VA'S FLU VACCINATION PROGRAM

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

DECEMBER 15, 2005

Printed for the use of the Committee on Veterans' Affairs

Serial No. 109-29

25-176.PDF

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 2006

For sale by the Superintendent of Documents, U.S. Government Printing Office
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Fax: (202) 512-2250 Mail: Stop SSOP, Washington, DC 20402-0001

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VA'S FLU VACCINATION PROGRAM

THURSDAY, DECEMBER 15, 2005

U.S. House of Representatives,
Subcommittee on Oversight and Investigations,
Committee on Veterans' Affairs,
Washington, D.C.

The Subcommittee met, pursuant to notice, at 10:05 a.m., in room 334 Cannon House Office Building, Hon. Michael Bilirakis [Chairman of the Subcommittee] presiding.

Present: Representatives Bilirakis, Boozman, and Strickland.

Mr. Bilirakis. The hearing will come to order. Good morning. Today's hearing will provide the Subcommittee an opportunity to learn more about the Department of Veterans Affairs (VA) influenza vaccination program.

Since the National Response Plan, published by the Department of Homeland Security, is a blueprint for the coordinated efforts of Federal agencies during disasters, the Subcommittee had also intended to hear testimony regarding interagency collaboration, and I underline that for emphasis, interagency collaboration or lack thereof, between VA, the Department of Defense (DoD), the Department of Health and Human Services (HHS), and the Department of Homeland Security, with regards to potential outbreak of a pandemic flu.

Unfortunately, it is a busy time of the year, and the Department of Homeland Security's key witness regarding a potential flu pandemic is on travel. I learned yesterday morning that DoD was also unable to send a witness to discuss their role in a possible flu pandemic.

The Subcommittee had also requested testimony from the Surgeon General. However, according to HHS, the Surgeon General is not involved in the planning and preparation for a flu pandemic, which I find puzzling since the Surgeon General's duties, I believe, would require him to mobilize, deploy and exert leadership and oversight of the Commission Corps in the event of a pandemic.

I would also expect that the Surgeon General's office would be the lead in any national public health education campaign. The Subcom-

mittee will continue to explore this issue.

I do have, as you might imagine, serious concerns regarding the level of interagency collaboration and coordination between Federal departments in their ability to adequately respond to a flu pandemic.

The need for interagency collaboration and coordination on this issue is a matter that I will be recommending the Committee pursue in a second session of this Congress. Full Committee Chairman Buyer and I serve on the Energy and Commerce Committee, which has jurisdiction over public health issues.

Given the cross jurisdiction issues, I'm sure that we will be working with our colleagues and the Energy and Commerce Committee on this important matter.

As we are all aware, influenza is highly contagious, spreading through direct contact and aerosol exposure. The virus can also persist for several hours on inanimate objects, such as toys or doorknobs. In addition influenza is infectious before symptoms appear in its victims which enhances the virus's ability to spread.

While the virus is usually non-lethal in healthy individuals, it can cause severe medical complications in a hospital environment, especially in an in-patient setting. The complications can severely degrade a sick individual's medical condition and in some cases, cause death. Since VA provides care to millions of older veterans who are considered high risk, this certainly is a serious concern.

Over the past several years, there has been widespread discussion in preparation for a potential flu pandemic. As numerous health officials have previously stated, an influenza pandemic is likely at some point in time. My Energy and Commerce Health Committee devoted an entire hearing to this subject some time ago -- historical records suggest that influenza pandemics have occurred periodically for at least four centuries.

In the 20th Century alone, there have been three influenza pandemics. The 1918 Spanish flu pandemic killed between 20 and 100 million people worldwide and at least 500,000 in the United States. The 1957 Asian flu pandemic killed about 69,800 people in the United States. The 1968 Hong Kong flu killed about 33,800 people in the United States.

In 1997, the H5N1 avian flu emerged in Hong Kong and reemerged in 2003, this virus has caused the greatest concern for the potential of a flu pandemic.

According to the VA, which as I understand it, has very good story to tell and I am proud to say, influenza prevention is a public health priority for the Department.

On an annual basis, the VA Undersecretary for Health issues a VHA directive that provides policy and implementation guidance in the use of influenza vaccine. The VHA flu directive and VA's flu vac-

cination coincides with the national vaccination campaign.

We are anxious to learn more about VA's annual flu immunization program. As I have said earlier, it is my understanding that the department has been extremely proactive in its efforts to educate and administer a highly successful preventative health campaign, and, again, I commend them for that.

I would now like to recognize Ranking Member Mr. Strickland from Ohio. Mr. Strickland.

MR. STRICKLAND. Thank you, Mr. Chairman, for holding this hearing. We are all interested in knowing how the Department of Veterans Affairs handles what some may think of as routine and reoccurring function by hearing testimony on VA's annual flu vaccination program.

We are also interested in testimony regarding the threat of emerging or reoccurring infectious diseases, and the VA's preparedness to meet such threats, especially the avian flu threat.

To call VA's annual flu program routine really does not alert one to the seriousness of the potential threat; and, I think we all realize that. For example, as has been mentioned, the 1918 influenza pandemic, also called the Spanish Flu, killed between 20 and 40 million people worldwide in a one-year period of time.

This flu was easily transmitted from person-to-person and had a mortality rate of 2.5 percent, much higher than other influenzas of the day and was particularly deadly for the age group, those between 20 and 40 years of age. This age group is a different group from those usually impacted severely by other strains of influenza.

In fact this particular strain of the flu is considered so virulent that the U.S. Department of Health and Human Services has published an interim final rule to add some reconstructed replication competent forms of the 1918 pandemic influenza virus to the list of HHS select agents and toxins.

The HHS select list contains biological agents or toxins that could pose a severe threat to public health and safety, to animal and plant health, or animal or plant products. It affects their possession use and transportation.

A review of the HHS list finds other select agents, mostly viruses, which will kill humans quickly in horrible and effective ways. Variants of the 1918 Spanish influenza have now joined the ranks of Ebola, Lassa Fever, Marburg, Crimean-Congo and South American Hemorrhagic Fever and the Rift Valley Fever virus.

Considering the company that at least one strain of the flu now keeps, we certainly can't think of influenza and our efforts to combat it as routine.

Now today we will hear how the VA administers its annual influenza vaccination program. We will hear about the program's problems and successes. We will also hear about resources and methodology

for assuring that the flu vaccine need is met.

We remember the vaccine shortages of last year, something we do not want to repeat nationally or VA-wide for the upcoming flu season. We hope to also hear about the surveillance and control problems for infectious diseases that are used by VA.

Finally, I anticipate we may hear testimony regarding the possible avian flu pandemic. The threat is a real threat that we hope we do not have to face unprepared. I'm interested in how the experts today rank the threat of H5N1 strain of the avian flu. Some experts see similarities between this strain of the avian flu and the Spanish Flu of 1918.

We know that viruses do mutate, so the question becomes, is the H5N1 strain of avian influenza a significant threat today as compared with other infectious diseases and will future mutations likely make it more or less of a threat to humans?

Our panel of witnesses today contains several distinguished VA experts on infectious diseases and we thank you for being here. Unfortunately, other invited guests were unable to be with us from HHS and DoD. I am sure that they would have provided the perspective of their respective agencies on this general problem had they been here. Perhaps there will be a hearing in the future, Mr. Chairman, when we can invite them to testify before us.

To reduce the threat of dangerous viruses, we may isolate, we may vaccinate or treat the problem. We have sometimes, as a nation and as a healthcare community, taken special steps to vaccinate against emerging strains of what was considered a viral agent.

For example, in 1976, the U.S. implemented a massive program to vaccinate the nation against the swine flu. The decision to begin the swine flu vaccination program is still questioned from many viewpoints, but the target strain of the swine flu never reappeared after the first case that was found at Fort Dix, New Jersey.

But this fact alone does not invalidate the 1976 decision to implement that national vaccination program for swine flu.

So I anticipate the VA and this nation's healthcare community will keep one eye firmly fixed on the avian flu, and the other eye scanning the horizon for newly emerging strains or other communicable and deadly agents.

We must strike a balance of anticipation for what is the known threat and the anticipation of threats that are not known or anticipated.

Where national security and the welfare of this nation's citizens are at stake, we must not let our general and broad-based preparedness lapse because we anticipate a single threat vector.

Mr. Chairman, I thank you once again for this hearing, and I thank the witnesses for being here, and I look forward to hearing what they have to share with us.

MR. BILIRAKIS. Would the gentleman from Arkansas have an opening statement?

MR. BOOZMAN. No, I don't. I just appreciate you and the Ranking Member having this hearing at this time. It certainly is a topic that is so important and really look forward to the testimony. I thank you, sir, and I thank you for making the hearing this morning.

MR. BILIRAKIS. So at this time, I would like to recognize our first and only panel. Dr. Lawrence Deyton is Chief Consultant, Public Health, Strategic Health Care Group of the U.S. Department of Veterans Affairs. Dr. Deyton will be accompanied by Victoria Davey, Deputy Chief Consultant, Public Strategic Health Care Group, the U.S. Department of Veterans Affairs.

Dr. Robert Muder is the staff physician hospital epidemiologist with the Veterans Affairs of Pittsburgh Health Care System, and Dr. Denise Cardo is director of the Division of Health Care Quality Promotion with the Centers for Disease Control and Prevention (CDC), of HHS.

Thank you so very much for taking time to come here and extending us the courtesy of meeting our invitation, and I say invitation, we use these terms a little loosely, and it is a very soft term.

But I am always concerned that you are all busy people, as are those who could not be here with us today, and I am always concerned that we have given them adequate notice, because plans are made well in advance sometimes. But once we're satisfied that we have given adequate notice, then it is more than just a invitation, and it should be that way.

Your written testimony will be made part of the record. I would ask you to limit your testimony to five minutes if you could, or as close to it as you can, and I would now recognize Dr. Deyton, I suppose will be first. Yes. Dr. Deyton, please proceed.

STATEMENTS OF DR. LAWRENCE DEYTON, MSPH, M.D., CHIEF CONSULTANT, PUBLIC HEALTH, STRATEGIC HEALTH CARE GROUP, U.S. DEPARTMENT OF VETERANS AFFAIRS AND VICTORIA DAVEY, RN, MPH, DEPUTY CHIEF CONSULTANT, PUBLIC STRATEGY HEALTH CARE GROUP, U.S. DEPARTMENT OF VETERANS AFFAIRS

DR. DEYTON. Thank you very much, Mr. Chairman.

MR. BILIRAKIS. Is that mike on? It doesn't look like it is.

DR. DEYTON. Now it is.

MR. BILIRAKIS. Okay. Now it is.

