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GLOBAL HEALTH EMERGENCIES HIT HOME: THE "SWINE FLU" OUTBREAK

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH

OF THE

COMMITTEE ON FOREIGN AFFAIRS
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GLOBAL HEALTH EMERGENCIES HIT HOME: THE "SWINE FLU" OUTBREAK

WEDNESDAY, MAY 6, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:07 a.m. in room 2172, Rayburn House Office Building, Hon. Donald Payne (chairman of the subcommittee) presiding.

Mr. PAYNE. This hearing will come to order. Let me begin by saying generally hearings do begin a bit later, but because we felt the urgency of this matter, we had to take the only time available so that we can vacate the room for another previously scheduled hearing; I appreciate all of you coming early this morning. This meeting, as I mentioned, will officially come to order, and thank you for joining the Subcommittee on Africa and Global Health this morning for this hearing entitled "Global Health Emergencies Hit Home: The 'Swine Flu' Outbreak."

The recent outbreak of a new strain of influenza, a subtype H1N1 virus commonly referred to as "Swine Flu," sparks significant global concern and attention and reminds us that global health challenges are challenges to the health of our own Nation and the entire international community. We truly live in a global village and it has been no more apparent than it is today. Indeed to date, our own hemisphere is most affected. The first identified cases occurred in Mexico in March where 590 cases and 25 deaths had been reported, followed by 286 cases and one death in the United States and 140 cases and 0 deaths in Canada. On April 29th the World Health Organization raised its influenza pandemic alert to level five, a strong signal that a pandemic is eminent. Many questions remain as to the exact origin of the virus strain. And while it contains genetic material from flu strains usually found in swine, pigs have not yet been identified as a source of human transmission. The association with pigs could be injurious to the swine industry; and there has been a request that Members of Congress refer to the strain by one of its technical terms.

There are many issues associated with this H1N1 virus. The WHO Phase 5 alert level carries with it a series of public health measures that countries are expected to adopt to avert a crisis. Among other issues, this hearing will focus on is how global health emergencies such as this one challenge the public health infrastructures of developing nations; and we hope to learn more about the assistance that the United States is providing to address these

worldwide weaknesses. While no cases have been confirmed to date in African countries, I am concerned that the lack of reported cases of H1N1 in Africa may actually represent the absence of the ability to detect the virus strain, which could mean that the true impact of this strain is yet to be seen. Adding to concerns there have been several recent deaths in Southeast Asia and Africa caused by the avian flu. These issues underscore the need for greater investment in health systems in Africa in particular and in other developing regions.

We will also discuss funding.

As you know, the 2009 Supplemental Appropriations include $2 billion to fight pandemic flu—$1.5 billion which goes to Health and Human Services and Centers for Disease Control for Federal stockpiles, vaccines and detections. Of the remaining funding, $350 million goes toward State and local response, and $200 million for global efforts.

President Obama has shown incredible leadership on global health this week, just yesterday, announcing $63 billion to be spent over the next 6 years, starting in Fiscal Year 2010 shaped by a new comprehensive global health strategy. Under President Obama's new plan, $51 billion will go toward fighting HIV/AIDS, tuberculosis and malaria through the President's Emergency Plan for AIDS Relief, as we all know as PEPFAR. The remaining $12 billion will go toward other global health priorities such as child and parental health, neglected tropical diseases and an overall investment in building capacity in health systems. And this is something that African nations have said this is what we really need. As we get assistance to deal with the health crisis, we need to be able to build a health system, and that is what we will concentrate on. So when the need for overall assistance from the U.S. dissipates, the health systems will be in place.

I commend the President for this quantum leap in global health funding. It shows the United States understands global health challenges and what we must do because these challenges can hit us here at home as we have seen in the outbreak of H1N1 virus. As we may recall in 2007, the case of the Atlanta lawyer, Andrew Speaker, who traveled to Europe and back to the United States all while infected with the deadly extensively drug resistant tuberculosis strain known as XDR–TB. There is also a geopolitical dimension to the H1N1 outbreak. The World Health Organization cautions that those who are ill should delay international travel; however, warns that "limiting travel and imposing travel restrictions would have very little effect on stopping the virus from spreading, but also would be highly disruptive to the global community."

Despite this warning, China has reportedly quarantined a number of Mexican nationals living in China. Mexico's response to this was a ban on flights to China. Last week, the European Union Health Commission urged Europeans to avoid nonessential travel to the United States and Mexico, following the confirmation of a case of the H1N1 virus in Spain. U.S. Homeland Security Secretary Janet Napolitano explained in a Senate Homeland Security Committee hearing here last Thursday stated that closing the United States-Mexican border would incur more costs and benefits to the

United States Government's effort to stop the spread of the virus. I am sure these and other issues will allow us to have an in-depth discussion on this important topic.

So we are pleased today to be joined by our distinguished panel of government witnesses. First, you will hear from Dr. Anne Schuchat, the interim deputy director for science and public health program at the Center for Disease Control and Prevention. Our second witness is a long-time friend, Dr. Anthony Fauci, director of the National Institute of Allergies and Infectious Diseases at the National Institute of Health. And last but not least, a long-time associate also, Dr. Dennis Carroll, who serves as special advisor to the acting administrator on influenza pandemic at USAID. And we will go through the biographies after we hear remarks from the other members.

And at this time, I will turn to my colleague from New Jersey, the ranking member, Mr. Smith, for his opening statement.

[The prepared statement of Mr. Payne follows:]

Remarks of Chairman Donald M. Payne
Hearing of the Subcommittee on Africa and Global Health
"Global Health Emergencies Hit Home: The Swine Flu Outbreak"
Wednesday, May 6, 2009
9:30 a.m. 2172 Rayburn House Office Building

Thank you for joining the Subcommittee on Africa and Global Health for this hearing entitled "Global Health Emergencies Hit Home: The Swine Flu Outbreak".

The recent outbreak of a new strain of influenza A subtype H1N1 virus, commonly referred to as "swine flu", sparked significant global concern and attention and reminds us that global health challenges are challenges to the health of our own nation and the entire international community.

Indeed, to date our own hemisphere is the most affected. The first identified cases occurred in Mexico in March where 590 cases and 25 deaths have been reported, followed by 286 cases and one death in the U.S., and 140 cases and zero deaths in Canada. On April 29th the World Health Organization raised its influenza pandemic alert level to Phase 5 "… a strong signal that a pandemic is imminent…"

Many questions remain as to the exact origin of the virus strain, and while it contains genetic material from flu strains usually found in swine, pigs have not yet been identified as a source of human transmission. The association with pigs could be injurious to the swine industry and there has been a request that Members of Congress refer to the strain by one of its technical names.

