family has a responsibility. So this discussion is the same in virtually every State. I believe that they are sufficiently involved in the process.

Mr. ROGERS. I see my time has expired. I look forward to the next round of questions.

Mr. LINDER. The gentleman from Oregon is recognized for 5 minutes.

Mr. DEFAZIO. Thank you, Mr. Chairman.

Dr. Agwunobi, gee, I just feel so much better to hear about the massive stockpiling. Unfortunately, it seems to be defied by reality.

Let us talk about that a little bit. The Secretary of Health and Human Services recently came to my State. I will just give you a few quotes. He urged Oregonians to take planning seriously. Unlike natural disasters, such as Hurricane Katrina, there will be no help from the outside.

If Katrina was good, I am really wondering about the Federal response. People of Oregon will have to take care of the people of Oregon, Leavitt said. Federal Government can't be in 5,000 communities.

Surge capacity. Well, he said, elected officials should put a higher priority on healthcare. Maybe they should build in surge capacity instead of remodeling the swimming pool.

Now, I am not quite sure what he is talking about here and what you are talking about. Let us talk about a few issues. You have a stockpile of 4,000 to 5,000 ventilators. The Center for Biosecurity says that the—no, excuse me, the shortage is estimated—that is another shortage—at about 637,000 from that which we would need.

Have you developed triage guidelines for doctors to tell them who to disconnect and who to deny service to? Because in a regular flu year, we use 100,000 of our 105,000 ventilators. We are talking about a pandemic. You have got a stockpile of 4,000 to 5,000, are you sanguine about that? Do you think that is enough?

Dr. AGWUNOBI. Sir, as we work with States and with providers, hospitals and doctors, we recognize that each State is going to have to establish a plan.

Mr. DEFAZIO. So the States are responsible for buying ventilators?

Dr. AGWUNOBI. Each State and local community will have to respond—

Mr. DEFAZIO. Right. So the States and local communities should be buying ventilators, not the Federal Government. You were talking about a stockpile. I am just confused.

When you talk about a stockpile, you think, hey, the Federal Government has got a big stockpile. They are going to distribute them. Now you are saying, no, the State is going to distribute them. The State and the local hospitals, which can't get reimbursed for things that aren't needed for annual occurrences or regular Medicare won't factor in their surge capacity for pandemic or ventilators; will it? They won't allow that in reimbursement.

Dr. AGWUNOBI. Some States, sir, require—some communities won't need to buy ventilators because they need to have plans for how to manage the resources that they have.

Mr. DEFAZIO. Right. So you say, then, the article from The New York Times that says that we are 637,000 ventilators short is inaccurate.

Let us go to the development and the stockpiling of, you were very sanguine also you said, about 3 years, we will have our capacity. The plan says, the primary objective, depending on availability of future appropriations and responsiveness of the vaccine industry, is for domestic manufacturers to be able to produce enough vaccine for the United States population within 6 months, beginning in 5 years. You said 3 years. I am confused.

Dr. AGWUNOBI. Three to five years is the number we—

Mr. DeFazio. Okay, so 3 to 5 years, not 3. It depends on the response of these manufacturers. Why are we relying on the private sector here? Is this more privatization? Don't you think maybe that the government should be mandating that?

Do we have, currently, any modern cell-based manufacturing capability or any U.S.-owned old-fashioned egg-based capability in the United States of America for producing vaccines?

Dr. AGWUNOBI. Sir, we definitely have a need to improve our capacity.

Mr. DEFAZIO. Right. So we don't have any U.S. based. The two we have are foreign-owned, and they are pretty obsolescent, 100-year-old technology, but they sort of work. We haven't been able to meet the annual flu needs.

Dr. AGWUNUBI. Sir, our plan fixes all of those—

Mr. DEFAZIO. It fixes them in 3 to 5 years, not 3 years.

Dr. AGWUNUBI. In 3 to 5 years—

Mr. DEFAZIO. Right. Dependent upon appropriations and the good will of—do you have a commitment from a pharmaceutical manufacturer to build one of those plants today, in writing?

Dr. AGWUNOBI. Sir, our contracts with these pharmaceutical manufacturers contemplates the journey to that point.

Mr. DEFAZIO. We are going to journey to a point. I mean, so it just kind of—I don't want to give false assurance to the American people. I mean, I think Secretary Leavitt, when he came to Oregon, said you are on your own and was a little more accurate. You painted a picture we are stockpiling. How about—let us talk about, okay, antivirals, how big is the stockpile?

Dr. AGWUNOBI. In terms of an antiviral?

Mr. DEFAZIO. Yes.

Dr. AGWUNOBI. We have 5.1 million courses, but we also have a little less than 5 million courses of ramantidine. We also have some stockpiles of Tamiflu liquid for infants. We also have stockpiles—

Mr. DEFAZIO. Tell us how quickly we will build that up. Again, we are going to be dependent on the private sector, foreign manufacturers. As I understand it, we are kind of last in line, because we didn't order early.

Dr. AGWUNOBI. Well, sir, our goal is to stockpile 50 million regimens of antivirals.

Mr. DEFAZIO. In how long?

Dr. AGWUNOBI. Over the same period of time.

Mr. DICKS. Would the gentleman yield for just one point? I am having a hard time understanding what happens if the pandemic is 6 months from now.

Mr. DEFAZIO. In 5 years, we will build a plant that could make the vaccine to take care of it.

Mr. DICKS. Thank you.

Mr. DEFAZIO. My time has expired. I will wait for the next round.

Mr. LINDER. Chairman King is recognized for 5 minutes.

Chairman KING. Thank you, Chairman Linder.

First of all, I regret the fact that I was in a prior meeting and wasn't here to begin.

I want to thank all of you for testimony and all of you for your efforts and all of you for the contributions you make.

I also want to thank Chairman Linder for the initiative he has shown on this issue and for the concern he has demonstrated on this issue. I want to thank him very much.

I am not going to make the mistake too many members make of coming in after the opening statements have been made and other questions have been asked and repeat the same questions.

I would like to ask Secretary Verga a few questions though. Is the Department of Defense monitoring troops overseas, especially in Asia and Africa, for any signs of avian flu infection?

Mr. VERGA. Yes, sir. We have a very aggressive biosurveillance program to include some Department of Defense-operated laboratories overseas to monitor. We have an aggressive force health protection program designed to be able to very early detect any possible infection that might come about.

Chairman KING. I don't know if this was covered before I came here, but in the event we have to use the military for a pandemic response in this country, do you feel we have sufficient forces to do that? Are you confident that the military could make the appropriate response to a pandemic episode here in this country?