DR. DEYTON. Thank you very much, sir. Mr. Chairman, members of the Committee, we do sincerely appreciate the opportunity to be here today to discuss VA activities related to both the seasonal influenza as well as the pandemic influenza, other infectious disease is-

sues confronting the VA and particularly glad that Dr. Cardo is with us. We work very closely with the CDC and other agencies and look forward to discussing that with you.

Mr. Chairman, influenza vaccination is one of the VA's highest priorities in public health. We have established an annual program to promote influenza vaccination that, frankly, Mr. Chairman, is unequaled in effectiveness by any other integrated health care system.

The annual VA seasonal influenza vaccination campaign is composed of five interrelated system-wide activities that I will very briefly review. First, as you are already said, the Undersecretary for Health issues an influenza vaccination directive to the entire VA health care system that requires our health care facility directors to implement an annual active influenza vaccination program for both patients and staff.

Second, each year the VA launches a systemwide influenza vaccine campaign and distributes an influenza vaccine tool kit to each VA facility with resources to help those facilities organize, promote and carry out their local vaccination programs.

Third is VA's timely purchase and distribution of influenza vaccine itself. VA solicits bids for our vaccine supply every January and distributes that supply each fall and winter. Over the past eight years, VA has steadily increased the amount of influenza vaccine purchased by slightly less than a million doses back in 1998, and an estimated 2.4 million doses for this influenza season at a cost of approximately $18.5 million.

Fourth, VA provides ongoing guidance to front-line health-care staff during each influenza season. Last year the Undersecretary for Health issued seven separate advisories to our front-line staff between October and February, mostly to deal with the issues related with the shortage that you have already referred to, Mr. Chairman. Already this year, we have issued three advisories to the field.

VA's fifth activity, which is key to the success of our influenza vaccination program is that we hold our health-care managers accountable through a VA-wide performance measure on influenza vaccination.

The results of our approach to influenza vaccination are better than any other health care organization for which there are data. By our chart review program, VA-wide influenza vaccination rate for veterans age 50 or older, was 75 percent in 2003 season and 75 percent again last year, despite the shortages last year.

By a phone survey that we performed, 88 percent of veterans report that they have been vaccinated for influenza.

In contrast the CDC phone survey report of adults over the age of 65, and that is a high risk group, much more likely to be vaccinated than those over the age of 50, the CDC survey showed only 68 percent of average citizens were vaccinated in 2003, and 63 percent in 2004.

MR. BILIRAKIS. Is that 88 percent or 85 percent, whatever the figure, is that of all veterans or just those that are qualified for treatment at the VA centers, in other words on the list?

DR. DEYTON. The 88 percent is of veterans who are eligible for VA care who are over the age of 64.

MR. BILIRAKIS. Okay.

DR. DEYTON. So the highest risk group that we know that we want to make sure and get vaccinated, because they are at higher risk of complication.

MR. BILIRAKIS. Thank you.

DR. DEYTON. A survey of the Medicare population, sir, again, over the age of 65, but Medicare population has the advantage of having influenza vaccine covered under Medicare. That survey showed a rate that was nearly identical to the VA rate for those over the age of 50.

CDC has also shown that commercial insurance plan influenza vaccination rates for ages 50 to 64 were also only 52 percent in 2003, and it dropped to 28 percent in 2004. Again, that is year, last year, when we had the shortage.

So we are proud of the success that VA has had in the seasonal influenza vaccination program. But we constantly are seeking ways to improve it, such as putting emphasis this year on vaccination health care facility staff to make sure they stay healthy and that they don't transmit influenza to their patients.

VA also strongly supports the President's proposal currently being considered to create capacity for annual influenza vaccination for every man, woman, and child in this country.

Mr. Chairman, let me now turn to pandemic influenza.

We don't know when or where pandemic influenza will strike, but based on its history that you reviewed for us, we believe that it will, and because the VA health care facilities are located in all states and nearly every community in the nation, we liken VA to a fine-meshed sieve when it comes to infectious disease and public health threats to our nation. If it happens anywhere in the nation, veterans will be affected and VA facilities will need to be read to respond.

VA's pandemic influenza preparedness program is compromised of eight interrelated activities. First, VA's pandemic influenza preparedness is being built on the foundation of our successful seasonal influenza vaccination program which I just described.

Second, VA has established a stockpile of the anti-viral drug oseltamivir, or Tamiflu, which may be the only effective human drug against the current strain of influenza that is causing disease in birds and sporadically in humans in Asia.

Last fall, the VA stockpiled 5.5 million capsules of this drug oseltamivir for pandemic emergencies which will be distributed only if and when a pandemic might occur.

Third, Mr. Chairman, there is a worldwide shortage of this drug, oseltamivir, and VA researchers have initiated a study that may help us extend the effective supply of that drug by co-administration with a drug called probenicid. That is a drug that can slow the elimination of other drugs from the body.

Positive study results could have a significant impact on the VA supply as well as the nation's supply of the drug oseltamivir.

Fourth, we developed and distributed a Respiratory Infectious Disease Emergency Plan for VA facilities. Based on our experiences with preparation for other recent infectious disease challenges, including Anthrax in 2001, the smallpox vaccination program several years ago, SARS, the influenza vaccine shortages from last years, and now the specter of pandemic influenza.

This plan is a resource for VA front-line providers and administrators for preparations, planning and responses needed to assure continued patient care, communication, staffing and facility operations.

Fifth, VA has been a full participant, Mr. Chairman, in U.S. Government-wide pandemic influenza planning efforts led by the White House and led by the Department of Health and Human Services.

VA also is helping to develop the national pandemic influenza plan being coordinated by the White House from which Federal-agency-specific plans will flow. The national plan is due January 1st of 2006, and the VA plan which is well along in development is due February 1st.

Sixth, because even the best plans need to be tested, we will conduct an operational tabletop exercise on pandemic influenza to test the VA plan, and as we would in a pandemic, also test coordination and communication among VA, state and local health officials, and our other Federal agency partners that will need to respond.

Seventh, by smart use of the VA's national electronic medical record system, we hope to provide realtime surveillance in reporting of illness suggestive of influenza if a pandemic looms. The President's budget request on pandemic influenza preparedness, now pending before Congress included resources to allow the VA to do realtime reporting of influenza syndromic activity directly to the centers for disease control, as part of a system already being built to improve VA surveillance of health-care-associated infections.

Finally, Mr. Chairman, we have developed and we actively promote a national education campaign called "Infection, Don't Pass It On," to engage VA staff, VA patients and visitors to any of our medical centers around the country in preventing transmission of infection because even in the absence of an affective vaccine or supplies of antiviral medicines, there is something each of us can do to limit the impact of a pandemic influenza.

Common sense approaches that our mothers and grandmothers all taught us really do work. Wash your hands frequently. Cover your

coughs and sneezes. If you are sick, stay at home so you don't infect other people.

This campaign, "Infection: Don't Pass It On," uses over a hundred educational posters and other materials and is actively promoted across the VA health care system and is used in some local, state and private health care organizations. DoD health care providers use this, and other countries have adopted the VA plan, including Wales and Australia.

Mr. Chairman, around us are some posters from that campaign as an example of the kinds of materials that we have available.

In summary, VA has a successful program for seasonal influenza vaccination and has begun to apply that approach to prepare for a possible pandemic influenza. I assure you, Mr. Chairman, VA will continue to protect our veterans, our employees, and the VA health care system against seasonal influenza and to build strong defense against pandemic influenza as we fully implement the national strategy outlined by the President. VA will be there for veterans who rely on us for their health care.

This concludes my statement. We are happy to answer any questions you have, sir, and, again, thank you very much for this opportunity.

MR. BILIRAKIS. Thank you, Doctor.

[The statement of Dr. Deyton appears on p. 23]

MR. BILIRAKIS. Ms. Davey, is there any brief comments you would like to make at this point, brief, of course, but at the same time you have taken time to be here?

MS. DAVEY. Thank you, no, nothing.

MR. BILIRAKIS. No? All right.

Dr. Muder, you are on, sir.

STATEMENT OF ROBERT MUDER, M.D., STAFF PHYSICIAN, VETERANS' AFFAIRS PITTSBURGH HEALTH CARE SYSTEM, U.S. DEPARTMENT OF VETERANS AFFAIRS

DR. MUDER. Mr. Chairman, members of the Committee, thank you for inviting me here. My invitation came somewhat late, so as your staff know, I did not submit written testimony.

At the VA Pittsburgh Health Care Center, I am the hospital epidemiologist which means I am in charge of preventing infection transmission in our hospital. Under the direction and encouragement of VA central office, we have a multi-faceted approach toward combating influenza in our health care system which consists of three separate campuses.

We have a very aggressive immunization program, directed at getting the vaccine to our veterans. It consists of reminders both by mail

and by telephone. Through the months of October through December, we run a walk-in influenza clinic for our patients. We actively promote receipt of influenza during regular clinic visits, and we have a program to immunize essentially all of our long-term care residents.

In addition we have a very good success in getting our employees immunized. Seventy-five percent of our employees have received the flu vaccine so far this year, including 95 percent of our direct care givers in our long-term care facility.

We also have a program to identify cases of influenza rapidly, both presenting from the community and occurring in an epidemic fashion or long-term care facility. This involves regular communication with our local health department for documentation of influenza activity in our community, rapid influenza antigen testing, and this year, we are going to be able to back that up through a collaboration with the University of Pittsburgh to get rapid molecular confirmation through PCR testing at the University of Pittsburgh virology lab.

We have a plan which we actually have used several times in past years to combat influenza outbreaks in our long-term care facility, which may occur despite near universal immunization, and this involves isolation, exclusion of sick employees, and providing influenza prophylactic drugs to our patients at risk. We have actually done this five times in the 20 years since I have been working at the VA.

In addition to our influenza activities, we have a number of innovative approaches to infection control and the spread of other infectious diseases within the hospital which are really one of the most significant risks that a hospital patient undergoes.

Four years ago, we entered into a collaborative agreement with the Centers for Disease Control and the Pittsburgh Regional Health Care Initiative, which is a group of hospitals, employers and insurers in Western Pennsylvania, to pilot a control program for Methicillin Resistant Staph or MRSA, which has historically been the number one hospital-acquired pathogen in our facility.

This involved bringing industrial engineering processes to bear on solving the problem. It included increasing staph education and awareness of the consequences of MRSA infection, the means of transmission, and the approaches necessary to prevent transmission, and also included removing those barriers to hand hygiene and isolation.

This included identifying patients with surveillance cultures from MRSA on admission, immediately isolating patients, developing a computerized system to notify the wards each day of patients who needed to be in isolation, providing appropriate hand sanitizer, isolation equipment for staph and monitoring their usage.

We initially started this in Fiscal Year 2001, on a general surgical unit. Within two years, we had experienced a 75 percent decrease in MRSA infection on that unit. We then applied this to our surgical intensive care unit, and within one year, had a similar reduction in

the rate of MRSA infection.