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While no cases have been confirmed to date in African countries, I am concerned that this may actually represent the absence of the ability to detect the virus strain, which could mean that the true impact of this strain is yet to be seen. Adding to concerns, there have been several recent deaths in Southeast Asia and Africa caused by avian flu. This issue underscores the need for greater investment in health systems in Africa in particular, and in other developing regions.

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I commend the President for this quantum leap in global health funding. It shows the U.S. understands global health challenges can and do hit home, as we have seen with the outbreak of the H1N1 virus and with the 2007 case of the Atlanta lawyer Andrew Speaker who traveled to Europe and back to the U.S., all while infected with the deadly extensively drug resistant tuberculosis strain, known as XDR-TB.

There is also a geopolitical dimension to the H1N1 outbreak. The World Health Organization cautions that those who are ill should delay international travel, however it warns that "limiting travel and imposing travel restrictions would have very little effect on stopping the virus from spreading, but would be highly disruptive to the global community". Despite this warning, China has reportedly quarantined a number of Mexican nationals living in China. Mexico's response to this was a ban of flights to China.

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We are pleased to be joined by our distinguished panel of government witnesses. First we will hear from Dr. Ann Shuchat, the Interim Deputy Director for Science and Public Health Program at the Centers for Disease Control and Prevention. Our second witness is Dr. Anthony Fauci, Director of the National Institute of Allergies and Infectious Diseases at the National Institutes of Health. Last but not least is Dr. Dennis Carroll who serves as the Special Advisor to the Acting Administrator on Influenza Pandemic at USAID. I will read the witness bios following Members' opening remarks.

I will now turn to our Ranking Member, Mr. Smith for his opening statement.

Mr. SMITH. Thank you very much, Mr. Chairman, for calling this very important hearing on the issue of the recent outbreak of the H1N1 influenza. I am particularly appreciative that our witnesses have taken the time to be with us this morning, as they are extremely busy addressing the current situation in their representative agencies. Thank you for your tremendous service on behalf of all those who potentially could become sick, as well as those who are. In its latest update, the World Health Organization has officially reported 1,516 cases of the influenza, including 30 deaths, 29 in Mexico. This count does not include the death of the first United States resident that is being reported this morning.

Despite that tragic news, it seems that in general, the virus within the United States is no more infectious or deadly than the seasonal flu. It is still uncertain as to why Mexico experienced so many deaths from the Swine Flu and cases in the United States have been relatively mild. In any event, experts are warning that we must remain vigilant and take prudent precautions until more is known about the virus, and there is concern that a more dangerous reemergence of it could occur in the fall.

Our country has benefited from procedures set in place during the Bush administration to respond to such a potential crisis. President Bush implemented the national pandemic strategy in 2005 and the domestic readiness group, a broad interagency panel, which he established to respond to national emergencies and has been active from the beginning of the outbreak. We have been fortunate to have a well-developed system in place for the new administration to utilize, and they have done so well.

However, despite these efforts that have apparently served us well, so far some experts are asserting that we need to be doing even more to prepare for likely pandemics. The National Biosurveillance Subcommittee that was created by a presidential directive in 2008 is expected to release its first report soon. Dr. Larry Brilliant, chairman of that subcommittee, stated in an article published in last weekend's Wall Street Journal that the report concludes that our country and the world do not have adequately early warning biosurveillance capabilities. The NBA subcommittee will be recommending that "governments need far better early warning systems for potential pandemics and other epidemic threats."

Dr. Brilliant added that the subcommittee is also emphasizing that public health be restored to a position of respect and be given resources commensurate with its duty to protect us from these and other threats to our health. I look forward to hearing from our witnesses whether they agree with this recommendation, and if so whether they have concrete ideas as to what actions our Government should undertake to address it. Mr. Chairman, the Global Health Initiative announced yesterday by President Barack Obama could be an early and timely response to this recommendation by the National Biosurveillance Advisory Subcommittee.

In his announcement, President Obama referred to the outbreak of the H1N1 virus and the need to address public health challenges beyond our borders. The additional resources he is proposing could prove extremely useful to help save lives as we all become more aware of the importance of addressing health threats, not only within our own borders, but around the world.

However, the President emphasized that his initiative will be pursuing a "integrated approach to global health," and the administration has indicated that reproductive health is high on its list of priorities. Therefore this new initiative must be assessed in the context of the statements made by Secretary of State Hillary Clinton during a Foreign Affairs Committee 2 weeks ago that this administration's definition of reproductive health also includes access to abortion.

I would note with extreme concern that this announcement follows the President's rescission of the Mexico City policy that prevented taxpayer monies from going to foreign nongovernment organizations that perform and promote abortion as a method of family planning. As you know, Mr. Chairman, the bipartisan support that resulted in the passage of the Tom Lantos and Henry J. Hyde U.S. Global Leadership Act against HIV/AIDS, tuberculosis and malaria last year was the result of a consensus that rejected references to the integration and other linkages of reproductive health services with HIV/AIDS and malaria programs.

Any attempt by this Congress or the new administration to break that consensus and to direct billions of dollars to organizations that kill unborn babies by way of chemical poisoning or dismemberment, and wounding their mothers instead of to organizations and programs that will save lives and improve the health of all children, born or unborn, women and men, will destroy that consensus.

President Obama and his administration should be working to galvanize bipartisan political support to address the major global health challenges of our time, not to channel money to groups that seek to destroy the most vulnerable, the unborn child. I look forward to learning more from the administration as to how they will address this sensitive and extremely important human rights issue. The human rights of the unborn is the human rights issue of our day, and I believe, passionately, that the most persecuted minority in our world today are unborn children.

In his brilliant article, Dr. Brilliant also describes his participation in eradication of smallpox and the importance of pursuing public health initiatives to prevent or end other health threats.

Early in my tenure in Congress, I had personal experience of both the importance and the possibility of making public health a priority even in most difficult circumstances. During the FML conflict in El Salvador in the early 1980s, I visited on several occasions vaccination sites sponsored by UNICEF and the United States during which days of tranquility were agreed to by both fighting factions. For 3 days the fighting stopped on one of those occasions so that upwards of 250,000 children could be vaccinated against polio, measles, diphtheria, tetanus and whooping cough.

Since then, days of tranquility have been implemented in other countries including and Lebanon, Sudan, Iraq and Sierra Leone. This experience impressed upon me the public can be galvanized when people realize that the goal is to save the health and life of children. I am sure the same public will exist to address major health hazards that threaten our global community as a whole. It is extremely important for those of us in Congress to understand the health threats that face our world, including this new virus and the possible means of preventing or eradicating them. And again,

I thank you, Mr. Chairman, and again, I welcome our distinguished witnesses.

Mr. PAYNE. Thank you very much. At this time we will hear from our other subcommittee members. Ms. Woolsey, an opening statement?