Mr. VERGA. Yes, sir, I am very confident. We are in the final stages of our implementation plan for a pandemic influenza. It is done, written, staffed and is merely awaiting signature to cover the 116 of the tasks out of the national plan that we are required to do. Coincidentally, as we speak, there is an exercise ongoing that is addressing pandemic influenza as one of the items that we have to do, and we are going through the, in DOD speak, the force sourcing of the forces that might have to be used in that. I am confident that we will do what we have to be able to do.

Chairman KING. Thank you, Mr. Chairman. I will yield back my time to you, Mr. Rogers, Mr. Simmons, if you want to.

Mr. LINDER. Dr. Christensen is recognized for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

At the outset, I want to say that I share the concern of my colleague, Mr. DeFazio, that even a national strategy says, tells States that the assistance that they will receive will be limited, especially in light of the fact that the funding isn't there to help them prepare.

I want to say at the outset to say to the panelists, what I say to my fellow committee members, is that in the plan, I am still not satisfied, and my fellow delegates are not satisfied the territories are not explicitly listed in the plan.

We are glad, as a State, that we get the same status, but we do run the risk of being overlooked. For example, when we said that Dr. Runge had 49 States had summits—

Dr. RUNGE. That includes territories.

Mrs. CHRISTENSEN. Exactly. But if I didn't know, it wasn't my territory, I would have asked you, well, what about the territories? I think it is important that while we don't want to lose anything, that some of the unique considerations of territories are included and are listed separately.

To begin my questions, Assistant Secretary, Admiral, Dr. Agwunobi, I note, I think his name was Simmons, that was the Assistant Secretary for Emergency Preparedness and Response.

Dr. AGWUNOBI. Simonson.

Mrs. CHRISTENSEN. I think he has left. Is there a new Assistant Secretary at the Department for Emergency Preparedness and Response?

Dr. AGWUNOBI. There is currently an Acting Assistant Secretary, Gerry Parker. He was the deputy when Stuart Simonson was in that seat.

Mrs. CHRISTENSEN. Does he have a public health background?

Dr. AGWUNOBI. Oh, extensive. He has worked for a number of years both within the military side and now on the civilian side on public health emergency preparedness. He is an expert.

Mrs. CHRISTENSEN. Dr. Runge, in your testimony, you said that the Secretary has someone in mind to head up the preparedness and response, to be the PFO in the case of a pandemic. Is that you?

Dr. RUNGE. No, it is not.

Mrs. CHRISTENSEN. Doesn't that create some confusion over roles here?

Dr. RUNGE. Not at all. Under the National Response Plan, the Secretary will appoint a PFO, which truly is not—this individual needs to have a large operational experience and capacity. Certainly the public health and medical knowledge will be at his or her elbow when we need to draw upon it.

Mrs. CHRISTENSEN. We are not talking about any kind of a counterterrorism attack. We are not talking about any nuclear incident or a hurricane. We are talking about a health event.

Dr. RUNGE. This is much bigger than a health event, ma'am. We anticipate—by the way, HHS is responsible for that piece of it. There is the distinct possibility that as we see large numbers of people ill, demanding health care, demanding medications that

they may not have access to, and all the things that have been articulated in the room today, we want to make sure that Americans are safe and secure, that the supply chain for food and goods and chlorine to the water treatment plans and so forth, that there are sufficient resources in the Nation's critical infrastructures to maintain them in the event—

Mrs. CHRISTENSEN. What is your role in the case of a pandemic. Is it clear what the Department's role, the HHS's role in the medical arena is?

Dr. RUNGE. Yes, it is very clear to us. I will be the Secretary's principal advisor on medical issues, which is a distinct role from the principal Federal official, who will be guiding the operational command of the incident coordination.

Dr. AGWUNOBI. I would concur on that. The Department of Homeland Security and Department of Health and Human Services, I think we are very clear on what our relative roles would be in response to a pandemic.

Mrs. CHRISTENSEN. Dr. Agwunobi, the plan for vaccination presumes—well, even though it may be a few years hence—that the virus would be contained and slowed enough, for enough time that that estimated 6 months time for the development of a vaccine, in every case of pandemic flu it the local public health infrastructure, the health system in place, that first line of defense, which will buy us the time to get us to be maybe that 6 months while protecting lives.

Do you really think that $644 million or somewhere in that vicinity can prepare this country with reportedly faulty public health infrastructure—hospitals have no surge capacity in general, emergency rooms are over capacity, lab capacities inadequate, we have a lower number of workers in health and local health, State and public health than we did in 1979.

So given the fact that it is the local health system, the public health infrastructure, the private health infrastructure in communities that is going to be that first line of defense and maybe now for 3 to 5 years, is that enough money?

Dr. AGWUNOBI. Since 2001, $6.7 billion has been invested in public health strengthening, strengthening the infrastructure of our public health communities across the Nation, designs to make them better able, better ready to respond to public health emergencies, and by all definitions a pandemic falls squarely into that. In addition to that, this $7.1 billion that has been requested, of which 3.8 has already been appropriated, I think adds to that investment in our Nation being prepared.

We also have a number of other assets designed at the local level to help strengthen their ability, like Medical Reserve Corps and others. Ultimately I do believe that as we continue this ongoing investment, whether it be for bioterrorism preparedness, public health emergency preparedness, and these next few years of investing in pandemic influenza preparedness, that we will be a Nation ready at the local, State and at the Federal level.

Mrs. CHRISTENSEN. I am still concerned that despite that investment hospitals are still saying they just don't have the capacity.

Thank you, Mr. Chairman.

Mr. LINDER. Does the gentleman from Connecticut wish to inquire?

Mr. SIMMONS. I thank you, Mr. Chairman, for holding this hearing, which I think is tremendously important and timely, and I appreciate the testimony of the witnesses, even though I have not heard it but I have read it, and I thank you all for being here.

I would like to focus—I have two questions; one on the prepared statement of Dr. John Clifford with regard to outbreaks of avian influenza in commercial bird flocks. A couple of years ago in the State of Connecticut a private company reported the outbreak of avian influenza in a population of up to 7 million birds and the Department of Agriculture in the State of Connecticut, working with the Federal Department of Agriculture, initiated a program not to depopulate 7 million birds but to vaccinate them, with the idea that vaccination could work to control the outbreak, which was very limited but nonetheless it was within this large commercial flock.

That program was a complete success. The flocks continue in good health and the outbreak was contained and eventually eliminated. My understanding is the vaccinations were conducted through the food that was provided to the birds.

The Federal Government through the Department of Agriculture does reimburse commercial activities for depopulated flocks and has the authority to reimburse for vaccination but never has. I wonder if a practical matter is that it isn't smart to focus on vaccination rather than depopulation as a strategy, but current funding does not support that strategy. Would you comment on that?