Starting this past fall, we initiated a comprehensive MRSA control program throughout our facility which included all units in both the acute and long-term care facility. We are doing surveillance cultures on all patients. We are putting those patients in isolation, providing staff with the training and equipment that they need in order to isolate these patients effectively.

We continue to have the collaboration and support of the CDC and the Pittsburgh Regional Health Care Initiative. In addition our hospital administration has been very, very supportive in addition to actively promoting this. They have actually enlisted our hospital in a community-wide effort, under the auspices of the CDC and the Allegheny County Health Department to make this a regional initiative.

They have also invited the directors of our VISN to Pittsburgh for a meeting in which we presented this program to the directors of our VISN and are continuing to promote this as a potential VISN-wide initiative, and we have had a great increase and a great deal of interest from a number of the hospitals within our VISN, who have contacted us to get additional information in terms of the particulars of the program, the results and the resources necessary to recreate our experience in their hospitals.

Mr. Bilirakis. Thank you very much, Doctor. Dr. Cardo. Is that correct? Did I pronounce that correctly?

Dr. Cardo. Yes, you did.

Mr. Bilirakis. Okay.

STATEMENT OF DENISE CARDO, M.D., DIRECTOR, DIVISION OF HEALTHCARE QUALITY PROMOTION CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. Cardo. Good morning and thank you for the invitation to testify on influenza pandemic planning. CDC and other agencies are working together to prepare the United States for this potential threat to our nation.

In order for an influenza virus to cause a pandemic, it must first be a virus to which there is little or no preexisting immunity in the human population.

Second, the virus must be able to cause illness in humans, and third, have the ability for sustaining person-to-person transmission. So far the H5N1 virus circulating Asia meets the first and two criteria, but not yet the third.

In the current H5N1 outbreaks in Asia since January 2004, 138 human cases have been confirmed by the WHO. These cases have resulted in 71 deaths, a fatality rate of around 50 percent. We cannot

predict the severity and impact of an influenza pandemic, whether from H5N1 virus currently circulating in Asia, in Europe or the emergency of another influenza virus of pandemic potential.

However, modeling studies that a medium-level pandemic could result in 89 to 170,000 death. A more severe pandemic, as happened in 1918, could have a much greater impact.

There are several important points to note about pandemic, about influenza. First, pandemics happen. There were three during the past century. Second, the capacity to intervene and control the spread of the virus, once it gains the ability for sustain person-to-person transmission, will be extremely limited. An outbreak anywhere in the world increases the risk everywhere.

Third, H5N1 avian influenza strain that is circulating in Asia among birds, is currently considered the leading candidate to cause the next pandemic. However, it is possible that another influenza virus which could originate anywhere in the world, could cause the next pandemic.

This uncertainty is one reason we need ongoing laboratory surveillance on influenza viruses that affect humans.

And, fourth, because early detection means having more time to respond, it is critical for the United States to collaborate with domestic and global partners to expand any strength the scope of early warning surveillance activities.

In the United States, the HHS pandemic influenza plan is a blueprint for pandemic influenza preparedness and response and provides guidance to national, state and local policymakers in health departments with the goal of achieving a national state of readiness and quick response.

Among CDC's roles in preparation for a pandemic, we are working to ensure that states have sufficient epidemiologic and laboratory capacity, both to identify new viruses throughout the year and to sustain surveillance during a pandemic.

We are improving our reporting systems so that influenza information needed to make public health decision is available quickly, and we are enhancing monitoring of resistance to current antiviral drugs, to guide policy to their use.

Another aspect of preparedness and one with which I work directly involves the health care system. Health care facilities, including those in the VA, need to be prepared for the potential rapid pace and changing characteristics of a pandemic.

With input from our partners, CDC has developed guidance that provides health care facilities with recommendations for developing plans to respond to an influenza pandemic and guidance on the use of appropriate infection control measures to prevent transmission during patient care. Tabletop exercises have identified gaps and provided recommendations for health care facilities to improve their

readiness to respond.

In conclusion, although much as been accomplished, more preparation is needed for a possible human influenza pandemic. As the President mentioned during the announcement of his national strategy for pandemic influenza, our first line of defense is early detection. CDC is closely monitoring the international situation in collaboration with WHO, current affected countries, and other partners. We are using our extensive networks of partners to enhance pandemic influenza planning.

And, lastly, the national response to the animal domestic influenza seasons provides a core foundation for how the nation will face and address pandemic influenza.

Thank you for the opportunity to share this information with you, and I am happy to answer any questions.

[The statement of Dr. Denise Cardo appears on p. 33]

MR. BILIRAKIS. Thank you, Doctor. I would tell you all at the outset that obviously our time to ask questions of you is limited, but there are many questions that we have of you and many of those will be submitted to you in writing by the staffs. Hopefully you would respond to them in a timely fashion, because we are here, after all, to help you, so to speak, to do the job.

Dr. Deyton, you mentioned a VA research study that might help with antiviral treatment for a pandemic influenza. Will you tell us more about that without using, hopefully, all of my five minutes?

DR. DEYTON. Yes, sir. I think you refer to our study of the combination of the drug oseltamivir with a drug called probenicid. Probenicid is an old drug that has been around a long time, sir, that is actually a generic drug, that we have observed has a property that it slows down the excretion or metabolism of other drugs that I might take.

And so by giving that drug with the drug, oseltamivir, we might effectively stretch the limited supply that we have of that drug. So VA has now initiated that study. It has been approved by the FDA. It has been approved by VA for funding. We expect to start in a few weeks, where we will study the combination of those two drugs to see the blood level of the drug, oseltamivir, and hopefully the results will demonstrate if we can use that drug to effectively extend our nation's supply of oseltamivir which is in a limited worldwide shortage.

MR. BILIRAKIS. Now tell me, I have always been curious about research and concerned about overlap, although I realize a lot of overlap just necessarily has to take place. Is your research coordinated, let's say, with CDC, DoD, HHS, et cetera?

DR. DEYTON. The research study itself involves probably less than 100 patients. We can do it interior to the VA, pretty quickly and pretty easily. We have got a pretty vigorous research program. Obviously we have communicated with CDC, DoD and other agencies

that we are doing this research, and we, fortunately, received lots of encouragement to move ahead rapidly.

I get a call about every other week from staff at CDC and HHS and DoD, about the status of that research project, because if there the results are positive, it is going to help all of us.

MR. BILIRAKIS. So CDC is sort of depending upon and looking to the VA to sort of continue on with this research so that it can be helpful, well, not only just to the veterans or the VA, but to all Americans, is that right, or everything in the world actually? Is that correct, Doctor?

DR. CARDO. Yes, and I think that is the beauty of the collaboration. We work very closely with the VA when we're developing recommendations. A lot of the research that is being done at the VA can help us then to review and revise some national policies.

I think MRSA is a very nice example. We started the collaboration with a local VA, and we saw major improvement in the prevention of MRSA. Now it is a CDC recommendation, and we are expanding our collaboration, not just for more VA hospitals, but for the whole region in Pennsylvania.

So I think that is the beauty of the collaboration, and we agree with your initial points, Mr. Chairman, that the only way we will be able to fight the pandemic is really working together and learning from each other.

MR. BILIRAKIS. Well, is CDC basically, if anybody in effect is in charge, because you have DoD, HHS, and VA, et cetera, so if anybody is in charge to determine this collaboration and coordination, is it CDC?

DR. CARDO. HHS is responsible for the health piece of the plan. The President is responsible for the whole response, and there are several activities related to public health. They are related to CDC.

Some of the research related to pandemic evolve not just from CDC, but NIH and other groups, but there are lots of groups that are looking at that and working together, so not just CDC, but HHS. We are really looking at all the pieces with research.

MR. BILIRAKIS. I just hope that they are working together as much as you say that they are. That is why we intended to have the other agency departments here.

In terms of sufficient stockpiles, VA has their stockpiles. DoD has their stockpiles, et cetera. Who is responsible? Are they just responsible for their own stockpiles? Someone has to be in charge to determine whether there are adequate stockpiles and where they are located, so that one group can maybe use the other stockpiles if needed?

DR. DEYTON. Very good question, sir, particularly as we are planning for the possibility of a pandemic. There are limited supplies of the drug oseltamivir, which may be useful. There is very limited sup-

plies of vaccine for a possible pandemic influenza.

So the national plan is being developed specifically to articulate those kinds of issues. Each agency has different stockpiles. There is the strategic national stockpile which CDC operates for the whole nation, mostly to distribute to states and Federal health care systems. VA and DoD also have established some stockpile of the drug oseltamivir, and what the plan will be doing, and again the national plan is due to be released January 1st, will be articulating how the coordination of whatever supply we have will be used when we need it. Dr. Cardo may have another point.

DR. CARDO. No, I agree 100 percent with what you said. One example of how we collaborated with the VA during the shortage of influenza vaccine illustrates the collaboration.

The VA has its own vaccine supply and it had enough for their population, and donated vaccines to CDC to be used for additional needs.

Most of the things we predicted that may happen, may be different. So I think the communication not just at the national level, but also at the local levels have been extremely important to facilitate the collaboration.

I just want to highlight again that the stockpiles for both antiviral drugs and vaccines are currently limited in comparison to the potential needs.

MR. BILIRAKIS. Thank you. I know my time is long over. Mr. Strickland.

MR. STRICKLAND. Thank you, Mr. Chairman. I have been interested in your questions about collaboration and coordination, because it seems to me with the government, being as big as it is, and these agencies, being as complicated as they seem to be to me, that it is really important that there be some way to make sure that all agencies understand what is being done by various other parts of our government and I would just hope that is happening.

I have a couple of questions about this oseltamivir. How long does it take to get a larger supply of this? You say it has been around a while and it is kind of a generic, is that correct, and you are finding that it may have this beneficial effect.

DR. DEYTON. Yes, sir. The drug oseltamivir is an antiviral drug that may be effective against this avian flu, this pandemic flu, that may be circulating.

The drug that we are studying to give in combination with the oseltamivir is called probenicid, and that is the drug, sir, that is a generic drug and it has been around a long time.

MR. STRICKLAND. Now do you have an adequate supply of that drug?

DR. DEYTON. Good question. First, we don't know if it is really going to be effective in doing what we hope it will. If it is effective, then

I think certainly everybody will be interested in making sure we have an adequate supply to give in combination with the drug oseltamivir. It is a drug which is -- I am not a chemist -- but I understand is relatively easy to make, and so I would expect, particularly the manufacturer of the drug, oseltamivir, would be very interested in making sure that there was enough probenicid.

Certainly the strategic national stockpile, I am sure, would be very invested in making sure that there was enough oseltamivir to give in combination to make maximal use for the public. And I bet you the Generic Manufacturer's Association would be very interested in ramping up a supply of that drug, and quite frankly, if there is inadequate supply, the various agencies of the Federal Government would roll up our sleeves and make it ourselves probably. We have that capability.