Ms. WOOLSEY. Thank you, Mr. Chairman. If everybody else would waive their opening statements, I will because we have a 10 o'clock markup and these nice people have been sitting here.

Mr. PAYNE. Thank you. Dr. Boozman.

Mr. BOOZMAN. I agree.

Mr. PAYNE. Thank you. Ms. Lee. Thank you. Ms. Jackson Lee, do you waive your opening statement?

Ms. JACKSON LEE. Mr. Chairman, I will have to leave for a markup as well, so I will just simply say that because of the two deaths in the United States were in Texas, let me thank the witnesses for the faith they put on this cause. I do think we have a pending pandemic. And I want to thank the chairman for holding this hearing, and I hope to be able to engage with all of you as witnesses. Thank you very much. I yield back.

Mr. PAYNE. Thank you very much. We have a very distinguished panel today. And we will hear from them. Dr. Schuchat, Dr. Fauci and Dr. Carroll. First, Dr. Anne Schuchat, the interim deputy director for science and public health program, has been at CDC since 1988 when she entered the U.S. Public Health Service as an epidemic intelligence service officer. She has made significant contributions to prevent infectious diseases in children through her work, informing vaccine and prevention policies, developing guidelines and disease monitoring systems, conducting pre- and post-licensure vaccine evaluations and collaborating with international, national and state partners to accelerate the availability of vaccine and prevention programs. Internationally she has worked in West Africa on meningitis and pneumonia vaccine studies, in South Africa on surveillance and prevention projects, and in China on SARS emergency.

Dr. Schuchat graduated with highest honors from Swarthmore College and with honors from Dartmouth Medical School. She completed residency training in internal medicine at New York University's Manhattan VA Hospital. She has co-authored more than 180 scientific articles and received numerous awards, including the Public Health Services Meritorious Service Medal, and the Physicians Research Officer of the Year for her contributions to preventing group B streptococcal infections in newborns.

Dr. Schuchat assumed leadership of CDC's National Center for Immunization and Respiratory Diseases in December 2005. In 2006, she was promoted to the rank of assistant surgeon general within the U.S. Public Health Service; and in 2008, she was elected to the Institute of Medicine. In February 2009, she began a detail serving as CDC's deputy director for science and public health program.

Next we have Dr. Anthony Fauci, who has been the director of the National Institute of Allergy and Infectious Diseases (NIAID) since 1984 and came to the National Institutes of Health in 1968. In his position, he oversees an extensive research portfolio on basic and applied research to prevent, diagnose and treat infectious dis-

eases, such as, HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illnesses from potential agents of bioterrorism. NIAID also supports research on transplantation in immune related illnesses, including audio-immune disorders, asthma and allergies.

Dr. Fauci serves as one of the key advisors to the White House and the Department of Health and Human Services on global AIDS issues and on initiatives to bolster medical and public health preparedness against emerging infectious diseases such as pandemic influenza.

Dr. Fauci received his M.D. degree from Cornell University Medical College in 1966 and completed his residency at the New York Hospital Cornell Medical Center. Dr. Fauci has made many contributions to basic and clinical research on pathogenic and treatment immunizing mediated and infectious diseases.

He has pioneered the field of human immunoregulation by making a number of scientific observations that served as the basis for a current understanding of the regulations of the human immune response. In addition, Dr. Fauci is widely recognized for delineating the precise mechanism whereby immunosuppressive agents modulate the human immune response—I am going to end up being a doctor—Dr. Fauci is a recipient of many awards, including the Presidential Medal of Freedom, which is very prestigious, and 34 honorary doctorate degrees from universities.

Finally, testifying on behalf of USAID is Dr. Dennis Carroll, who is the special advisor for the United States Agency for International Development's, acting administrator on pandemic influenza. He also serves as director of the USAID's Avian and Pandemic Influenza Preparedness and Response Unit, which oversees the agency's response to avian and pandemic influenza. From 1991 to 2005, Dr. Carroll served as the senior infectious disease advisor for USAID and was responsible for providing strategic and operational leadership for USAID's infectious disease program. Dr. Carroll has a Ph.D. in molecular biochemistry from the University of Massachusetts at Amherst with a specialized focus on tropical infectious diseases. He was a research scientist at Cold Spring Harbor Laboratory where he studied the molecular mechanisms of viral infections.

At this time now, I will turn to our first witness, Dr. Schuchat.

STATEMENT OF REAR ADMIRAL ANNE SCHUCHAT, M.D., INTERIM DEPUTY DIRECTOR FOR SCIENCE AND PUBLIC HEALTH PROGRAM, CENTER FOR DISEASE CONTROL AND PREVENTION

Dr. SCHUCHAT. Good morning, Chairman Payne, Ranking Member Smith, and other distinguished members of the subcommittee. I am Dr. Anne Schuchat, the acting deputy director for science and program at the Centers for Disease Control and Prevention, and I appreciate the opportunity to speak with you this morning about the current outbreak of a novel H1N1 influenza virus and to focus on the global implications of the outbreak and the steps being taken by CDC and our global partners to mitigate this problem. We share the concern of people around the U.S. and the globe, and particularly those in Texas, who have been impacted by this outbreak,

and are responding aggressively at the international, Federal, State and local level, to understand the complexities of this situation and to implement control measures. Our aggressive actions are possible in many respects because of investments and support of the Congress in U.S. pandemic preparedness, which has provided us with many of the tools we are using today to detect, track and control the outbreak and its impact. This support has also enabled the critical work of State and local public health officials across the country.

In a global context the work of the committee in promoting global health through programs such as PEPFAR and the President's Malaria Initiative have been critical in improving the capacity of health systems that will be relied upon with this outbreak. Once again, we are reminded that global public health is inextricably linked with the health of the American people and that investments in global health have a direct benefit to our own health. I have noted in the written statement some of the important investments we have made in global pandemic preparedness, in global disease detection and the remarkable international collaborations taking place to address the threat from this new virus. In summary, without these global mechanisms to detect disease, share information across the globe and cooperate on response we would not be able to mount the effective response we have carried out to date.

Influenza viruses are extremely unpredictable, making it hard to anticipate the course of this outbreak with any certainty. We have seen an increase in the number of cases and the number of States and the countries affected and we expect more. We are carefully monitoring the severity of illness caused by this virus. While the primary evidence as of today is encouraging we understand that this too could change. Amid this uncertainty, we hope to be clear in communicating what we do know, acknowledge the uncertainties, clearly communicate what we are doing to protect the health of Americans and people around the world and help people understand the steps that they can take to protect their own health and that of their families and their communities.

As we look to the future, we will be looking carefully and are already providing assistance to countries in the southern hemisphere where influenza season is now beginning, both to help them respond and to examine clues about the direction that this epidemic will take. Unfortunately, as with many public health problems, lack of infrastructure and resources mean developing countries in particular can expect to bear a significant burden in this epidemic, and we hope to provide assistance to mitigate the impact that the epidemic may have.