Dr. CLIFFORD. Yes, Congressman. I think there is a very important distinction we need to make here. The particular situation you were talking about in Connecticut was what we referred to as low path, low pathogenic avian influenza. That was one of the first times we used vaccine successfully. It had been tried in Europe and it was a success. And you can use those types of strategies dealing with low path avian influenza, not with high path AI. High path AI is going to kill 80 to 90 percent of the birds and you would need to stop the virus from circulating, you need to go in and depopulate. The only time we would use vaccine in that type of situation is to try to build a firewall around that particular area of infection to prevent and slow the spread of that virus, so that is when vaccine would be used.

In addition, we do not want to use wide scale vaccine in the U.S. poultry industry. Vaccine will not prevent the virus from circulating. You can still have virus present while it was successful in eliminating and it would also—it is not an approach that we think is wise with regards to wide scale use. Limited use, certain specific circumstances, and very controlled use.

Mr. SIMMONS. Does low path lead to high path in some circumstances?

Dr. CLIFFORD. Low path AI can mutate and become high path AI, and that is why we actually, beginning in 2005, we have developed and actually started in 2004 with what we referred to as our low path AI program to heighten the level of surveillance activities both in the commercial sector as well as what we refer to as the live bird marketing system.

We have had an H7N2 into low path AI virus that has been circulating in the live bird marketing system in the New England area for years and have been monitoring that actually since the late 80s. Recently, with the new program we put in place we have seen great reductions in the circulation of that virus in those bird markets.

Mr. SIMMONS. Thank you for that response. I guess, again, I felt that the Department of Agriculture did a great job of monitoring the situation and saving the industry whereas depopulation essentially is very, very expensive and destroys the industry. And for those human-cost infections, depopulation accomplishes the task. People want to disrupt the economy, they want to disrupt the food supply, and depopulation certainly does that.

My second question—I am out of time. I will wait for the next round.

Thank you, Mr. Chairman.

Mr. LINDER. Does the gentleman from North Carolina wish to inquire?

Mr. ETHERIDGE. Thank you, Mr. Chairman.

Let me follow that up, Mr. Clifford. When you talk about depopulation, especially with flocks, the person who really gets burned is the grower. All he has is his time and effort. If you depopulate the whole thing, and they have a contract, they are still paying their revenues.

Does the Department have funds to reimburse for the depopulation for the farmers or is that a direct appropriation from Congress?

Dr. CLIFFORD. No, sir. We have the authority for use for depopulation.

Mr. ETHERIDGE. I understand you have the authority for depopulation; my question was for reimbursement.

Dr. CLIFFORD. Yes, sir.

Mr. ETHERIDGE. At what rate?

Dr. CLIFFORD. For highly pathogenic avian influenza, it is at 100 percent rate.

Mr. ETHERIDGE. For the birds. That would go directly to the grower as well?

Dr. CLIFFORD. The split on that, we are trying to address that in some rulemaking, but obviously if you go back to the situation where we dealt with the low path AI in Virginia a few years ago, we did split that out with the growers as well. So we will need to work that with the poultry companies.

Mr. ETHERIDGE. I would encourage you to look at it because the company is in a far better position to absorb loss than the individual at the end of the line. They are the ones that are going to go broke. So I would hope you would follow up, and I look forward to hearing from you personally on that one.

Mr. SIMMONS. Would the gentleman yield for 15 seconds?

Mr. ETHERIDGE. I will be happy to.

Mr. SIMMONS. The depopulation is getting reimbursed. In our case the vaccination did not. So the company accrued about a $20 million bill to preserve and protect the flock.

Mr. ETHERIDGE. I recognize the company, but the grower is the one who stands to have the great loss. The companies will lose, but they have more to absorb.

Let me go to Dr. Runge, and, Dr. Agwunobi, if would please answer this one because you have been talking about a number of the issues. Recently Secretary Leavitt has stressed that State and local government, schools and private businesses will bear much of the preparation and response burdens during the pandemic.

My question is what role will the Federal Government expect schools to play in this crisis. Secondly, have any of you given any thought to what the trigger point will be for closing schools if you are going to play a role?

While I am at it let me get the third one in so we can get it quickly. What kind of support would the Federal Government give to school districts to prepare for these roles? You are only talking about 50 some million students and a lot of personnel in a place where if you have an outbreak it is going to spread like that.

Dr. AGWUNOBI. There are some obvious situations in which schools are going to have to close, and that would be those circumstances where—

Mr. ETHERIDGE. I understand that. My question is: Is there a plan in place, has it been distributed to the local schools and to the States?

Dr. AGWUNOBI. Sir, we recognize that no two school districts are the same and we are working very closely with them.

Mr. ETHERIDGE. I don't want to keep butting in. I was a State superintendent of schools. Have you corresponded with the State superintendents and with the local independent school districts across America?

Dr. AGWUNOBI. We have actively reached out to the State governments in each State urging them to pass on, and we are reaching out to schools in those State pandemic summits, they are all invited, school districts are invited to send their leadership to those pandemic summits in which the Secretary and experts from CDC and others sit and have usually an all day long event in which we dialogue with those very leaders that you described.

Mr. ETHERIDGE. So the superintendents are involved in every State?

Dr. AGWUNOBI. In every State they are invited to these pandemic summits, and we have made available written guidance that schools can use, they can draw down from the website, *www.pandemic.gov,* that offer not just guidance in terms of universities and day cares but also specific guidance for K through 12 that school superintendents can use to build their plans. So the answer would be yes, sir.

Mr. ETHERIDGE. How about Homeland Security?

Dr. RUNGE. We have been attending these State summits with HHS, and the ones I have been to, 8 of the 49 myself, the schools are very well represented, not only the public school systems but also colleges and universities.

Dr. AGWUNOBI. I find teachers and PTA are also showing up.

Mr. ETHERIDGE. Let me—I am about out of time but let me come back to the amount of money appropriated. I think it is woefully inadequate for what we are talking about when we could be facing

this within 6 months, a year. We have no idea what it is and yet we have put so little funds out there to prepare the public. Would you not agree with that?

Dr. AGWUNOBI. Sir, we invested, as I said, $6.7 billion since 2001. I would like to make the point that States haven't drawn down all that money. There is still about a billion dollars sitting, waiting on States to draw that money down so that they can prepare their public health infrastructure for a public health emergency. And that is before we began—

Mr. DICKS. Would the gentlemen yield? Bob, would you just ask him are you talking about the problems with DHS grants, are you talking about some HHS grants for public health?

Dr. AGWUNOBI. I am talking about public health dollars that went out to States through the CDC and HRSA, both agencies within the Department of Health and Human Services, a total of about $6.7 billion invested since 2001, of which $1 billion has yet to be drawn down.