MR. STRICKLAND. Now when you talk about a stockpile, do these drugs degrade overtime? When you place a drug in a stockpile, how long is it likely to be effective or does it have to be continuously replaced?

DR. DEYTON. We manage stockpiles very aggressively, in fact, to make sure the drugs that are in stockpile are active and they haven't expired. So there is a routine of rotation and replacement of drugs that might be coming close to their expiration date. And that is how we manage all stockpiles, and CDC manages the strategic national stockpile in exactly that fashion, and there are smart people who understand logistics that have tracked expiration dates and make sure they are rotating older drugs out and replacing them with new drugs.

Vicky, did you want to add?

MS. DAVEY. Fortunately, the shelf life of oseltamivir is quite long. It is at least five years.

MR. STRICKLAND. Great. Dr. Deyton, you had described using resources to make sure that staff was vaccinated and appropriate vaccinations took place of your patient population and so on, the hope being that you could prevent illness and perhaps save lives, but also save resources and save money.

That just seems to make common sense -- but I am wondering if you have collected any data to support the beneficial effects of what you have tried to do.

DR. DEYTON. There is a considerable amount of literature and research studies and data that do demonstrate that the more people get influenza vaccination, the less illness there is both from influenza, other respiratory infections, cardiac disease and other diagnoses. So there are lots of literature on that, some of it actually has been done by VA researcher.

Dr. Kristin Nichol is part of our system and she has done a lot of the work here. CDC has sponsored really most of this research.

There is very good evidence that that is the direction to go, which is why we take so seriously the influenza vaccination because in the VA system, obviously, we care for a group of veterans who, on average, are older, and have other chronic medical conditions.

So the more veterans who use our system that can be vaccinated, the better everybody is, certainly the individual veterans and their families. And as you say, sir, also the whole VA system.

That is also why we are taking very seriously making sure our staff do a better job of getting vaccinated. We saw last year with the shortage, we saw staff that were actually sort of stepping back and saying, "No, I'll hold off and not be vaccinated because let's save this vaccine for our veterans."

Well, that is penny wise and pound foolish, and so we are working on making sure the penetration of vaccination among our staff gets better and betters. So the kind of results like Dr. Muder told us about is very exciting, that we want to make sure and learn from that and replicate that across the system.

MR. STRICKLAND. Mr. Chairman, I just had one more question for Dr. Muder. Dr. Muder, you take care of a lot of my constituents, because I represent the Southern Ohio border, and a lot of my constituents come to your hospital, and I have been there to visit. I have always been incredibly impressed by the Pittsburgh VA facilities, but you described for us what you are doing, and its beneficial effects.

But I am wondering if the model that you are using is unique to your facility because of what exists in Pittsburgh and you talked about collaboration with the University and so on. Can the model that you have described be easily implemented in your judgment across the VA system, or is it something that is unique to your particular circumstances?

DR. MUDER. I think that much of what we do can actually be implemented throughout the VA. We are very fortunate. We are on the University campus. Our physicians are faculty members. We have lots of resources at our disposal in terms of expertise, but many of the things that we do, I think, are things that don't necessarily require that level of expertise. I think they require the determination of the people in the individual facilities to do it.

One example would be our MRSA initiative. We have actually gotten a lot of inquiries from other VAs in our VISN who are seriously considered doing it, and they range in complexity from the Philadelphia VA, which is very similar to ours, the Butler VA which is essentially a rural long-term-care facility.

Things like immunizing people, you know, doing surveillance for infectious diseases, providing isolation practices, really don't require a university faculty to do it. I think there are things that perhaps we all should be doing, things that can be done in the community, and I think the thing that what it takes is actually the knowledge

and a little bit of resources, but I think the resources necessary are not overwhelming and are well within the capability of most medical centers.

And in fact, again, I am speaking for myself and not for the VA as an institution, but I think there is ample evidence that comes both from the CDC, from the VA and the private sector that efforts to decrease infection through immunization or through appropriate infection control, really are very, very cost effective, and they are highly effective at preventing illness and death.

So, for example, some estimates of MRSA infection depending on whether it is a soft tissue infection or a bacteremia, range from 10,000 to 30,000 dollars per episode, so that you don't have to prevent a lot of illness to really recoup your investment in terms of personnel or laboratory supplies or immunization supplies.

And I think we have been very fortunate and our administration understands this, and I think that they understand that this is an important thing to do from appropriateness of medical care and also from a cost-effectiveness standpoint.

MR. STRICKLAND. Thank you. Thank you, Mr. Chairman.

MR. BILIRAKIS. Thank you, sir. Mr. Boozman to inquire?

MR. BOOZMAN. Thank you, Mr. Chairman. I want to compliment you all. It sounds like you have a great story to tell and are well on the way to being very, very prepared and certainly, you will support you in any way we can in helping you to get further prepared.

I just have a couple kind of curious questions. Your role is such that in the VA, you know, certainly we have the function of providing for the VA family. And then also in the role of a disaster, you kind of kick into another gear.

If we had a full-blown, 1918-type situation, how do you prioritize? Do the VA, do they give first priority, or at that point is it you declare something else, and is it just kind of first come, first serve, or --

DR. DEYTON. It really depends upon what is going on and what the President has said and whatever the governor has said. So certainly the VA priority always is to deliver high-quality health care to our veterans.

Our second priority, congressionally mandated priority, is also to back up the Department of Defense health care system. So that is our second priority.

Our third priority is obviously to be there for the nation when any disaster hits. So if the President invokes the Stafford Act, and there is a Presidentially-declared emergency, each VA actually is delegated authority to do what they think is the best thing to do for both the veterans if there is DoD health care, as well as the communities in which they reside.

And so since you can't say that what is going to work in the Pittsburgh area is going to be exactly what is going to work in, say, South-

ern California, you do want each individual VA facility to have the authority to respond in whatever way is necessary for what's going on there.

MR. BOOZMAN. And then I guess hopefully, in our modeling exercises, that that is part of what goes on. How about the other things? I know we talked about Tamiflu and this is a respiratory disease. Are we adequately stocked with the other things that you need to fight this kind of situation?

You know if you had a 1918 or I guess the important thing with this is, is that is also a great exercise. In getting ready for this, we are also getting ready for a biological attack or a nuclear attack or whatever to some extent. So, again, are we looking at, I hope in our modeling, are we looking at being able to have adequate supplies of the other --

DR. DEYTON. Yes, sir. That certainly is a factor that is being built into the tabletop exercises and the modelings. It is hard to know exactly what to respond to until it starts to happen and what you are really going to need. But we already have learned from the activities that we have done.

For example, the plan that we are putting in place in the VA system, that we are building, again, flowing from the national strategy and the national plan for pandemic influenza, we are actually modeling after what we did for smallpox. It is not that different.

And so we have all developed a lot of expertise in the kind of systemwide responses that have to be put in place, all the resources that have to be brought to bear. How do you ensure staff are adequate and are protected to come in and do their job, the facilities stay open, the housecleaning continues on, the cafeteria workers continue. They are all serious and very important aspects of preparation.

The stockpile issue is one of many. Do we have enough antibiotics, enough IV fluids and things like that?

MR. BOOZMAN. Very good. Thank you.

MR. BILIRAKIS. Thanks, gentleman. Dr. Deyton, let me ask you very quickly, all veterans are eligible for the flu shot?

DR. DEYTON. Veterans who are eligible and enrolled for VA care can come to any VA facility --

MR. BILIRAKIS. But only those veterans. Not veterans -- I don't have a purple card, for instance. Forget about being a member of Congress. Am I eligible for it?

DR. DEYTON. If you have not enrolled for VA health care, VA can't take care of you until you do. But veterans who have not yet enrolled for eligibility, I would encourage --

MR. BILIRAKIS. Well, but for a veteran that doesn't qualify under our criteria, they have not enrolled for VA health care, therefore that veteran is not going to be eligible to walk into the VA. In other words, these posters, which are great posters, are used where? In the VA

facility?

DR. DEYTON. Yes, sir.

MR. BILIRAKIS. Okay.

DR. DEYTON. I am proud to say, sir, that they have been adopted by many other private health care providers, DoD, Australia, Wales, et cetera. But these, what you see here, are taken from VA facilities.

MR. BILIRAKIS. So the veterans post, VFW, American Legion, et cetera, et cetera, something like this would not be posted in their facility, because many of those people do not have the purple card and consequently would not be able to get the flu shot?

DR. DEYTON. Well, two responses, sir. VA has legal authority to deliver care to eligible veterans. I can't give health care to veterans who aren't eligible and enrolled for VA health care.

However, you raised another point. I should probably, as soon as I get back to the office, call the VFW and the American Legion and start distributing these posters to them because in fact I don't care how veterans get the message as long as they get the message.

All veterans should be seeking a flu shot, be it from the VA if they are eligible enrolled, from their private provider, from their public health clinic, from their state health department, wherever they can get the flu shot, because we think it is going to be good for all of them.

MR. BILIRAKIS. Good. All right, I would suggest that you do that because that is all part of the game here, and they could be as just susceptible to serious illness as anyone else as a result of the flu.

DR. DEYTON. Absolutely. For example, we know data. I mean we study this intensively because we are so concerned about it. We know that last year and the year before, 45 percent of veterans who did get a flu shot, got their flu shot outside of the VA.

So of those veterans who could come to the VA, 45 percent of them got their shots --

MR. BILIRAKIS. Well, they are not expensive. I know my son is an internist, and they are far from expensive. In fact, a heck a lot of more, but more expense than the reimbursement would be for giving them.

DR. DEYTON. Right.

MR. BILIRAKIS. Well, I don't know, it would be less than $15, I think, isn't it? Something like that.

DR. DEYTON. What is the question?

MR. BILIRAKIS. Do you know, Dr. Cardo, the reimbursement to a physician who gives a flu shot? Do you know the Medicare reimbursement, for instance?

DR. CARDO. No, I don't have that information.

MR. BILIRAKIS. It is such a ridiculous -- does anybody in the audience know? It is such a ridiculously low figure.

DR. CARDO. It seems it is about 18.

MR. BILIRAKIS. 18? All right.

DR. DEYTON. But, Mr. Chairman, you have raised a very, very, I think important and interesting point, and that has to do with the demand for influenza vaccination, which has been, quite frankly, from an infectious disease point of view, from a public point of view, the demand has not been anywhere close to what it should be.

All of us at this table, I hope all of you up there, also, will really work hard to promote the importance of influenza vaccination for the public. It is a -- I forgot who asked the question -- but it is a good preventive tool. It works at what it is supposed to do.

It decreases respiratory infections. It decreases hospitalizations and we all need to get behind it and let the public know that this is good preventive practice. It is not as valued as it should be, and I think all of us would want to work out ways for VA, for CDC, for the Congress, for the President, all, to get behind a major national campaign of influenza vaccination.