Influenza arises from a variety of sources. And in this case, we have determined that we have a novel 2001—2009 H1N1 virus circulating around the globe that contains genetic pieces from four different virus sources. We have been able to move within 2 short weeks to identify this novel virus, understand the complete genetic characteristics and compare the genetic composition of specimens from U.S. patients to others around the globe to watch for mutations.

We have also with unprecedented speed developed and deployed test kits for use in a widening network of laboratories, both here

in the United States and around the world. These steps, along with capacity in place as a result of effective planning, have allowed for the rapid diagnostics in epidemiology that have contributed to a clearer understanding of the transmission and the current severity of illness caused by the virus. These scientific accomplishments have provided the basis for an evolving set of responses that greatly enhance our Nation's ability to address this threat. CDC has determined that this virus is contagious. It is spreading from human to human, similarly to the way that seasonal influenza spreads through causing or sneezing.

Sometimes people may become infected by touching something with a flu virus on it and then touching their mouth or nose. There is no evidence to suggest that this virus has been found in swine in the U.S. and there have been no illnesses attributed to eating pork or pork products, so there is no evidence you can get this influenza from eating pork or pork products. As of this morning, according to the World Health Organization, a total of 1,516 cases have been confirmed in 22 countries, including Guatemala, which was added to the list today. Here in the U.S., we have 403 confirmed cases and 702 probable cases for a total of 1,105. Aggressive actions are being taken here as well as abroad.

We are working very closely with state and local health officials around the U.S. to investigate and implement control measures. We are providing both technical support on the epidemiology, as well as laboratory support for confirming cases. We are working with our international partners on this outbreak, including a collaborative effort in Mexico to better understand the outbreak to enhance surveillance and strengthen laboratory capacity, and we are working closely with multiple Federal partners to ensure that our efforts are coordinated and effective.

Yesterday we updated our guidance on school closings based on a more clear understanding of the severity of illness. A key message we have from CDC is that there is a role for everyone to play during an outbreak, at the individual level for people to understand how they can prevent respiratory infections, with frequent hand washing, staying home if you are sick, keeping your children home if they are sick and if you are ill not getting on an airplane or taking public transport where you may spread the infection. We think that personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory illnesses. The path this outbreak may take may change and we need to be prepared for a return of this virus here in the U.S. in the fall.

It is important that public officials continue to think about what might be needed if this outbreak deepens in communities here in the U.S. We have encouraged communities, businesses, schools and local governments to make specific plans for how to manage this outbreak if cases appear in their communities and advise parents to prepare for what they would do in terms of their own children's illness. We continually monitor the path and severity of the outbreak and have adapted our guidance accordingly, as we did yesterday with the change in our school guidance. We are mindful that science is a critical component in decision making about how communities respond and that there are many other considerations that communities must evaluate in making appropriate decisions.

Whenever we see a novel strain of influenza, we begin to work toward the development of a vaccine in case one will need to be produced.

CDC is working to develop a vaccine seed strain specific to this novel virus, the first step in manufacturing. We have initiated steps so that should we need to manufacture a vaccine in terms of the U.S. Government's role we can work toward that goal very quickly. And rapid progress will be possible through the combined efforts of CDC, NIH, FDA, BARDA and the manufacturers. Another critical component of our response has been our deployment of the strategic national stockpile of medications and personal protective equipment.

Finally, it is important to recognize that with the strong support of the Congress, there have been enormous efforts in the U.S. to prepare for this kind of an outbreak and a pandemic. Our detection of this strain in the U.S. came as a result of that investment and our enhanced surveillance and laboratory capacity are critical to understanding and mitigating the threat. The investments made in global health and development will prove crucial pieces of the global health system that will be needed to respond.

While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our history have we been more prepared to face this kind of challenge. And as we face the challenge in the weeks ahead we look forward to working closely with you in the committee and Congress in general to best address this evolving situation. Thank you.

Mr. PAYNE. Thank you very much.

[The prepared statement of Dr. Schuchat follows:]

Testimony
Committee on Foreign Affairs
Subcommittee on Africa and Global Health
U.S. House of Representatives

U.S. Global Health Response to a Novel 2009-H1N1 Influenza Virus

Anne Schuchat, M.D.
Acting Deputy Director for Science and Program,
Centers for Disease Control and Prevention
Assistant Surgeon General, U.S. Public Health Service
U.S. Department of Health and Human Services

For Release and Delivery
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Good morning, Chairman Payne, Ranking Member Smith and other distinguished members of the Committee. I am Dr. Anne Schuchat, Acting Deputy Director for Science and Program at the Centers for Disease Control and Prevention. I thank you for the opportunity to update you on current global efforts the U.S. government is taking to respond to the ongoing novel 2009-H1N1 influenza outbreak. Our hearts go out to the people in the United States, in Mexico, and around the globe who have been directly impacted. We share the concern of people around the country and around the globe; and are responding aggressively at the international, federal, state, and local levels to understand the complexities of this outbreak and to implement control measures.

However, I would like to first take a moment to recognize that our nation's current preparedness for both domestic and global public health threats is a direct result of the support of the Congress. In addition to the support for pandemic preparedness and planning, investments that this Committee has supported have been critical. This outbreak is a stark reminder that global public health is inextricably linked with the public health of the American people and investments in global public health have a direct benefit on our own public health. Congressional investment in global public health programs such as the President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative (PMI), and international pandemic influenza preparedness plans has strengthened our global outbreak response efforts. These and other programs have improved health systems throughout the world by building capacity at ministries of health, strengthening disease detection, surveillance, response, and lab capacity, improving sustainability of public health programs, and training and deploying health professionals on the ground. As a result we are better equipped and prepared to handle these new and emerging outbreaks. For that, we thank the Committee and the Congress for your support.

It is important for all of us to understand that flu viruses – and outbreaks of many infectious diseases -- are extremely unpredictable. As with any public health investigation, our response has evolved as our investigation proceeds and we learn more about the situation. We have seen an increase in the number of cases and the number of states affected, and we can expect more. We are carefully monitoring the severity of illness caused by this virus – and while preliminary evidence is encouraging, we understand that this, too, could change. Our goal in our daily communication – to the public, to the Congress, and to the media – is to continue to be clear in what we do know, explain uncertainty, and clearly communicate what we are doing to protect the health of Americans. It has also been a clear priority to communicate the steps that Americans can take to protect their own health and that of their community. As we continue to learn more, these communications and our guidance to health care providers, schools, businesses, and the public has changed and will continue to evolve.