Mr. ETHERIDGE. Mr. Chairman, would it be possible for us to get that—the States that haven't drawn theirs down? I think that would be helpful for this committee to know that.

Mr. LINDER. The Department will respond in writing. Thank you.

Dr. Runge, how much time did you engage the private sector in the planning process? We have got major corporations with plants all over Asia. An event is going to be a serious problem for them to keep their plants open. How much are they engaged?

Dr. RUNGE. Mr. Chairman, that is exceedingly important. Even as the President was unveiling the national strategy in November, our Critical Infrastructure Partnership Office was reaching out to the private sector. As you know, Mr. Chairman, 80 percent or so of our critical infrastructures are owned by the private sector. Our office was going and actually having tabletops just to begin to acquaint them with the issue.

I believe we have had 4 or 5 of those now among the critical infrastructures together and as recently as 2 weeks ago I was in Boston speaking with leaders of major health care companies who were very, very engaged in this topic, not only as to what they can do but also how they need to protect their employees and keep the country moving in the event of a pandemic. This is exceedingly important and we have been doing that outreach.

Mr. LINDER. Dr. Clifford, would you like to comment on that?

Dr. CLIFFORD. I am sorry, can you repeat that question?

Mr. LINDER. How much are you and the Department of Agriculture reaching out to the private sector for not only surveillance, because they have workforces that are affected, but responses?

Dr. CLIFFORD. We have actually been outreaching a lot with the industry side of the sector. Actually, just last month or at the beginning of this month we just held a meeting in Atlanta with the industry and the States as well as the Federal with regards to our response plan and preparedness.

Mr. LINDER. Dr. Agwunobi, how much are you including the CDC's BioSense program, which is in development? How much of that is being included in planning?

Dr. AGWUNOBI. All of the assets of the Department of Health and Human Services, as you can well imagine, are an integral part of

any response to a public health emergency, especially one of the size and scope of a pandemic.

BioSense offers us a great opportunity in the future as it develops out and strengthens the ability to not only identify perhaps the onset of a public health event of major significance but also, for example, it offers a great opportunity to manage resources because it gives us a sense of how the pandemic is affecting a community and how that community is responding to the pandemic. So it is a part of our plan, an integral part of our plan.

Mr. LINDER. Does the gentleman from Washington wish to inquire again?

Mr. DICKS. Yes, I would like to.

Who is in charge of assuring that States and localities create the surge capacity for treating people who become ill during a pandemic?

Dr. AGWUNOBI. That would be the Department of Health and Human Services working in concert with State governments.

Mr. DICKS. We have been informed that emergency rooms and trauma centers are closing all across the country because they are considered a money loser by many hospital administrators. What is the current state of readiness of our emergency departments?

Dr. AGWUNOBI. Sir, I read the same reports you do and we recognize that our emergency departments across the Nation continue to face significant challenges, in some communities more than others. We continue to work with them across the Nation to try and help them as they go through these transitions.

Mr. DICKS. But in light of the fact we could be facing a pandemic flu outbreak, don't you think people would—I mean they would turn to emergency rooms, so if they are being closed down, this is not good? And should we be doing more to help them financially as part of our preparation for this—to be prepared for this possible outbreak?

Dr. AGWUNOBI. As we work with State and local leadership we are urging them to do an inventory of their current capacity to meet the needs that might appear in a pandemic, not just the emergency room care but potentially inpatient care and outpatient care, and we are providing them with guidance on what they might expect in a pandemic and offering them, as I said, this significant investment in their infrastructure.

Mr. DICKS. Let me talk about one thing. Time is quite limited here. Congress has appropriated 350 million for assistance to the States and localities for pandemic preparedness. The goal of this program is to assure that all localities meet a minimum level of preparedness.

Are you going to create a single course set of performance standards that all jurisdictions must achieve with these funds?

Dr. AGWUNOBI. Yes. The guidance that is attached to these funds has very specific expectations of what a State will commit to achieving in its plan and across its community, not just a written plan but an exercise plan that proves those achievements have occurred.

Mr. DICKS. Given that one of the most critical aspects of preparedness will be the ability of local jurisdictions to rapidly distribute a pandemic vaccine, will the Department encourage States

to organize mass vaccination exercises during the next flu season to test their distribution plans?

Dr. AGWUNOBI. I won't tie the timeline to the flu season. I will tie it to the guidance issued associated with the 350 you mentioned. It has specific timelines around which we expect States will have developed distribution plans not just for vaccines but antivirals and other countermeasures. It has very specific timelines on when we expect those achievements to have occurred, including, as you state, exercises.

Mr. DICKS. While significant funds are being invested in preparedness, when a pandemic hits, the cost for Federal, State and local governments will be significantly higher. Has anyone estimated what the cost would be to implement its pandemic preparedness plans?

Dr. AGWUNOBI. When you say its, you mean—

Mr. DICKS. For example, is there an estimate for what the actually pandemic flu vaccine will cost once it is available? Has the Department asked States and localities to estimate the cost of responding to the pandemic as opposed to planning for one? In other words, it is one thing to plan, it is another thing to then have to respond, and who is going to pay that bill?

Dr. AGWUNOBI. As we work with States we recognize each of them makes decisions in their plan. They have a number of options on how they might, for example, care for overflow patients. Each State, each community makes a decision based on what its specific plan says.

We haven't rolled up the costs of the hundreds or thousands of plans that might developed at the local, State and Federal level into one bottom line, but I would imagine that each State and each community as they develop their plans, that they contemplate where they might need increased costs or where they might use existing funds to develop our capacity use within those plans.

Mr. DICKS. Thank you, Mr. Chairman.

Mr. LINDER. Does the gentleman from Alabama wish to question further?

Mr. ROGERS. Thank you, Mr. Chairman. Before I go to my questions, I want to follow up on Mr. Etheridge's request. I would like to be included in being given a list of the State boards of education that have not drawn down their funds.

Dr. AGWUNOBI. Not boards of education, the State government; actually, the public health.

Mr. ROGERS. I would like to know if Alabama is on that list.

Mr. Clifford, also the point about the poultry growers, I would look to be given the same information that you are going to provide him about grower reimbursement, because he is absolutely right, the growers are the least able to absorb that loss.

Dr. Runge, where I left off before, talking about rural hospitals in particular, I have in my district a couple of large hospitals that have an average day census of 3 to 500 and I would expect them to be sophisticated enough to be included in any information systems. But I have about a half a dozen who keep an average day census of 10 to 15 and one that keeps 3. These folks are going to need their hands held in making sure they are prepared and I am interested in knowing along what timeline you think you will be

able to reach down to these smaller rural hospitals to make sure they are as prepared as they can be in the event you are dealing with a pandemic.

Dr. RUNGE. Is that question to me?

Mr. ROGERS. Yes.