DR. DEYTON. I can tell Dr. Cardo wants to say something.

MR. BILIRAKIS. Dr. Cardo.

DR. CARDO. Thank you. I just wanted to take this opportunity to highlight the importance of vaccination, flu vaccination, and also some of the strategies that they are doing at the VA to promote hand hygiene and respiratory hygiene.

While we know that the stockpiles may not contain enough antiviral medications currently, and we don't yet have a vaccine for potential pandemic virus, we know that there are several strategies that we can take right now that can help us, not just with the flu season, but also in preparing for a possible pandemic.

I think those are strategies that we see that the VA is doing, such strategies that we really encourage all health care facilities to do, and I think the communication piece that the VA has is something that CDC is using also to help other facilities to promote those strategies. I think it is important.

MR. BILIRAKIS. We have newsletters. Of course, we have curtailed those greatly, as a result of people saying we are using taxpayers' dollars to promote ourselves or whatever; but our newsletters, theoretically, goes into every household, and in our congressional districts, it would be a great way to do it.

MR. STRICKLAND. Mr. Chairman, I became a believer last year. Because of the shortage, I was over with the physician's office, and they offered me a shot, and I said, you know, there is a shortage. And so I chose not to take it. And I was sicker last year than I have been in maybe the last 20 years. It was an incredible experience. So no one had to convince me this year that this was an appropriate thing to do.

MR. BILIRAKIS. I am allergic to eggs, and so I haven't been taking it. I remember I took one many, many years ago, and I got sick. I

got the flu.

I commended the VA, because my staff have been reading through materials and doing their research and whatnot, they assured me that the VA was doing a good job and I meant that.

There are gaps. I know the big problem that I found in 24 years, next year will be my 24th and last year here, is turf. That is part of the problem of not being able to get some of these people here. It is turf fights and things of that nature. I know.

Then you have the bureaucracy and the organizational charts. If there are ways that you think that the Congress can be helpful to fill in some of those gaps and to take care of some of the problems that are a result of turf and jurisdictional fights, so please don't hesitate to let us know.

In the meantime, we thank you so very much, and I know we have learned a lot. There aren't many of us here, but this is a small Subcommittee. So I think there are only a couple of people missing as a matter of fact.

Thanks. Thanks so much and, again, we will be submitting a number of questions to you. Thank you very much for coming.

DR. DEYTON. Thank you, Mr. Chairman.

MR. BILIRAKIS. Hearing is adjourned.

[Whereupon, at 11:17 a.m., the hearing was adjourned.]

APPENDIX

STATEMENT OF
LAWRENCE R. DEYTON, MSPH, MD
CHIEF CONSULTANT, PUBLIC HEALTH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
HOUSE VETERANS' AFFAIRS COMMITTEE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
DECEMBER 15, 2005

Mr. Chairman and Members of the Committee, thank you for the opportunity to be here today to discuss the activities taken by the Department of Veterans Affairs (VA) health care system related to seasonal and pandemic influenza preparedness. As you know, Mr. Chairman, VA runs the largest integrated health care system in the Nation and provides health services to over 7 million enrolled veterans. The Centers for Disease Control and Prevention (CDC) estimates that seasonal influenza leads annually to 200,000 excess hospitalizations and 36,000 deaths in this country. The elderly and individuals with chronic medical conditions are especially vulnerable to influenza related diseases and death. This is significant because veterans using VA health care services are older and have more chronic medical conditions than the average American. Influenza vaccination is therefore one of our highest public health priorities and important preventive health programs. To that end, VA has established a seasonal influenza vaccination program that, frankly, Mr. Chairman, is unequalled in effectiveness by any public or private integrated health care system.

On November 1, 2005, President Bush announced the National Strategy for Pandemic Influenza. This strategy highlights the importance of the Nation preventing, recognizing, and preparing for, such a possible major public health problem, which could have far more serious consequences than seasonal influenza. Pandemic influenza is currently an uncertain threat – we do not know where it will strike, we do not know when. But based on the history of influenza, we believe it will. And because veterans and VA health care facilities are located in nearly every community in the Nation, we liken VA to a fine-meshed sieve when it comes to infectious diseases and public health threats – if it happens *anywhere* in our Nation, veterans will be affected, and VA facilities will respond.

I am pleased to report to you on the VA seasonal flu vaccination program and its effectiveness as well as on VA's efforts to prepare for a possible influenza pandemic.

VA's Seasonal Influenza Vaccination Program

Mr. Chairman, the annual VA seasonal influenza vaccination campaign is composed of five interrelated system-wide activities, which I will discuss in brief.

- Annual Under Secretary for Health Influenza Vaccination Directive

  Each fall, the Under Secretary for Health issues a national Influenza Vaccination Directive that articulates VA's vaccination policy for staff and patients. Under the Directive, each VA health care facility Director is required to implement a local vaccination program consistent with the guidance set out in the Directive, including special target groups. (In 2004-2005, the focus was to increase vaccination rates in racial and ethnic minorities. In 2005-2006 it is vaccination of all health care facility staff, along with veteran vaccination.) As part of their local programs, Directors conduct active and energetic flu vaccination programs, naming flu coordinators, setting local goals, and acting on that year's national strategies. I have provided your staff with a copy of the 2005-2006 Under Secretary for Health Influenza Vaccination Directive.

- Annual national high-profile flu vaccine campaign and toolkit

  Each year, VA launches a system-wide annual flu vaccine campaign that provides VA health facilities with the resources needed to organize, promote, publicize and carry out local flu vaccine programs throughout the flu vaccine season. As part of the campaign, VA Flu Vaccine Toolkits are developed and distributed to every VA health facility in the country. These tool kits are evaluated by staff surveys for effectiveness and improved, as needed, to help VA vaccinate as many enrolled veterans and health care facility staff as possible. I have also provided a copy of the toolkit to your staff.

- Timely purchase and distribution of flu vaccine supplies

Every January, VA solicits bids from vaccine manufacturers for the provision of influenza vaccines for the VA health care system in the upcoming flu vaccine season (October thru March). These contracts are signed each spring. Each October distribution of the vaccine begins to VA facilities, with rolling deliveries continuing through the fall and early winter, usually ending in December.

Over the last 8 years VA has steadily increased the amount of influenza vaccines it has purchased, based on past and anticipated needs and allowing for a small surplus. For the 1998-99 flu season VA bought less than 1 million doses; for the 2005-2006 flu season VA bought 2.24 million doses at a cost of $18.4 million.

- Provision of ongoing guidance during each flu vaccination season, as needed, to provide new information

Every flu season has its own unique issues and problems. For example, the year before last, increases in influenza cases occurring early in the season coupled with highly publicized deaths drove demand for influenza vaccines beyond capacity in many areas of the country. Last year, there was a national shortage of influenza vaccine because the vaccine supply expected from one major manufacturer was contaminated and could not be used.

We therefore provide ongoing guidance to the field and to veterans concerning any significant change in, or new information affecting, the influenza vaccine program. This guidance is in the form of timely Under Secretary for Health Flu Vaccine Advisories. Indeed, seven advisories were provided last year (between October and February) on a wide array of pertinent topics, such as updates on supply status, definitions of vaccination priority groups, recommendations on the use of antiviral medications and late vaccination. Already this year, we have distributed three advisories. Our front-line staffers inform us that these targeted advisories provide valuable and timely information.

- Establishment of VA-wide flu vaccine performance measures to which regional and local facility directors are held accountable.

VA's commitment to the national influenza vaccination program is reflected in the fact that rates of influenza vaccination are included as VA-wide performance measures for health facility directors and network directors. Specifically, the performance measure requires influenza vaccination for veterans over the age of 50 and for veterans at high risk of complications from influenza regardless of age. Acceptable levels of performance are based on levels achieved in the previous year, and are set to drive facilities to achieve ever higher performances.

The results of our influenza vaccination program are impressive, and, as I will demonstrate, are better than all other government and private sector results for which there is data. The VA-wide rate of influenza vaccination (documented through abstraction of medical charts) for the 2003-2004 influenza season was 75% and 75% again in the 2004-2005 flu season despite problems with vaccine shortages. By another measure, self-reporting by veterans, the VA rate for vaccination of patients over the age of 50 was 71% in 2004-2005.

In contrast, the non-VA self-report rates by a CDC phone survey of adults over 65—a high risk group much more likely to be vaccinated than those over 50—showed only 68% for 2003-2004 and 63% for 2004-2005, the year of the shortage. A survey of the Medicare population (also over 65 and with the added advantage of flu vaccine coverage) showed rates nearly identical to the VA rates for those over 50. VA also outperformed other groups as seen in data from the CDC that showed commercial insurance plan flu vaccination rates for ages 50-64 to be only 52% in 2003-2004, dropping to 28% in 2004-2005.

We are extremely proud of the success VA has had in seasonal influenza vaccination. Nonetheless, there are areas where improvement is needed. VA is working hard to promote optimal vaccination rates among our health care facility staff. They are both at risk of exposure and at risk of transmission of influenza to other employees or their patients. Particularly in times of vaccine shortage, we have found some employees will forego their own vaccination in order to assure adequate supply for our patients. We have therefore put an emphasis on increasing health care staff vaccination rates, while maintaining or increasing our excellent rate of vaccination of patients.

Most importantly, assuring adequate supply of seasonal influenza vaccine itself requires stabilization of the national influenza vaccine manufacturing capacity. Thus, VA strongly supports the President's proposal, as articulated in the National Strategy for Pandemic Influenza, to create capacity for annual influenza vaccination for every man, women and child in America.

VA Pandemic Influenza Preparedness

VA leadership has been concerned about how to minimize the impact pandemic influenza might have on the veterans we serve, on VA staff, and on vital VA systems that enable us to provide our services. Consequently, VA began to take specific steps in the summer of 2004 to protect veterans and the VA health care system from pandemic influenza.

VA's pandemic influenza planning efforts are supported by VA leadership at all levels and are being carried out by engaged and empowered VA staff. VA's pandemic influenza preparedness program is comprised of eight distinct and interrelated activities that I will describe.

- Use of the annual seasonal influenza vaccination campaign, both to prevent seasonal flu and to serve as a foundation for our pandemic flu efforts

  The VA's well-established proactive seasonal influenza vaccination program, just described, is essential to prevent unnecessary illnesses in our patients and staff and is also the foundation of leadership, cooperation, communications, policies, procedures, and systems upon which we are building our pandemic preparedness. This annual program is accomplished from the top down as well as from the bottom up. We actively communicate with eight categories of front-line staff--at every VA medical center nationwide about influenza and vaccination. These categories are flu coordinators, occupational health clinicians, prevention coordinators, infection control professionals, public affairs officers, patient educators, patient safety officers, and staff education contacts.