Influenza arises from a variety of sources; for example, swine influenza (H1N1) is a common respiratory disease of pigs caused by type A influenza viruses. These and other animal viruses are different from seasonal human influenza A H1N1 viruses. As you know, from laboratory analysis performed at CDC, we have determined that there is a novel 2009-H1N1 virus circulating in the U.S. and around the world that contains genetic pieces from four different virus sources. This particular genetic combination of H1N1 influenza virus is new and has not been recognized before in the United States or anywhere else worldwide. Additional testing is being done on the virus, and several isolates have undergone complete genetic sequencing. As a result

of our investment in pandemic preparedness, we have been able to move within two short weeks to identify a novel virus, understand its complete genetic characteristics, and compare the genetic composition of specimens from US patients to others around the globe to watch for mutations. We have also quickly developed and (working with FDA) deployed test kits for use in a widening network of laboratories. These steps, along with capacity in place as a result of effective planning, have allowed for the rapid diagnostics and epidemiology that have contributed to a clearer understanding of the transmission and severity of illness caused by the virus. These scientific accomplishments have provided the basis for an evolving set of responses that greatly enhance our nation's ability to address this threat.

CDC has determined that this virus is contagious and is spreading from human to human. It appears to spread with similar characteristics as seasonal influenza. Flu viruses are thought to spread mainly from person to person through coughing or sneezing of people with influenza. Sometimes people may become infected by touching something with flu viruses on it and then touching their mouth or nose. There is no evidence to suggest that this virus has been found in swine in the United States, and there have been no illnesses attributed to handling or consuming pork. In addition, the World Health Organization, the World Organization for Animal Health, the Food and Agriculture Organization, and the World Trade Organization have made it clear that there is no evidence that one can get this novel 2009-H1N1 influenza from eating pork or pork products. Of course, it is always important to cook pork to an internal temperature of 160 degrees Fahrenheit in order to ensure safety.

I want to reiterate that as we look for cases, we are seeing more cases. We fully expect to see not only more cases, but also more cases of severe illness. We have ramped up our surveillance around the country to try and get a better understanding of the magnitude of this outbreak. As we look to the future, we will be looking carefully (and are already providing assistance) to countries in the Southern Hemisphere where peak flu season is now beginning; both to help them respond, and for clues about the direction of this epidemic.

Let me provide for you an update in terms of the public health actions that are underway in the United States and abroad.

GLOBAL RESPONSE

On the investigation side, we are working very closely with public health officials around the world. As of May 3rd, CDC has deployed 16 staff to Mexico including experts in influenza epidemiology, laboratory, health communications, emergency operations including distribution of supplies and medications, information technology and veterinary sciences. These teams are working under the auspices of the Pan-American Health Organization / World Health Organization (PAHO/WHO) Global Outbreak Alert and Response Network and a tri-lateral team of Mexican, Canadian and American experts. The teams are working to better understand the outbreak, including clinical illness severity and transmission patterns, and answer critical questions such as why cases in Mexico initially appeared to be more severe than those that were first seen in the US. CDC's Emergency Operations Center is hosting liaisons from PAHO, the European Centre for Disease Prevention and Control (ECDC) and the China CDC to facilitate

coordination and collaboration. In addition, health communications support is being deployed to Guatemala.

We're providing both technical support on the epidemiology as well as laboratory support for confirming cases. We are also assisting Mexico to establish more laboratory capacity in-country; a critical step in identifying more cases on which to base our epidemiological investigation into the spread and severity of this new virus.

I would also like to use this opportunity to discuss CDC's Global Disease Detection Program, commonly known as GDD, which has not only been vital in dealing with the current situation but has also laid a foundation for the US to respond to infectious disease outbreaks globally. Established by Congress in 2004, GDD develops and integrates epidemiologic, laboratory, surveillance, veterinary, medical, and public health programs and resources. This integrated approach reduces the time it takes to identify and control public health risks. By working together, these programs are achieving greater results than any one program could alone. In coordination with a network of partners, GDD works globally within six core capacities: 1) Identifying and responding to emerging infectious diseases, 2) Improving pandemic influenza preparedness and response, 3) Strengthening capacity for zoonotic disease investigation and control, 4) Expanding training in field epidemiology and laboratory methods, 5) Focusing on health communication and information technology, and 6) Strengthening laboratory systems and biosafety.

GDD's Regional Center in Guatemala is providing evidence that this new virus is expanding south of Mexico. It is also serving as a regional laboratory for influenza A testing and is processing samples from suspected cases and identifying those that need further investigation, including additional testing at CDC laboratories. Other GDD Centers in Kenya, Thailand, Kazakhstan, Egypt, and China have increased their surveillance and laboratory testing activities for respiratory diseases and influenza-like illnesses and are sharing valuable surveillance information for those illnesses. These GDD Centers are also providing regional leadership.

Many countries lack the resources and health infrastructure to meet the World Health Organization's International Health Regulations (IHR), designed to develop the capacity and systems to detect, contain, and report health threats with the potential for international spread. GDD helps to close this gap by building and linking public health assets globally to contain emerging disease threats to support the WHO and uphold the IHR. Our six GDD Regional Centers function as members of the Global Outbreak Alert and Response Network during emergencies. When a CDC field response is indicated, the GDD Operations Center assists through access to CDC and world-wide resources. In non-emergency settings, the Centers work with country partners to implement disease detection and response trainings, protocols, and interventions.

In addition to GDD, in partnership with other agencies including USAID, CDC funds more than 30 countries in pandemic preparedness to improve countries abilities to detect and respond to pandemic influenza. Those investments have made us better prepared for an influenza pandemic than at any other time in history; though as always we have much more work to do.

CDC has over 2000 staff in more than 45 countries including contractors and locally-employed staff. These staff work side by side with staff of ministries of health to increase their public health capacity including high quality, sustainable laboratory infrastructure that is key to rapid detection and response to emerging infectious diseases. Over the past several weeks, CDC staff have been called upon repeatedly by embassies and ministry of health to provide emergency response leadership and coordination.

CDC's Global Health and Emergency Risk Communication Team is also responding to ongoing global requests for communication assistance, and providing daily updates, talking points and emergency risk communication materials to WHO, its regional offices, CDC field offices and counterparts in the Mexican and Canadian governments as requested.

In response to the current H1N1 situation, CDC is providing its real-time PCR protocol and kit for detection and characterization of swine influenza free of charge to any public institution anywhere in the world, and is providing laboratory testing of specimens which are not able to be characterized in their country of origin.

In addition to our close collaboration with WHO and affected country governments, CDC is working closely with other US government agencies. In this international response, we are working closely with the Department of Defense, Department of State and USAID. CDC has had staff assigned as a liaison to USAID working first specifically on influenza planning and now on response, and staff within CDC's Emergency Operations Center are in daily contact with USAID experts in Washington. Finally, CDC overseas field staff are sharing information and working closely with our embassies and USAID missions overseas in terms of preparedness and response in their host countries. As an example of our collaboration, CDC is hosting a visit tomorrow from our partners in the Department of State and USAID to discuss this outbreak.