Dr. RUNGE. I will go back to this issue, and quite frankly I don't want you to get the mistaken impression we think everything is going to be just fine out there if they have a plan. We expect if the pandemic hits us and if it maintains a virulence to anything like we are seeing in the current virus or what occurred during 1918, there will be unmet needs in every size hospital, whether it is an emergency department with 60 beds or whether it is one with 2 beds as the ones you are describing.

We have encouraged the Hospital Association, the American Hospital Association, as well as State entities to make sure that all of their members have a contingency plan on what happens if you have eight ventilators in a hospital and the ninth patient arrives who needs artificial ventilation.

Mr. ROGERS. So you are waiting for them to reach out to you?

Dr. RUNGE. No. Basically, this is an educational process we have entered into with States, with the private sector. Much of this health care is provided not by public health but also the private medical sector.

This is not something where we are coming in with a magic pill that can cure this. We want to make sure that every hospital, every ambulance service, every clinic has taken into account what could happen if it loses 40 percent of its workforce.

Mr. ROGERS. What I am interested in is if you develop a vaccine, if we see a pandemic coming and you are able to draw on the infrastructure to develop a vaccine, I want to know that there is a way that—because that is where people are going to go, to their local hospital to try to get a shot. I want to know that every hospital knows how they are supposed to draw down their proportioned amount of the vaccine.

Before my time runs out, I want to turn to Mr. Clifford for a minute. Poultry is the number one industry in my State, and obviously in my district it is the largest. You talked a little while ago about your action plans and vaccines but also I heard you make reference to Mr. Simmons' question about vaccines, certain vaccines not being useful. I know that Auburn University has developed a vaccine that you can put in the egg and it prevents the chicken that is producing that egg from being susceptible to vaccines that are known at present.

My question is: Are you all spending significant amounts of money or any money for continued R&D to make sure that when a bird flu arrives here that we are able to provide those kind of vaccines to prevent its spread, because we are going to be killing flocks?

Dr. CLIFFORD. Yes, sir. We already have on hand 40 million doses of avian influenza vaccine as well as purchasing an additional 70 million doses for our vaccine bank. Those are made up of four different subtypes of vaccine and we know that two of those subtypes are effective in assisting and helping protect the birds

and spread of the virus for the highly contagious H5N1 that we are seeing.

Mr. ROGERS. Do you have additional R&D funds to continue to make sure we are on the cutting edge of being able to fight this?

Dr. CLIFFORD. Yes, sir. There are research dollars there for ARS, part of USDA, to continue research and development as well.

Mr. ROGERS. You talked about firewalls in the poultry industry a little while ago. I have been through the processing plants and I agree there are incredible firewalls, but when it comes to growers what kind of firewalls do you see there and in the feed lots?

Dr. CLIFFORD. Actually, good biosecurity is the key to the prevention of spread of this disease. So if you have the disease introduced in an area you have got to quickly contain it and have good biosecurity, and that means in these grower facilities, or no matter what type of facility, people cannot have free access. They have got to clean and disinfect their footwear and outerwear. They should not have ongoing contact with birds outside of that. So there are a lot of things that the poultry industry is doing as well to beef up, as well as have very good sound biosecurity to protect that investment out there.

Mr. ROGERS. Thank you. I see my time is up.

Mr. LINDER. Does the gentleman from Oregon wish to inquire further?

Mr. DEFAZIO. On the issue of Tamiflu, Dr. Agwunobi, it adds apparently some potential utility as a prophylactic, is that correct?

Dr. AGWUNOBI. Yes, sir.

Mr. DEFAZIO. It is also used, as I understand, in treatment, it has been in the bird flu cases, massive doses have been given and it is not quite clear what role it played there. Is that correct?

Dr. AGWUNOBI. That is correct, sir.

Mr. DEFAZIO. Seems like it would be prudent to have on hand a significant amount, is that correct?

Dr. AGWUNOBI. And a diversity of anti-virals, number of different anti-virals.

Mr. DEFAZIO. At the moment we have only 4 or 5 million courses, which if you were treating people, would maybe treat a couple million. I guess you give a double dose.

Dr. AGWUNOBI. Our goal is to maintain a stockpile of 25 percent of the population. 26 million doses by the end of this year, sir.

Mr. DEFAZIO. 25 percent would be—

Mr. LINDER. Would the gentleman yield on that point? What is the shelf life of those vaccines?

Mr. DEFAZIO. This is the anti-viral.

Mr. LINDER. Could you tell us about the shelf life?

Dr. AGWUNOBI. Different anti-virals have different shelf lives. I believe Tamiflu is 5 years, but there are a number of others and they may have different shelf lives. If I might get back to you on the record on each of the different anti-virals.

Mr. DEFAZIO. Thank you, Mr. Chairman.

So what is the major constraint; is it production capability?

Dr. AGWUNOBI. Constraints in regards to? One is appropriations, obviously.

Mr. DEFAZIO. So there isn't money; we don't have enough money, right?

Dr. AGWUNOBI. Our plan is to purchase it over the course of the 3 years, and by the end of this year—

Mr. DEFAZIO. If we had more money could we purchase it more quickly? Is the capability there to produce it more quickly?

Dr. AGWUNOBI. I am not sure about the companies in terms of whether they can deliver it all today or tomorrow.

Mr. DEFAZIO. I am thinking back to Cipro. Worldwide panic, anthrax, a few countries said hey, we don't care about the WTO and the patent rights, we are just going to produce it. After a while the company said okay, all right, we will license the production. I am wondering if we are looking at a similar thing here.

Dr. AGWUNOBI. I think appropriations is the key limitation at the moment. We are getting everything we can buy. 26 million courses by the end of this year, our goal being to provide for 25 percent of the population; 81 million courses.

Mr. DEFAZIO. That is good. How about something very simple like surgical masks? My understanding is that the French have 200 million on order, we have 100 million on order and they have one-fifth our population and we recently saw guidelines you shouldn't reuse them. A hundred million isn't going to go too far. I assume that has a prophylactic effect, both putting it on the affected person or healthy wearing it to avoid the infection.

Dr. AGWUNOBI. I am not sure what the French are stockpiling.

Mr. DEFAZIO. Let's go to are surgical masks useful?

Dr. AGWUNOBI. Some are.

Mr. DEFAZIO. M–95s.

Dr. AGWUNOBI. As opposed to surgical masks. Surgical masks can be useful in certain circumstances. There isn't an awful lot of science on whether or not what their use—how you might optimally use them in a pandemic because we don't have that science available.

Mr. DEFAZIO. Would it be prudent to have perhaps a few for every American? Looking toward a million as opposed to hundred million.