- Establishment of a stockpile of the antiviral drug oseltamivir (Tamiflu ®) and a distribution policy

Oseltamivir is an antiviral drug licensed for treatment or prevention of certain common types of influenza. It may be effective in treating or, in some cases, preventing the current strain of avian influenza (H5N1) now causing disease in birds and other animals and sporadically in humans in Asia. An influenza pandemic could result either from mutation of this H5N1 strain or from the genetic reassortment of the H5N1 strain and a human strain of influenza virus; or from mutation or reassortment of another strain of influenza. Therefore, in the fall of 2004, VA purchased 5.5 million capsules (550,000 treatment courses) to establish a VA stockpile of oseltamivir. This quantity is based on the supply needed for treatment of a total of 550 patients and staff and prophylaxis of a total of 5,000 patients and staff at approximately 25% (about 40) of our medical centers. The VA oseltamivir stockpile will be made available via seven geographically diverse distribution centers and is held for use for response to pandemic influenza in accordance with a plan approved by the Under Secretary for Health and carried out in concert with the national planning efforts.

- Initiation of a research study to extend the effective supply of oseltamivir

Oseltamivir is a drug for which there is a world-wide shortage. To make the best use of VA's limited stockpile of this drug, VA public health leaders and researchers have initiated a study to see if the supply of oseltamivir can be extended by co-administration with probenicid. Probenicid is a drug already used in several medical situations to slow elimination of other drugs in order to achieve an improved therapeutic profile. This study has been approved for conduct by the FDA and has just been approved by VA's Office of Research and Development. If the co-administration of oseltamivir and probenicid is found to be safe and effective, then the results of this study could have a significant impact on the Nation's ability to use oseltamivir.

- Development of a Respiratory Infectious Disease Emergency Plan for VA facilities

In the last 4 years, VA has mounted responses to respiratory infectious disease challenges, such as anthrax events in 2001, smallpox vaccination, SARS, seasonal influenza vaccine shortages, and now pandemic influenza. Many of the preparations and responses needed to manage those

challenges are relatively similar regardless of the pathogen causing the emergency. Thus, VA has developed a Respiratory Infectious Disease Emergency Plan for Facilities that is an appendix to the VA Emergency Management Guidebook. This plan is a compendium of information, guidance, and resources for VA facility directors and chiefs of staff. It articulates the preparations, planning, responses, and follow-up actions needed to manage a pandemic from a variety of perspectives, i.e. communications, education, staffing and human resources, environment/facility/equipment, and patient care management. This Plan, and other VA pandemic flu information, is posted at www.publichealth.va.gov/flu/pandemicflu.htm.

- Active participation in White House, national and HHS planning activities and development of a VA-specific pandemic influenza plan of operations

The Department has been a full participant in the U.S. Government-wide planning and response activities led by the White House and the Department of Health and Human Services (HHS). These discussions have been conducted under the auspices of various Federal leaders in HHS in the National Vaccine Program Office, CDC, and a Policy Coordinating Committee sponsored by the White House Homeland Security Council. Through this interagency effort, VA with other Federal agencies has sought to better understand the threat of pandemic influenza and the specific potential problems/challenges that would be posed by such a pandemic, particularly in the areas of public health, surveillance, medical response, vaccine development and antiviral drug supply, communications, and continuity of operations. These efforts culminated in the President's National Strategy for Pandemic Influenza mentioned previously.

The President has also charged a group of agency representatives to develop a draft national pandemic influenza plan that will provide guidance for implementation of the President's National Strategy and elaborate the roles and responsibilities of Federal agencies as well as that of state and local agencies, the private sector, and individuals. VA's clinical and management expertise is heavily involved in assisting with the development of this national plan, which is due to be completed by January 1, 2006.

In addition, the President has directed each Federal agency to develop an agency-specific pandemic influenza plan using the national plan as a template. The VA plan is due by February 1, 2006, and I am pleased to report that VA's plan is well along in development.

- Necessary improvement in timely reporting of VA patients seeking medical treatment with illnesses suggestive of influenza, with the goal of providing real-time clinical data to CDC surveillance for US influenza-like disease.

A crucial component for an optimal nationwide response to a pandemic influenza is rapid and accurate surveillance that will alert our public health authorities as soon as possible of an outbreak. VA's national health care system, existing in every state and territory in the Nation and utilizing a fully deployed electronic medical record and reporting system, can provide important surveillance information. Thus, VA has requested resources to support application of commercially acquired software to allow the agency to do real-time reporting of influenza syndromic activity directly to the Centers for Disease Control and Prevention. This software will be part of a system already being built to improve VA's surveillance of health care-associated infections that will also be reporting directly to the CDC. These resources are part of the President's pandemic flu preparedness budget request currently pending in Congress.

- Development and ongoing promotion of "Infection: Don't Pass It On," a VA campaign to engage staff, patients, and visitors in preventing transmission of infection

Even in the absence of an effective vaccine against pandemic flu or sufficient supplies of antiviral drugs, there exist public health strategies that will lessen the risk of a respiratory infectious disease like pandemic influenza. Essentially, the common sense approaches that our parents taught us really work: wash your hands, cover your mouth when you cough, and stay home if you are sick.

VA is very proud of a public health campaign that we developed as a result of our work on SARS in the spring of 2003. Improving hand and respiratory hygiene in VA became an educational priority (launched, along with VA education materials, in fall 2004) with other themes added over

time, and an overall call to action – "Infection: Don't Pass It On." Flu prevention was incorporated into the campaign in spring 2005.

The purpose of this public health campaign is to educate all staff, patients, and visitors throughout the VA health care system, about basic, common sense steps they need to take to prevent infection. We believe this is an essential aspect of preventing "regular" infectious diseases, such as seasonal flu and health care-acquired infection, as well as infectious disease emergencies, particularly pandemic flu. Indeed, widespread use of such effective public health measures may buy us the time we need to deal effectively with a pandemic.

To date, about 100 educational posters and other materials have been developed, including some in Spanish. The majority of them address hand-washing and respiratory hygiene, but we have also prepared materials, particularly posters in English and Spanish, to show the correct use of personal protective equipment. Please see our Web site at www.publichealth.va.gov/InfectionDontPassItOn/ for a lot of colorful information about our campaign.

The materials on hand-washing and respiratory hygiene have been widely disseminated to VA health care and long-term care facilities. These four-color posters range from serious to humorous, are targeted to clinical or all audiences, and are designed to be rotated and used repeatedly. Articles on the campaign have appeared in national and local VA publications and information about the campaign has also been presented at local and national medical conferences. Not only has the material has been distributed across the VA system, it has been used by local and state private health care providers, Department of Defense health care providers, and other countries, including Wales and Australia. Importantly, we continually solicit feedback on how we can improve our messages, materials, and approaches. Thus far, results of a national VA Web survey have shown that staff throughout the VA health care system have heeded our message to improve their hand hygiene.

- Planning of an operational tabletop exercise on pandemic flu conducted with several VA sites and in concert with Federal, state, and local agencies to focus on patient flow, employee needs, and system functionality designed to improve our national plan.

We all have learned that even excellent plans need to be tested. Once the VA-specific pandemic influenza plan is completed, VA will conduct a series of simulation exercises to test how it may be implemented to protect the veterans for whom we care and our employees as well as to ensure continuing of healthcare operations. Because VA facilities are located across the Nation, the VA simulation exercises will involve both state and local health officials with whom VA would need to coordinate in the event of a real pandemic influenza. It will also involve other Federal agencies, such as the Departments of Homeland Security, Health and Human Services and Defense.

In summary, VA has an active and successful approach to seasonal influenza and has begun to apply that approach to the possibility of pandemic influenza. Large health care organizations, like VA, have special responsibilities to have plans in place that will afford patients and employees the best possible protections against disease and its consequences and continue health care operations. We are pleased with the actions VA has taken to date that have started us down the path of preparedness for pandemic influenza. It is a long and not always easy path. Nonetheless, I assure you VA will continue to take whatever actions are needed to protect our veterans and employees and the VA health care system against seasonal influenza by continuing our annual program as I outlined and learning how to continue to improve it. We will also continue strong efforts to prepare VA for pandemic influenza as we fully implement the National Strategy outlined by the President. VA will be there for the veterans who rely on us for their health care.

More information on VA, flu, and pandemic flu--and the tools we are using to fight these diseases--is available at www.publichealth.va.gov/flu.

This concludes my statement. I will be pleased to answer any questions. Thank you.

Testimony
Before the Veterans' Affairs Subcommittee on Oversight and Investigations
United States House of Representatives

AVIAN INFLUENZA: Preparing for a Possible Influenza Pandemic

Statement of
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U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Thursday, December 15, 2005

Mr. Chairman and members of the Subcommittee, I am pleased to be here today to describe the current status of avian influenza around the world; the consequences of a possible human influenza pandemic; and efforts within the Department of Health and Human Services (HHS) to prevent, prepare for and respond to such a pandemic, including the *HHS Pandemic Influenza Plan*. Thank you for the invitation to testify on influenza pandemic planning and preparedness, which Secretary Mike Leavitt has made a top priority. As you know, the President has requested emergency supplemental funding for the HHS Pandemic Influenza Plan, which is an integral component of his National Strategy for Pandemic Influenza. In the event that an outbreak of pandemic flu hits our shores, it will surely have profound impacts on almost every sector of our society. Such an outbreak will require a coordinated response at all levels of government – Federal, State, and local – and it will require the participation of the private sector and each of us as individuals. HHS has been a leader in this effort. With this budget request and the release of the HHS Pandemic Influenza Plan, we are taking another major step forward to improve our preparedness and response capabilities.

The Centers for Disease Control and Prevention (CDC) and other agencies within HHS are working together formally through the Influenza Preparedness Task Force that Secretary Leavitt has chartered to prepare the United States for this potential threat to the health of our nation. We are also working with other federal, state, local and international organizations to ensure close collaboration.

As you are aware, the potential for a human influenza pandemic is a current public health concern with an immense potential impact. Inter-pandemic (seasonal) influenza causes an average of 36,000 deaths each year in the United States, mostly among the elderly and more than 200,000 hospitalizations. In contrast, scientists cannot predict the

severity and impact of an influenza pandemic, whether from the H5N1 virus currently circulating in birds in Asia and Europe, or the emergence of another influenza virus of pandemic potential. However, modeling studies suggest that, in the absence of any control measures, a "medium-level" pandemic in which 15 percent to 35 percent of the U.S. population develops influenza could result in 89,000 to 207,000 deaths, between 314,000 and 734,000 hospitalizations, 18 to 42 million outpatient visits, and another 20 to 47 million sick people. The associated economic impact in our country alone could range between $71.3 and $166.5 billion. A more severe pandemic, as happened in 1918, could have a much greater impact. Estimates based on extrapolations from research on the 1918 pandemic have predicted that a similarly severe pandemic could result in up to 9.9 million hospitalizations and 1.9 million deaths.