In terms of travel advisories, CDC continues to evaluate incoming information from WHO, PAHO, and other governments to determine the potential impact of the outbreak on international travel. On Monday, April 27th, CDC issued a travel health warning for Mexico, and this remains in effect. With this warning, we recommend that travelers postpone non-essential travel to Mexico for the time being. CDC is also evaluating information from other countries and will update travel notices for other affected countries as necessary. As always, persons with flu or flu-like symptoms should stay at home and should not attempt to travel.

DOMESTIC RESPONSE

CDC has and will continue to develop specific recommendations for what individuals, communities, clinicians, and others professionals can do. It is important that people understand that there is a role for everyone to play during an outbreak. At the individual level, it is important for people to understand how they can prevent respiratory infections. Very frequent hand-washing is something that we talk about time and time again and that is an effective way to reduce transmission of disease. If you are sick, it is very important to stay at home. If your children are sick, have a fever and flu-like illness, they should not go to school. And if you are ill, you should not get on an airplane or any public transport to travel. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other

respiratory illnesses.

The path of this outbreak may change; and we need to be prepared for a return of this virus in the fall. It is important that we (in partnership with state, local, tribal, and territorial officials) continue to think about what might be needed if this outbreak deepens in communities across the US. We have encouraged communities, businesses, schools, and local governments to make specific plans for how to manage this outbreak if cases appear in their communities, and advised parents to prepare for what they would do if faced with temporary school and child care center closures.

We also have additional community guidance so that clinicians, laboratorians, and other public health officials will know what to do should they see cases in their community. All of these specific recommendations, as well as other regular updates, are posted on the CDC web site – www.cdc.gov.

We continually monitor the path and severity of this outbreak, and have adapted our guidance accordingly. We are mindful that science is a critical component in decision-making about how communities respond – and that there are many other considerations that communities must evaluate in making appropriate decisions.

We will continue to provide support to states and communities throughout this outbreak. In addition to the epidemiologic and laboratory support that CDC provides, CDC maintains the nation's Strategic National Stockpile of medications that may be needed for this or other outbreaks. As part of our pandemic preparedness efforts, the US Government has purchased extensive supplies of antiviral drugs -- oseltamivir and zanamivir – for the Strategic National Stockpile. Laboratory testing on the viruses so far indicate that they are susceptible to oseltamivir and zanamivir. Acting quickly after we identified this virus and its potential impact on our population we have released one-quarter of the states' share of antiviral drugs and personal protective equipment to help them prepare to respond to the outbreak, and exercising emergency use authorities to facilitate their effective use. As of Sunday, May 3rd –within weeks of a new virus having been identified – this deployment of the stockpile was completed for all states and areas. Last week the Secretary announced that HHS will purchase an additional 13 million treatment courses of antiviral drugs which will more than replace those that have been dispensed from the SNS. States also have purchased millions of additional treatment courses of antiviral drugs with support from an HHS subsidy program.

Whenever we see a novel strain of influenza, we begin our work in the event that a vaccine needs to be manufactured. The CDC is working to develop a vaccine seed strain specific to these viruses – the first step in vaccine manufacturing. This is something we often initiate when we encounter a new influenza virus that has the potential to cause significant human illness. We have isolated and identified the virus and discussions are underway so that should we need to manufacture a vaccine, we can work towards that goal very quickly. HHS discussions to consider the needed pathways to provide rapid production of vaccine after the appropriate seed strain has been provided to manufacturers are currently ongoing. As this progresses, HHS operating divisions and offices including CDC, NIH, FDA, and ASPR/BARDA will work in

close partnership. Additionally, as a WHO Collaborating Center, CDC provides influenza vaccine seed strain, at no cost, to vaccine manufacturers.

That said, returning to global public health for a moment, in resource-limited settings, such a new vaccine is not likely to be widely available. This situation will require coordinated planning and efforts across the US Government and with other international and private sector partners to leverage new and existing global health resources to implement local community mitigation measures and provide other supportive measures as needed.

CONCLUSION

In closing, we are simultaneously working hard to understand and control this outbreak while also keeping the public and the Congress fully informed of the situation and our response. We are working in close collaboration with our federal partners including our sister HHS agencies and other federal departments, including those that have unique expertise that helps us provide guidance for multiple sectors of our economy and society, as well as our international partnership with WHO and ministries of health. While events have progressed with great speed, this will be a marathon, not a sprint. Even if this outbreak yet proves to be less serious than we might have initially feared, we can anticipate that we may have a subsequent or follow-on outbreak several months later down the road. Steps we are taking now are putting us in a strong position to respond.

The Government cannot solve this alone, and as I have noted, all of us must take constructive steps. If you are sick, stay home. If children are sick, keep them home from school. Wash your hands. Take all of those reasonable measures that will help us mitigate how many people actually get sick in our country.

Finally, it is important to recognize that there have been enormous efforts in the U.S. and abroad to prepare for this kind of an outbreak and a pandemic. The Congress has provided strong support for these efforts. Our detection of this strain in the United States came as a result of that investment and our enhanced surveillance and laboratory capacity are critical to understanding and mitigating this threat. While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our nation's history have we been more prepared to face this kind of challenge. As we face the challenges in the weeks ahead, we look forward to working closely with the Congress to best address this evolving situation.

Mr. PAYNE. Dr. Fauci.

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGIES AND INFECTIOUS DISEASES, NATIONAL INSTITUTE OF HEALTH

Dr. FAUCI. Thank you very much, Mr. Chairman, Ranking Member Smith, members of the committee, thank you for calling this hearing and thank you for giving me the opportunity to briefly describe for you today the role of the NIH's research efforts in addressing the problem that we are facing now with the H1N1 new novel influenza A. On this first visual I would like to first take a brief moment to describe the difference between what we call seasonal flu and pandemic flu. As you see on this visual, the influenza virus is made up of a number of components. We identify influenza by two proteins on its surface called hemagglutinin and neuraminidase, and hence, the terminology H and N and the designation here of H1N1; and seasonal flus also have H3N2.

Each year, we have a relatively predictable annual occurrence of seasonal flu that from one year to another may modify slightly in what we call a drift, a little bit different from one year to another, which necessitates sometimes a modification of our seasonal influenza program for vaccination. However it doesn't change enough to leave the population vulnerable with no background immunity. Rarely in the last century—three times—we have a major change which we refer to as a shift. This situation is unpredictable. And the population is naive to this particular virus because they have never had any personal experience with it. That is the case that we are facing now with the novel H1N1.