Dr. AGWUNOBI. A pandemic lasts anywhere from 12 to 16 months with waves that might be 6 weeks long sweeping through communities. I think it would be impractical to have every citizen maintain a stack of 5 M–95 mask. These require specialized fitting techniques.

Mr. DEFAZIO. You can buy them on line for less than a buck each or buy the ones that you can breathe more easily through for a little bit more, over $2.30 each. I realize you may be concerned about how I fit myself or other people but I think the American people might want—if they have to go to work, if they are running a nuclear plant and make sure they are there, they would want some protection in addition to the hand washing and the other things. Don't you think it would be prudent to have masks?

Dr. AGWUNOBI. We are not sure that science supports surgical mask use by the general population.

Mr. DEFAZIO. We should forget about them. Tell people to go out and breathe, right? Don't put them on.

Dr. AGWUNOBI. We have the tried and true public health interventions.

Mr. DEFAZIO. I sit next to people on airplanes. My doctor wears a mask on the airplane. He is recommending I should too because he is tired of people getting sick on the plane, people snorting on you. It would be kind of good to have some protection at that point, wouldn't it?

Dr. AGWUNOBI. The question is does the mask protect them at all.

Mr. DEFAZIO. My doctor thinks it does. I guess you don't.

Just back to the—this is a pretty basic thing. I hear over here HHS is in charge, it is an incidence of national significance—I mean DHS. Over here, HHS is in charge, it is a health emergency. I am just concerned that we saw this kind of interplay and problem with Katrina and FEMA within DHS and the gentleman wanting to call the White House. I am concerned here. Have you guys really worked this all out?

Dr. AGWUNOBI. Yes, sir.

Mr. DEFAZIO. How is it going to work? Who are you in charge of and what are you in charge of?

Dr. AGWUNOBI. In a pandemic I think it is critical that we restate the fact it is not just about health and medical. They are clear, we all know what they are, the need for surge capacity and the numbers of individuals who might be ill. But in a pandemic there is so much more; it is about maintaining our society, our businesses, it is about educating our children, conducting our lives through the course of 18 months.

The Department of Health and Human Services is very clearly responsible for the public health, the health and the medical aspects of the response to a pandemic, while our colleagues Dr. Runge and others in the Department of Homeland Security will handle the maintaining of society.

Mr. DEFAZIO. Civil order, logistics, National Guard.

Dr. AGWUNOBI. I will let my colleague go into those details.

Mr. DEFAZIO. Is that correct?

Dr. RUNGE. Particularly the maintenance of critical infrastructures of maintaining of civil order, of coordinating the various Federal responses to this that are needed by many, many departments, not just the two of ours.

Mr. DEFAZIO. Thank you. Thank you, Mr. Chairman. My time has expired.

Mr. LINDER. The gentleman from Connecticut is recognized.

Mr. SIMMONS. Thank you, Mr. Chairman.

For any members of the panels, we have talked a lot about vaccines and vaccinations, and the testimony shows that there are plans to stockpile vaccines. Vaccines are usually administered with needles, I believe. How is our stockpile of needles?

Dr. AGWUNOBI. We are stockpiling, in addition to countermeasures, anti-virals and vaccines, the resources needed to administer them, including gloves, swabs, syringes and needles. Clearly that is an important part. We recognize that is important.

Mr. SIMMONS. The reason I ask is because a needle manufacturer in my State, not my district but in my State, has manufactured needles for vaccinations for the civilian population of France, but the orders from the United States Government have been a fraction of that amount, and so that is why I raise the issue.

Dr. AGWUNOBI. We currently are stockpiling vaccine, H5N1, for example, in bulk. It needs to go through certain final tests before we package it into smaller vials and therefore acquire the syringes and the needles necessary to administer it.

Our stockpile, however, today, where it does contain countermeasures that require needles and syringes, those needles and syringes alongside these push packs that are in the strategic national stockpile contain all that is necessary to get the countermeasure into the arm of the citizen.

Mr. SIMMONS. Thank you very much. My second question is to Secretary Verga. Thank you for your service to your country. Welcome home. And thank you for your continued service in this capacity.

You mention in your testimony on page 6 that one of the critical tasks identified by the Department of Defense is to provide surge medical capability to assist civilian authorities. I assume that would be through military hospitals, military personnel. In identifying those surge capabilities do you reach out to and include the facilities of the Veterans Administration?

Mr. VERGA. We in DOD don't but the Veterans Administration is part of what is called the National Disaster Medical System, of which DOD is a participant along with the Public Health Service, and that is also included. So the Veterans Administration is included.

Mr. SIMMONS. How would you evaluate the cooperation of the Veterans Administration with you as you engage in this reaching out?

Mr. VERGA. Very good. My experience in working with the Veterans Administration on all sorts of emergency planning aspects, not just pandemic influenza but the medical aspects of any emergency has been very good.

Mr. SIMMONS. Over the last year and a half or 2 years the VA has implemented the CARES program, which is a program to realign VA facilities. There has been a focus on community-based outpatient clinics and less focus on beds in traditional hospital environments.

Has any effort been made to identify those beds for purposes of surge capability?

Mr. VERGA. Sir, I am just not familiar with that. I would be happy to go back and try to get you an answer. I just don't know.

Mr. SIMMONS. Over the last year and a half or 2 years, the VA has implemented the CARES program, which is a program to realign VA facilities. There has been a focus on community-based outpatient clinics and less focus on beds in traditional hospital environments. Has any effort been made to identify those beds for purposes of surge capability?

Mr. VEGA. CARES (Capital Asset Realignment for Enhanced Services) plans are developed by individual Veterans Affairs Medical Centers and Veteran's Integrated Service Networks (VISNs) and use of surge capacity is one of the factors considered as part of the overall process for developing the CARES plan.

For example, during the response to Hurricane Katrina, the Veterans Administration established and staffed 2 Federal Medical Shelters provided by the Department of Health and Human Services for housing evacuees from both Hurricanes Rita and Katrina at the Waco and Marlin VA Medical Centers. These vacant buildings were mothballed under CARES and were able to be reactivated.

Also during the response to Hurricane Katrina, the Veterans Administration developed an inventory of vacant spaces created as a result of CARES or other reasons

that could be activated with some work to be used for surge capacity for shelters as well as beds.

Mr. SIMMONS. Thank you, Mr. Chairman. I yield back.

Mr. LINDER. Dr. Christensen, do you wish to inquire further?

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I would like to ask Dr. Agwunobi and perhaps Dr. Runge also to respond. We spent a lot of time in the committee on BioShield and authorized a great deal of funds to spur the development of countermeasures, and I am not really seeing this project being utilized to its fullest extent. But I have also introduced in this Congress and the one before the Rapid Cures Act. This bill would fund basic research on shortening the time, as we call it, from bug to drug, including vaccines.