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

- A pandemic could occur anytime during the year and could last much longer than typical seasonal influenza, with repeated waves of infection that could occur over one or two years.
- The capacity to intervene and 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 considered the leading candidate to cause the next pandemic. However, it is possible that another influenza virus, which could originate anywhere in the world, could cause the next pandemic. Although researchers believe some viruses are more likely than others to cause a pandemic, they cannot predict with certainty the risks from specific viruses. This uncertainty is one of the reasons why we need to maintain year-round laboratory surveillance of influenza viruses that affect 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 since the last pandemic in 1968, including 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 have made us more vulnerable.
- The current threat of a human pandemic due to lethal highly pathogenic avian influenza A (HPAI H5N1) should be addressed at both the human and animal levels, recognizing that this is currently an animal disease. But because pandemic influenza viruses will most likely emerge in part or wholly from influenza viruses among animals, such as birds, it is critical for human and animal health authorities to closely coordinate activities such as surveillance and to share relevant information as quickly and as transparently as possible.

The Current Status of H5N1 Virus in Asia

Beginning in January 2004, the World Health Organization (WHO) confirmed reports of new outbreaks of HPAI H5N1 infection among poultry and waterfowl in several Asian countries. In 2005, outbreaks of H5N1 disease have also been reported among poultry in Russia, Ukraine, Kazakhstan, Turkey, and Romania. Mongolia has reported outbreaks of the H5N1 virus in wild, migratory birds. In October 2005, outbreaks of the H5N1 virus were reported among migrating swans in Croatia. In 2004, sporadic human cases of avian influenza A (H5N1) were reported in Vietnam and Thailand. In 2005 additional human cases have been reported in Cambodia, China, Indonesia, Thailand, and

Vietnam. Cumulatively, as of December 14, 2005, 138 human cases have been reported and laboratory confirmed by WHO. These cases have resulted in 71 deaths, a fatality rate of approximately 51 percent among reported cases. Almost all cases of H5N1 human infection appear to have resulted from some form of direct or close contact with infected poultry, primarily chickens. In addition, a few persons may have been infected through very close contact with another infected person, but this type of transmission has not led to sustained transmission.

For an influenza virus to cause a pandemic, it must: (1) be a virus to which there is little or no pre-existing immunity in the human population; (2) be able to cause illness in humans; and, (3) have the ability for sustained transmission from person to person. So far, the HPAI H5N1 virus circulating in Asia and Europe meets the first two criteria but has not yet shown the capability for sustained transmission from person to person.

The highly pathogenic avian influenza A (H5N1) epizootic (or animal) outbreak in Asia that is now beginning to spread into Europe is not expected to diminish significantly in the short term. It is likely that H5N1 infection among birds has become endemic in certain countries in Asia and that human infections resulting from direct contact with infected poultry will continue to occur. So far, scientists have found no evidence for genetic reassortment. Reassortment can occur when the genetic code for high virulence in an H5N1 strain combines with the genetic code of another influenza virus strain resulting in a new virus that is more easily transmitted. However, the animal outbreak continues to pose an important public health threat, because there is little preexisting natural immunity to H5N1 infection in the human population.

In October 2005, CDC Director Julie Gerberding accompanied HHS Secretary Mike Leavitt when he led a delegation of U.S. and international health experts on a 10-day trip

to five nations in Southeast Asia. The purpose of this trip was: 1) to learn from countries that have had first-hand experience with avian influenza; 2) to emphasize the importance of timely sharing of information and samples in fighting the disease; and, 3) to determine the best use of our resources abroad to protect people in the United States. They learned several important lessons. First, international cooperation is absolutely essential; an outbreak anywhere increases risk everywhere. Second, surveillance, transparency, and timely sharing of information and samples, such as virus strains, are critical. The ability of the United States and the world to contain or slow the spread of an influenza pandemic is highly dependent upon early warning of outbreaks. Finally, it is vital to strengthen preparedness and response capabilities in Asian countries and other parts of the world. The delegation also concluded that pandemic preparedness and preparation must be both short- and long-term in scope. These critical elements form the basis of the Administration's diplomatic engagement strategy through the International Partnership on Avian and Pandemic Influenza, launched by the President in September, and drives our efforts with the international health community to prepare effectively for a pandemic. As I stated earlier, there is no way to know if the current H5N1 virus will evolve into a pandemic. However, we do know that there have been three pandemics in the past 100 years, and we can expect more in this century.

The Secretary's trip reaffirmed the value of several actions undertaken by HHS and its agencies over the last few years. It is vital to monitor H5N1 viruses for changes that indicate an elevated threat for humans, and we are continuing to strengthen and build effective in-country surveillance, which includes enhancing the training of laboratorians, epidemiologists, veterinarians, and other professionals, as well as promoting the comprehensive reporting that is essential for monitoring H5N1 and other strains of highly pathogenic avian influenza. In collaboration with international partners and other U.S.

Government Agencies, HHS is also pursuing a strategy of active, aggressive international detection; investigation capacity; international containment; and laboratory detection support.

Development and Manufacture of Vaccine

The development and role of a pandemic influenza vaccine is a principal component of the *HHS Pandemic Influenza Plan*, which I will describe later in the testimony. During an influenza pandemic, the existence of influenza vaccine manufacturing facilities functioning at full capacity in the United States will be critically important. We assume the pandemic influenza vaccines produced in other countries are unlikely to be available to the U.S. market, because those governments have the power to prohibit export of the vaccines produced in their countries until their domestic needs are met. The U.S. vaccine supply is particularly fragile; only one of four influenza vaccine manufacturers that sell in the U.S. market makes its vaccine entirely in the United States.
Another important factor is that public demand for influenza vaccine in the United States varies annually. Having a steadily increasing demand would provide companies with a reliable, growing market that would be an incentive to increase their vaccine production capacity. In FY 2006, CDC will direct $40 million through the Vaccines for Children (VFC) program to purchase influenza vaccine for the national pediatric stockpile as additional protection against annual outbreaks of influenza. To secure a year-round egg supply for egg-based influenza vaccine manufacturing in the U.S. and provide pilot investigational lots of pandemic-like influenza vaccine candidates for clinical evaluation, HHS awarded a contract to sanofi pasteur for $41.8 million in September 2004. HHS also signed a $100 million contract in April 2005 with sanofi pasteur to develop cell culture influenza vaccines and build domestic manufacturing capacity. The President is requesting $4.7 billion in FY 2006 to encourage greater production capacity that will

enhance the U.S.-based vaccine manufacturing surge capacity to help prepare for a pandemic and further guard against annual shortages and to develop pandemic vaccines towards licensure utilizing antigen sparing and universal cross subtype vaccine technologies.

Clinical testing of pilot investigational lots of H5N1 vaccine as antigen-alone formulations to determine safety, dosage, and schedule began in April 2005 with funding from NIH. Initial testing shows that, in its current form, a much higher dose of vaccine will be needed to produce the desired immune response in people. To that end HHS and NIH are working with sanofi pasteur, formulations of H5N1 vaccine produced in 2004 at commercial scale and formulated with an adjuvant – aluminum hydroxide- have been manufactured and are scheduled for clinical testing early next year. Other adjuvants and other delivery strategies are under study by the NIH with H5N1 and other avian influenza vaccines. Lastly, HHS awarded contracts in 2005 to sanofi pasteur and Chiron for $180 million and $63 million, respectively, for the commercial scale production of H5N1 vaccine to establish pre-pandemic vaccine stockpiles.

One of the main efforts by HHS in pandemic preparedness is to expand the nation's use of influenza vaccine during inter-pandemic influenza seasons. This increase will help assure that the United States is better prepared for a pandemic. Influenza vaccine demand drives influenza vaccine supply. As we increase annual production efforts, this should strengthen our capacity for vaccine production during a pandemic. We are also developing strategies to increase influenza vaccine demand and access by persons who are currently recommended to receive vaccine each year.

Domestic Preparedness

On November 1, 2005, President Bush released *The National Strategy for Pandemic Influenza*, which outlines the roles of the Federal government, State and local governments, private and international partners, and individual citizens to prepare for and respond to an influenza pandemic. The following day, Secretary Leavitt introduced 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 a national state of readiness and quick response. The HHS plan also includes a description of the relationship of this document to other federal plans and an outline of key roles and responsibilities during a pandemic. In the event of a pandemic and the activation of the National Response Plan, HHS has a critical role to support the Department of Homeland Security in their role of overall domestic incident management and Federal coordination. CDC will support the responsibilities designated to HHS. The President is requesting additional FY 2006 appropriations for HHS totaling $6.7 billion in support of the *HHS Pandemic Influenza Plan*. In seeking this funding, the goals are: to be able to produce a course of pandemic influenza vaccine for every American within six months of an outbreak; to provide enough antiviral drugs and other medical supplies to treat over 25 percent of the U.S. population; and to ensure a domestic and international public health capacity to detect and respond to a potential pandemic influenza outbreak.

In addition to outlining the federal response in terms of vaccines, surveillance, and planning, the *HHS Pandemic Influenza Plan* makes clear the role of individual Americans in the event of an influenza pandemic. The importance of such ordinary but simple steps as frequent hand washing, containing coughs and sneezes, keeping sick

children (and adults) home until they are fully recovered are widely seen as practical and useful for helping control the spread of infection. The Plan also describes options for social-distancing actions, such as "snow days" and alterations in school schedules and planned large public gatherings. While such measures are, ordinarily, unlikely to fully contain an emerging outbreak, they may help slow the spread within communities.

State and Local Preparedness and Planning

All states have submitted interim pandemic influenza plans to CDC as part of their 2005 Public Health Emergency Preparedness Cooperative Agreements. Key elements of these plans include the use of surveillance, infection control, antiviral medications, community containment measures, vaccination procedures, and risk communications. To support the federal and state planning efforts, CDC has developed detailed guidance and materials for states and localities, which are included in the HHS Plan. CDC will work with states to build this guidance into their plans. CDC has taken a lead role in working with the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) which recommend strategic use of antiviral medications and vaccines during a pandemic when supplies are limited.

CDC is working to: (1) ensure that states have sufficient epidemiologic and laboratory capacity both to identify novel viruses throughout the year and to sustain surveillance during a pandemic; (2) improve reporting systems so that information needed to make public health decisions is available quickly; (3) enhance systems for identifying and reporting severe cases of influenza; (4) develop population-based surveillance among adults hospitalized with influenza; and, (5) enhance monitoring of resistance to current antiviral drugs to guide policy for use of scarce antiviral drugs.