But before we go on, it is important to put into context seasonal influenza which is underappreciated as a serious issue with 36,000 deaths each year in the United States and about 200,000 excess hospitalization and significant economic impact. The concern we all have is that will this turn into a pandemic. So if you look on this slide here, there were three historic pandemics in the 21st century. One which was catastrophic, the 1918, what we call Spanish flu, in which about 50 million people died worldwide. In 1957 was another new virus that was moderately severe. And in 1968 was the first time we saw the H3N2, which, in fact, was relatively mild in the sense that it wasn't significantly different than what we see in a regular seasonal flu.

So the point to be made is that pandemics occur for sure, but they vary widely in their degree of severity. So now quickly moving on what about the NIH and what we are doing in partnership with our sister agencies, the CDC and the FDA, our responsibility is the basic and clinical research. As shown on this slide, what we do is founded in a basic research study and research resources which we make available to the academic research community and the pharmaceutical companies. We also have clinical research networks that allow for clinical trials. All of this is directed to the ultimate goal of developing countermeasures in the form of therapeutics, diagnostics and vaccines. So, quickly, we will start with basic research.

The CDC, as you have heard from Dr. Schuchat, has already isolated and characterized the virus and made it available to the NIH

as well as to giving us the opportunity to make it available to our grantees and contractors to study intensively. And when we say study intensively, we do sophisticated work on delineating the molecular analysis or the molecular fingerprints that might predict which way this virus may go, because as you have heard, it is quite unpredictable; studies on transmissibility in animal models such as the mouse, the ferret and the nonhuman primate; how the virus might molecularly evolve; and importantly its pathogenesis and virulence, what are the molecular correlates for it being a very virulent virus or not; and finally, relevant to vaccine development, what kind of immune response does it elicit and what kind of immune response is protective.

On the next visual, you see the map of the United States showing the network of a Vaccine and Treatment Evaluation Units which will be used in clinical trials of pilot lots that will be made from the seed viruses that the CDC is now growing in preparation for the multi-step process of developing a vaccine, which is shown on this next slide. It is a very well-delineated process that we go through when we develop a vaccine for any microbe, in this case, influenza. First you get the virus. The CDC has done that. You start to grow it up as a reference strain or aseed virus. This allows the further growth. And in this case we get that seed virus which is currently now being grown by the CDC and will be made available to the pharmaceutical companies to grow up for what we call pilot lots.

A pilot lot is tested in humans for three things: Is it safe, does it induce an immune response that you would predict would be protective, and thirdly what is the right dose and dose regimen, how many doses would you need? The decision to scale up and manufacture tens of millions of doses has not been made at this point, nor has any decision been made regarding the administration. We are just in the early part of the step-wise process of developing a vaccine. And on this final slide I just want to reiterate what we said in the very beginning. The relationship between the preparedness of seasonal influenza versus pandemic influenza. What we learn from one we apply to the other and vice versa. We had a pandemic plan from 2005 which we have implemented. And the resources that have been put in thanks to the Congress and your support for us have allowed us to be at the level of preparedness where we are right now. Thank you very much. I would be happy to answer questions after. Thank you.

[The prepared statement of Dr. Fauci follows:]

Testimony
Committee on Foreign Affairs
Subcommittee on Africa and Global Health
United States House of Representatives

The Role of NIH-Supported Research in the Response to 2009-H1N1 Influenza

Statement of
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Mr. Chairman and members of the Subcommittee, thank you for the opportunity to discuss the NIH research response to the public health threat that the Nation and world face with regard to outbreaks of the novel 2009-H1N1 influenza A virus, which was initially referred to as "swine flu."

Over the past several years, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS), has conducted a major research effort that builds on long-standing programs related to seasonal influenza in order to improve our preparedness for pandemic influenza. Although we have focused a good deal of attention recently on H5N1 avian influenza, it always has been clear that the next pandemic threat could come from another influenza virus altogether.

That threat is now upon us. In response, NIH has closely reviewed the research agenda that underpins the development of countermeasures for all influenza subtypes, but the 2009-H1N1 in particular. NIH plans to invest more than $200 million in various types of influenza research, including H1N1 this fiscal year.

In my remarks today, I will outline what is known about the basic biology of this virus and discuss the research response being mounted by NIH that is synergistic with—and complementary to—the efforts of other components of HHS such as the Biomedical Advanced Research and Development Authority, and in particular of our sister agencies, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), as well as other organizations around the world.

Seasonal and Pandemic Influenza

Influenza viruses affect many animal species, including birds, pigs, and humans. As influenza viruses circulate, the genes that determine the structure of their surface proteins undergo small changes called mutations. These discrete mutations accumulate to cause a gradual "antigenic drift" that allows an influenza virus in a typical influenza season to substantially evade immunity that was developed from prior exposure to influenza viruses or from vaccination. Antigenic drift in human influenza viruses is the basis for the predictable patterns of seasonal influenza seen in most years and is the reason that we annually reassess the strains to be included in the seasonal influenza vaccine.

In humans, seasonal influenza epidemics in the Northern hemisphere usually occur in winter months. These seasonal events cause symptomatic illness in 15 to 60 million people in the United States every year; they result in an average of about 200,000 hospitalizations and 36,000 deaths. With seasonal influenza, some residual or background immunity may exist in the population due to prior exposure or vaccination. This background immunity tempers the number of illnesses, hospitalizations, and deaths we see every year. Most of the severe

outcomes from seasonal influenza occur among people aged 65 years and older, in very young children, and those with chronic health conditions. Globally, seasonal influenza causes 3 million to 5 million cases of severe illness each year, and an estimated 250,000 to 500,000 influenza-related deaths, according to the World Health Organization.

Influenza viruses also can undergo more extensive changes that lead to what is called an "antigenic shift," and these can pose a more serious threat to human health. One way antigenic shifts occur is through humans acquiring a novel influenza virus from a non-human source. For example, influenza viruses infecting birds can, on rare occasions, also infect humans. Although the result is usually a "dead-end" infection that does not spread further, the virus might undergo mutations that allow limited human-to-human transmission. Once transmission begins, further mutation can make human-to-human transmission more efficient and sustainable. Another way that antigenic shifts occur is through a process called reassortment, in which two virus strains co-infect a host and exchange genes. Whatever the mechanism, the result may be the evolution of a new virus to which the human population has little or no immunity. If this new virus is able to efficiently transmit from human to human, then an influenza pandemic may result. Pandemic influenza is an unpredictable and rare event that can occur at any time of year.

In the 20th century, influenza pandemics occurred three times—in 1918, 1957, and 1968. The pandemics of 1957 and 1968 were serious infectious disease events that killed approximately two million and 700,000 people worldwide, respectively. The 1918-1919 pandemic, however, was catastrophic: epidemiologists estimate that it killed more than 50 million people worldwide, including more than 500,000 people in the United States, and caused enormous social and economic disruption.