Are we focusing enough on that particular area, shortening that time, since we can't predict even how this particular virus will look like if and when it begins to be transmitted from human to human, and do you think the Department has enough authority to do what is needed or does it require more like our legislation would provide?

Dr. AGWUNOBI. The $1 billion that was recently announced as being invested in five companies to develop and further their ability to produce cell-based vaccine technology, one of its ultimate goals is to try and shorten that process. We have five companies from around the world. The commitment is to build the technology, develop plans—

Mrs. CHRISTENSEN. Just focusing on one cell right now.

Dr. AGWUNOBI. Our strategy also involves investing in other technologies, not just about diversifying the number of ways we can get to a vaccine, it is about trying to find and improve the speed it will take for us to get there.

Mrs. CHRISTENSEN. You agree that it is really—that is where we need to be focusing. BioShield will take us from—if you have a countermeasure to manufacturing in large amounts, but we can't even get to shortening the time to get there. We don't have time. Six months is not a time that is available to us right now.

So you agree that we really need to put a lot more focus on shortening that.

Dr. AGWUNOBI. The process isn't just about industry though. If you think about it, it is about identifying the virus, getting a sample, bringing it into the system, studying that sample, developing a pilot vaccine, getting that into the industry, getting it approved and tested so we know it is safe for human beings.

So there is some process that has to go into this, but we have to get that as short as we can. We are trying to advance late stage R&D, and I think in this current budget request there is a request for an additional 160 million to find ways to shorten the process.

Mrs. CHRISTENSEN. I would ask this of all of the panelists. In studying the economic impacts of SARS and other past pandemics, economists have said that the most important factor attributing to the losses suffered were, quote, the behavior of consumers and investors. We will also depend on the citizenry to follow instructions now and should we have a pandemic.

The IOM did a survey of regular citizens and whether they would be likely to follow instructions; in this case it was a terrorist attack. I think it was up to two-thirds said no. Another IOM report on what we have learned from SARS says that research designed to identify why societies respond dramatically and irrationally to certain types of public health threats might help communicators develop messages and positively influence the public's behavior. This is really important. How much research is being done on that?

Dr. AGWUNOBI. I can't give you a measure of how much research is being done on this subject because I don't see into every university, but I do know social scientists and risk communicators recognize this is an important part of the challenge.

In the Department of Health we are investing heavily into trying to not only prepare ourselves and to work with our Federal agencies but urging State and local entities as well, the people who will be first on the scene, first on the stage, so to speak, to take the time to learn about what it takes to accurately and efficiently develop risk communication strategies and to develop—deliver those messages.

I think when all is said and done it is going to be about educating, sharing with the public the challenge, and making sure that on that day the leaders that do represent what we are doing and why we are doing it and what we need the public to do, making sure those leaders are the most trusted leaders for that particular community, meaning local leadership, will be key.

Mrs. CHRISTENSEN. Dr. Runge, did you want to answer either one of those questions?

Dr. RUNGE. I would add to what Dr. Agwunobi just said. Dr. Christensen, I am sure you are aware more than most people in this room how difficult it is to communicate a public health message and have it internalized. HHS, we are working on messages, message mapping, actually, since last August or September on this subject and they clearly have a way forward with doing this. Much of this information is on pandemicflu.gov.

There is no question we need to do more in communicating with our citizens as to what the real threats are. There is no prevention for irrational behavior better than good education.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. LINDER. The gentleman from North Carolina, do you wish to inquire further?

Mr. ETHERIDGE. I do. Thank you, Mr. Chairman.

Dr. Agwunobi, a few minutes ago you said there was over a billion dollars that had not been drawn down.

Dr. AGWUNOBI. Approximately, sir.

Mr. ETHERIDGE. Approximately. But here you are talking about HRSA and CDC grants because only 350 million has been appropriated for pandemic flu. Can you be more specific about what funding stream you are talking about?

Dr. AGWUNOBI. If I may, let me clarify. Since 2001 the Federal Government has been investing in State and local public health preparedness, getting the public health infrastructure to the point that it can respond to public health emergencies, all hazard-type emergencies. That funding has been about $6.7 billion since 2001,

of which approximately a billion dollars has yet to be drawn down by the States.

In actual fact, in this latest budget request that the administration has brought forward, we have an additional $1.3 billion that we propose to invest in public health preparedness, including surge capacity in hospitals, public health response to emergencies. This is before the investment in pandemic influenza preparedness, the $7.1 billion, of which 350 is focused on exercising and the development of plans such as distribution plans, the spreading of plans down into communities.

Mr. ETHERIDGE. Part of the recognition was that the public health infrastructure across this country was in horrible shape was a reason a lot of this money was put in place; I think that is correct, is it not?

Dr. AGWUNOBI. I recognize that that was probably one of the reasons Congress decided to invest in the public health infrastructure of our Nation.

Mr. ETHERIDGE. Yes. Can you also tell us how much of the 350 million allocated to the States has been drawn down thus far?

Dr. AGWUNOBI. We have actually distributed a hundred million already. I am not sure it has been actually spent. They are working on it. The remaining 250 million will come out later, I think within the next few months, with detailed guidance on what we are expecting the plans and the exercises to do for each State, what we are expecting them to be left with when they are done.

Mr. ETHERIDGE. Any one of you or all can respond to this because this is a challenge we face when we talk about getting information to the public and them believing it. Two years ago when we had a shortage in the regular flu vaccine and the President had to go on TV and say well, we don't have enough so those of you who are healthy just don't take the flu shot, and here we are talking about a pandemic that is very serious, can have catastrophic affects if it happens.

The point is how do we make the public believe us when we can't be prepared for the regular flu and we say to folks well, just don't take a shot, those of you that are healthy, do the best you can.

Dr. AGWUNOBI. This conversation and the many others like it that are happening around the Nation, both at the State and locals level, are an essential part of that dialogue. We are one of the first generations this planet has ever seen that has the ability to stand before a pandemic occurs in preparation for it, and it allows us the opportunity to have these discussions and to better educate the public as to the realities of pandemic preparedness and what it takes to be prepared.

And so I think, as my colleague Dr. Runge just stated, a better educated public is a public far more likely to respond appropriately to the threat when it occurs.

Dr. RUNGE. If I could also add to that, Congressman Etheridge. I have been talking a lot when we talk about flu preparation about collateral benefits, and I think that bolting together the public health community and the homeland security community in every State really puts us in a much better position to handle any sort of biological threat.

In this case this vaccine technology is as much about seasonal flu as anything else. If we do this right, if we gear up our vaccine manufacturers, if we invest in industry, if we get cell-based or DNA-based vaccines into industrial production and have universal vaccine every year for seasonal flu, we will save 30,000 lives a year.