Collaboration with the Council for State and Territorial Epidemiologists (CSTE) has considerably improved domestic surveillance through making pediatric deaths associated with laboratory-confirmed influenza nationally notifiable, and by implementing hospital-based surveillance for influenza in children at selected sites. CDC will continue to work with CSTE to make *all* laboratory confirmed influenza hospitalizations notifiable. Since 2003, interim guidelines have been issued to states and hospitals for enhanced surveillance to identify potential H5N1 infections among travelers from affected countries, and these enhancements continue. Special laboratory training courses to teach state laboratory staff how to use molecular techniques to detect avian influenza have been held. In the past year, CDC trained professionals from all of the 48 states that desired training.

Healthcare System

If an influenza pandemic were to occur in the United States, it would place a huge burden on the U.S. healthcare system. Medical surge capacity may be limited, and could be vastly outpaced by demand. Healthcare facilities need to be prepared for the potential rapid pace and dynamic characteristics of a pandemic. All facilities should be equipped and ready to care for a limited number of patients infected with a pandemic influenza virus as part of normal operations as well as a large number of patients in the event of escalating transmission. Preparedness activities of healthcare facilities need to be synergistic with those of other pandemic influenza planning efforts. Effective planning and implementation will depend on close collaboration among state and local health departments, community partners, and neighboring and regional healthcare facilities. However, despite planning, in a severe pandemic it is possible that shortages in staffing, beds, equipment (e.g., mechanical ventilators), and supplies will occur and

medical care standards may need to be adjusted to most effectively provide care and save as many lives as possible.

CDC has developed, with input from state and local health departments and healthcare partners, including other federal agencies, guidance that provides healthcare facilities with recommendations for developing plans to respond to an influenza pandemic and guidance on the use of appropriate infection control measures to prevent transmission during patient care. Development of and participation in tabletop exercises over the past two years have identified gaps and provided recommendations for healthcare facilities to improve their readiness to respond and their integration in the overall planning and response efforts of their local and state health departments. These exercises were valuable in showing the importance of having existing, accessible lines of communication and points of contact to facilitate the response both within the facility and between the facility and other response partners in the community. The tabletop exercises were also an important tool for directing facilities in how to set up an incident command structure and to assign staff to rapidly engage with the command structure. The healthcare system has made great strides in preparation for a possible pandemic, but additional planning still needs to occur.

Collaborations with the Department of Veterans Affairs

VA is participated in working groups to create the HHS pandemic influenza plan and is represented on the National Vaccine Advisory Committee. CDC flu vaccine materials are part of VA's annual flu campaign. CDC is currently engaged with the VA on various collaborations directed toward control and prevention of infectious diseases in general. For example, through the National Nosocomial Infections Surveillance (NNIS), selected VA hospitals have contributed data on bloodstream infections, surgical site infections,

and other infectious events occurring during hospitalization. This information has been combined with data from over 300 additional hospitals to calculate national trends in healthcare-associated infections. Recently, efforts are underway to incorporate multiple VA hospitals into the National Healthcare Safety Network, a broader initiative to monitor healthcare-associated infections that incorporates NNIS. Additionally, through CDC's Emerging Infections Program, VA hospitals contribute to regional surveillance systems that monitor various emerging pathogens and that determine the effectiveness of different public health interventions.

Antiviral Drugs

A component of the *HHS Pandemic Influenza Plan* is acquiring, distributing, and using antiviral drugs. CDC has been working to procure additional influenza countermeasures for the SNS. Because the H5N1 viruses isolated from people in Asia during the past two years appear resistant to the adamantine class of antiviral drugs but sensitive to the neuramidase inhibitor class of drugs such as oseltamivir (Tamiflu®), and zanamivir (Relenza®), the SNS has purchased enough oseltamivir (Tamiflu®) capsules to treat approximately 5.5 million adults and has oseltamivir (Tamiflu®) suspension to treat nearly 110,000 children. The SNS also includes 84,000 treatment regimens of zanamivir. With a goal to reach a national stockpile of 81 million treatment courses of Tamiflu by mid-2007, the President requested $1.03 billion for antiviral drug acquisition. WHO recently announced that the manufacturer of Tamiflu®, Roche, has donated three million adult courses. These will be available to WHO by mid-2006. Additional $400 million was requested in the FY06 HHS Budget Supplement for advanced development of new influenza antiviral drugs with broader and longer efficacy.

Enhancement of Quarantine Stations

CDC has statutory responsibility to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This effort includes maintaining quarantine stations. Quarantine stations respond to illness in arriving passengers, assure that the appropriate medical and/or procedural action is taken, and train Customs and Border Protection officers to watch for ill persons and imported items having public health significance. Currently, CDC's Quarantine Stations are actively involved in pandemic influenza preparedness at their respective ports of entry. CDC's goal is to have a quarantine station in any port that admits over 1,000,000 passengers per year. We are expanding the nation's Quarantine Stations; staff now have been selected for 18 Stations and are on duty at 17 of these Stations. HHS and the Department of Homeland Security (DHS) have recently established a Memorandum of Understanding setting out specific cooperation mechanisms to combat the introduction and spread of communicable diseases. These include DHS assistance with passive and, in certain instances, active surveillance of passengers arriving from overseas, as well as information sharing to assist in contact tracing of passengers with communicable or quarantinable diseases. HHS/CDC will provide training and other necessary support to prevent disease from entering the United States.

Informing the Public

Risk communication planning is critical to pandemic influenza preparedness and response. CDC is committed to the scientifically validated tenets of outbreak risk communication. It is vital that comprehensive information is shared across diverse audiences, information is tailored according to need, and information is consistent, frank, transparent, and timely. In the event of an influenza pandemic, clinicians are likely to detect the first cases; therefore messaging prior to a pandemic includes clinician

education and discussions of risk factors linked to the likely sources of the outbreak, in addition to information targeted for specific groups, such as businesses and state and local officials. Given the likely surge in demand for healthcare, public communications must include instruction in assessing true emergencies, in providing essential home care for routine cases, and basic infection control advice. CDC provides the health-care and public health communities with timely notice of important trends or details necessary to support robust domestic surveillance. We also provide guidance for public messages through the news media, Internet sites, public forums, presentations, and responses to direct inquiries. This comprehensive risk-communication strategy can inform the nation about the medical, social, and economic implications of an influenza pandemic, including collaborations with the international community. We are working through the International Partnership on Avian and Pandemic Influenza and with the WHO Secretariat to harmonize our risk-communication messages as much as possible with our international partners, so that, in this world of a 24-hour news cycle, governments are not sending contradictory or confusing messages that will reverberate around the global to cause confusion.

Conclusion

Although much has been accomplished, from a public health standpoint more preparation is needed for a possible human influenza pandemic. As the President mentioned during the announcement of his *National Strategy for Pandemic Influenza*, our first line of defense is early detection. Because early detection means having more time to respond, it is critical for the United States to work with domestic and global

partners to expand and strengthen the scope of early-warning surveillance activities used to detect the next pandemic.

Although the present avian influenza H5N1 strain in Southeast Asia does not yet have the capability of sustained person-to-person transmission, we are concerned that it could develop this capacity. CDC is closely monitoring the situation in collaboration with WHO, the affected countries, and other partners. We are using our extensive network with other federal agencies including VA, provider groups, non-profit organizations, vaccine and antiviral manufacturers and distributors, and state and local health departments to enhance pandemic influenza planning. The national response to the annual domestic influenza seasons provides a core foundation for how the nation will face and address pandemic influenza. We will continue to work with our partners, in implementing pandemic influenza preparedness efforts.

Thank you for the opportunity to share this information with you. I am happy to answer any questions.

Questions for the Record
Chairman, Michael Bilirakis
Ranking Member Ted Strickland
House Committee on Veterans' Affairs
Subcommittee on Oversight and Investigations

December 15, 2005

Department of Veterans Affairs (VA) Flu Vaccination Program and Preparations for a Possible Flu Pandemic

Question 1: In Dr. Deyton's oral testimony he indicated the benefit of cost savings by investing in a comprehensive influenza vaccination program that should yield a lower rate of infection or illness in the patient population. He also indicated that vaccinating the VA workforce against influenza has measurable cost savings. If there are any data to support these savings or any associated supportive studies, please identify and summarize that information for the record?

Response: Evidence for the benefit of influenza vaccination in patients.
Studies of influenza vaccination of adults have shown an association of vaccination with the following benefits:

- reduction in rates of reported influenza-like illness or laboratory-confirmed influenza by a range of 25 to 90 percent;
- fewer lost workdays due to respiratory illness (32 to 43 percent in vaccinated);
- fewer days of working at reduced efficiency;
- fewer health care provider visits (42 to 44 percent in vaccinated);
- reduction in transmission of influenza like illness to others;
- reduction in hospitalizations for all causes;
- reduction in hospitalizations for influenza and pneumonia by as much as 33 percent;
- reductions in hospitalizations for congestive heart failure;
- reduction in death from any cause by as much as 50 percent; and
- evidence of cost effectiveness or cost savings ($23 to $73 of reduced medical care costs and indirect costs (e.g. use of sick leave) among vaccinated persons in several studies).

Some of these studies have been conducted within VA health care settings or by VA researchers; others have been conducted within and outside of the United States
Evidence for benefit of influenza vaccination of employees:

Benefits of vaccination that apply to adults certainly also apply to health care workers, but it is believed that only about 40 percent of U.S. health care workers are vaccinated in any year. Low rates of health care worker vaccination may contribute to high rates of absenteeism and staffing strain, poor work performance and productivity, influenza-like illness among employees, transmission of influenza to patients and other

staff (and subsequent illness and death of patients), and transmission of influenza to family members during the annual influenza season.

VA medical facilities have provided no-cost vaccination for many years and have emphasized health care worker vaccination in annual vaccination programs. The special emphasis for the 2005 – 2006 VA Influenza Vaccine Toolkit is on vaccination of all VA staff who work in VA health care facilities, and for the first time this year, VA is collecting national data on the percentage of all health care staff who receive vaccine.

Question 2: Is the VA Central Office aware of the results of the MRSA program at the Pittsburgh VAMC as described by Dr. Muder, and if so, what has been done to promulgate this program VA-wide?

Response: VA Central Office is both aware and very proud of the work done by Dr. Muder and his colleagues to evaluate strategies to reduce health care associated transmission antibiotic resistant organisms such as MRSA (methacillin-resistant staphylococcus aureus – the name of a common bacterium which is resistant to many common antibiotics and an increasing problem in health care settings). Dr. Muder is currently evaluating the application of his work more broadly beyond just one facility. VA Central Office will review and is looking forward to integrating the lessons learned into a major new national program on surveillance and prevention of health care associated infections.

Question 3: What percentage of VA's enrolled population would be categorized as high risk by CDC flu vaccinations standards/guidelines?

Response: VA estimates that 80 percent of veterans served by the VA health care system are either 65 years of age or older, or have a medical condition placing them in a "risk" category for influenza illness.

O