To me, this is Y2K, that is fine; I had a brand new computer on my desk January 1st of 2000. What we are interested in here is the collateral benefits that this brings with us.

Mr. ETHERIDGE. Do I take that to be an indication there will be an adequate amount of flu vaccine this winter?

Dr. AGWUNOBI. Sir, this notion of the ability to deliver 300 million vaccines within 6 months is a strategy that inherently provides us with the guarantee down the road—perhaps guarantee is a little strong given in—

Mr. ETHERIDGE. How far down the road? When people talk about the flu—

Dr. AGWUNOBI. Our 3 to 5-year strategy is that we would have the capacity to not only address a pandemic but therefore to address the seasonal flu needs of our States.

One last point on that. The issue is not just vaccine manufacturing and stockpiling, whether it be for seasonal or pandemic, it is also about distribution. Ours is a plan today, this work we are doing with States, that would improve that aspect of the seasonal flu dilemma as well.

Mr. ETHERIDGE. Thank you, Mr. Chairman. I want to say for the last couple of years it hasn't been distribution, it has been supply.

Dr. AGWUNOBI. A little of both, perhaps.

Mr. LINDER. Thank you.

Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman. I regret I couldn't be here for all the testimony. I have a very special interest here. My district, your Nation's Capitol, suffered the worst of the anthrax biological attack and frankly I have in mind what could happen; that Members could be here, the entire Federal presence, certainly the Cabinet agencies are here, and somehow the word could come that something had been spotted and everybody should stay where they are and I could understand that.

I for one don't expect the government to have an instant answer here and indeed some people have speculated that this isn't going to happen at all and this is all much ado about nothing. They have gotten us all excited. I think you certainly have got to respond as if this were going to happen tomorrow.

This is my concern, and perhaps I have not gotten the information, but as I understand it, particularly with the minimal number of doses of anti-viral and of vaccine, of Tamiflu and the like, some kind of decision is going to have to be made about who gets what, particularly in a district like this.

Now I have always thought you always give it to the people who are the first responders, but that apparently is not necessarily the case here. I have been very confused by reports. One report said the notion that the old and the infirm and the disabled should get medicine first perhaps should not apply here, maybe that the young should get them.

But my understanding is that there has been no recommendation from the government concerning that matter. Is that true? Have you nothing to advise us about who should get what in case the word comes that we do have the virus in some form in this country?

Dr. AGWUNOBI. A prominent advisory panel, ACIP, has issued guidelines. They issued them last year, and they are actually written in the HHS plan that was originally—

Ms. NORTON. That is an advisory panel of who?

Dr. AGWUNOBI. Advises the Centers for Disease Control, the Immunization Practice Advisory Council, and they provided guidance that was placed in the HHS plan back in October.

One of the importance things that I think we need to talk about as we talk about this is the fact that seasonal flu, the seasonal flu virus, as you know, goes after the elderly and the frail, the infirm and the very young. They are its primary target in terms of its ability to hurt our citizens.

The 1918 pandemic, on the other hand, that virus went after the young, strong, healthy individuals in our community.

The point that I am trying to make is that until we see the pandemic virus itself, we won't know specifically which groups are most at risk. Now on top of that there is a growing body of—I don't know if it has a body of science, but there is recent modeling that seems to indicate that there might be a number of different strategies for addressing a pandemic.

Ms. NORTON. If I could just pause, the 1918—the notion that it went after the young and the healthy and the strong at a time when there were 12-hour working days and the people were out there associating with one another is one thing. People died earlier. I am not sure I would be instructed by that to in fact conclude that it did not go after the elderly.

Dr. AGWUNOBI. We really don't have a lot of evidence as to where this is going to go. We know H5N1 today in the human beings it has affected seems to have a predilection for the young and for younger members of a family. The question is, is that inherent with the virus or something to do with the way they interact with lifestyle?

The bottom line is there is a debate right now that we are encouraging around the Nation both in scientific circles and the community as we try to get a sense of what are the priorities that this community values, our Nation values, what is science really telling us about this.

I will end by saying that the scientific bottom line on this isn't in yet.

Ms. NORTON. Understanding that, does the government, given the state of knowledge, have any advice for the States and localities who certainly don't have as much as you do about who should get the anti-viral first, who should get the vaccine first, even understanding you don't have anything like perfect knowledge? Are really people supposed to guess at the local level on their own? What is your advice to local jurisdictions?

Dr. AGWUNOBI. Our health and human services plan contains guidance. We are urging each local jurisdiction as they develop

their plan to start with that guidance but to have a conversation in their community.

Ms. NORTON. I am trying to find out what that guidance is in general terms.

Dr. AGWUNOBI. I will be sure to on the record submit it to you. It is fairly detailed and it lays out a number of different categories, including first responders and the elderly and the like, and I will be sure to submit to you a copy.

Ms. NORTON. I wish you would because the press says you all have no recommendations of the kind you ordinarily give concerning who should get it. So everybody thinks that the people who have to administer to the sick should always get it.

Dr. AGWUNOBI. That guidance is available on *www.pandemicflu.gov*. It is readily available. We are urging people not to stop there. We are urging people to have a conversation both at the science level and in the communities at what the priority should be.

Ms. NORTON. I take that to mean that you don't—if people are having a conversation, it is one thing to have a conversation and to say you may change these priorities, because they really may differ. It is another thing not to have any recommendations at all from the Federal Government.

Mr. LINDER. Will the gentlelady yield?

Ms. NORTON. Yes, sir.

Mr. LINDER. This week's Science Magazine on page 855: Priorities for distribution of influenza vaccine.

We will get you a copy of that.

Ms. NORTON. Okay. All right. Well, I would think that one of the things we ought to do since some of the press is running that you don't have any recommendations, and I think you are doing the right thing to say to local jurisdictions make sure you have your own plan. Really, given the limited amount of anti-viral vaccine that is there, we really do need to tell people in advance that while your local jurisdiction may differ, and here my colleague is just giving me something here that says health care workers with direct patient contact and so forth, so we don't have people calling our offices to say how come I am not getting it, I am pregnant. If they know the Federal Government has advised this or it can be change in your local jurisdiction, then at least people understand because they trust the Federal Government to somehow have looked at all the possibilities, all of the options to come to this conclusion.

Mr. DICKS. They will call our offices, no matter what.

Ms. NORTON. I would like to minimize those in the District of Columbia at the very least. Thank you very much, Mr. Chairman.

Mr. LINDER. Thank you. I want to thank the witnesses for their testimony today and the members for their questions. Members may have additional questions, and we would ask you to respond to these in writing. The hearing record will be held open for 10 days.

Without objection, the committee stands adjourned.

[Whereupon, at 3:55 p.m., the committee was adjourned.]

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