Given this history, we long have expected that a new influenza virus would emerge and another pandemic would occur. As you know, the U.S. Government, and HHS in particular, has been preparing for an influenza pandemic for a number of years. These efforts were bolstered after H5N1 avian influenza reemerged in Southeast Asia in 2003. U.S. Government pandemic preparedness plans assign to the NIH the primary responsibility for scientific research and clinical trials needed to develop and test pandemic influenza vaccines and therapies.

NIH long has supported basic influenza research to understand better how influenza viruses replicate, interact with their hosts, stimulate immune responses, and evolve into new strains. Results from these basic research studies lay the foundation for the design of new antiviral drugs, diagnostics, and vaccines, and are applicable to seasonal epidemic and pandemic strains alike. NIH has worked with our partners in the biotechnology and pharmaceutical industries to speed

development of new influenza vaccines, diagnostic tools, and anti-influenza drugs. We also have built a substantial infrastructure of research centers, NIH intramural and NIH-supported extramural laboratories, highly trained personnel, and clinical research networks to rapidly conduct research should a virus with pandemic potential emerge.

A virus with clear pandemic potential, the 2009-H1N1 influenza virus, has now emerged. NIH is fully engaged in an accelerated effort to understand this virus and rapidly develop countermeasures. Scientists already have learned a great deal about the biology of the 2009-H1N1 virus, and we are taking all possible steps to learn more. NIH also is fully engaged in carrying out its mandate in developing vaccines and testing therapeutics to counter this newly emerged viral threat.

Basic Science

Scientists at CDC, FDA, NIH, NIH-supported laboratories, and elsewhere around the world have obtained samples of the 2009-H1N1 virus from the CDC. The complete genome sequences of numerous viral isolates already have been determined. Our studies tell us that this is a very unusual virus: its particular genetic combination of influenza virus segments has not been recognized before in the United States or elsewhere. As you know, the new 2009-H1N1 strain has been infecting humans. Although it is clear that the virus can be transmitted from one person to another, it is not yet known precisely how efficient transmission is. We also are now aware that pigs can become infected with the virus as well. Research is ongoing to understand the precise circumstances surrounding the origin of this strain.

When news of the emergence of 2009-H1N1 influenza first broke, NIH immediately began a thorough and rapid characterization of the virus in cell culture and laboratory animals in addition to participating with HHS agencies in assessing the immediate needs for further investigation. That effort includes intramural researchers on the NIH campus, researchers in preexisting NIH research networks such as the Centers of Excellence in Influenza Research and Surveillance (CEIRS) and Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), as well as industry partners and individual NIH grantees. We anticipate that these efforts will rapidly yield important information; for example, which animals the virus can infect, the mechanisms by which the virus causes disease, the viral molecular signatures of virulence and enhanced transmission, and the major viral and host factors important in mounting an immune response to the virus. NIH also has developed clinical protocols in New York and Texas to collect clinical samples from patients with 2009-H1N1, and the NIH Clinical Center has geared up to accept patients for participation in research protocols—should that be necessary. These and other anticipated clinical studies will provide crucial information about how the virus behaves in humans, how the human immune system responds to it, and how

much cross-protection, if any, is provided by antibodies to previously circulating human H1N1 viruses.

Vaccines
Generation of viral seed stocks in preparation for developing a vaccine against the 2009-H1N1 virus is proceeding rapidly. Making full use of our multifaceted research infrastructure, we are now working with our partners at HHS and in industry on the next stages in the multistep process of developing a vaccine against this novel virus.

Two types of vaccines are currently licensed for use in the United States. Inactivated vaccines are based on chemically killed influenza viruses and are injected intramuscularly. Live, attenuated vaccines are based on a weakened influenza virus engineered to contain the hemagglutinin and neuraminidase genes of a circulating influenza strain and are given as a nasal spray. Both require culture of virus in chicken eggs. The first step in creating both kinds of vaccines, now underway in CDC, FDA, private sector, and NIH-supported laboratories, is the development of virus reference strains suitable for use in manufacturing. These seed viruses will then be used by manufacturers to produce pilot vaccine lots suitable for testing in humans. NIH will use its longstanding vaccine clinical trials infrastructure—notably our network of Vaccine and Treatment Evaluation Units—to quickly evaluate pilot lots of vaccine candidates to determine whether the vaccine is safe, its ability to induce protective immune responses, and the appropriate dose and number of dosages. All systems are "go" for this stepwise process.

Adjuvants are additives that help create a more vigorous immune response to a vaccine, thereby reducing the amount of antigen required per vaccine dose. Results from clinical trials of candidate pre-pandemic avian influenza vaccines indicate that one adjuvant increases the immune response and could reduce the required dose. This adjuvant may be clinically evaluated in a 2009-H1N1 vaccine, and several other adjuvants are currently under development as well, but vaccines containing these novel adjuvants are not currently licensed in the United States.

NIH and its industry partners have been developing several other kinds of influenza vaccines that are not yet licensed for use. These include recombinant DNA technologies that yield subunit vaccines, in which various influenza virus proteins are selectively grown in cultured cells that are then purified and used in a vaccine; DNA vaccines, in which harmless influenza genetic sequences are injected directly into a person to stimulate an immune response against the proteins coded for by these genetic sequences; and approaches that insert the genes of influenza virus into a different, harmless virus (a "vector") that is used as a vaccine. Studies to create prototype 2009-H1N1 influenza vaccines that rely on these experimental strategies are underway. However, because these

"next-generation" vaccines will require additional safety and efficacy testing before they can be deployed, they are unlikely to reach the public before the more traditional types of vaccines described above.

Antiviral Therapies and Diagnostics
Antiviral medications are an important counterpart to vaccines as a means of controlling influenza, for treating infection after it occurs and, under certain circumstances, for preventing infection prior to or immediately after exposure. Although the 2009-H1N1 virus is sensitive to oseltamivir (Tamiflu®) and zanamivir (Relenza®), experience tells us that resistance to influenza antiviral medications frequently emerges. Indeed, over the past two years the circulating seasonal H1N1 influenza viruses have become oseltamivir-resistant, even while other influenza viruses have remained sensitive to the drug.

In recent years, NIH has been working to develop and test the next generation of influenza antivirals. Three drugs are now in clinical testing, including a long-acting neuraminidase inhibitor, an inhibitor of the enzyme that replicates viral genes, and a drug that prevents the virus from entering human lung cells. We will soon begin to evaluate how well these candidate antiviral drugs block the 2009-H1N1 strain and to screen other compounds for activity against the virus.

Improved methods of diagnosing 2009-H1N1 influenza infection at the point of care would be of substantial value in the months ahead, helping to differentiate people with the new influenza strain from those with other conditions who present with similar symptoms. Prompt and precise point-of-care diagnosis would help slow spread of the virus and maximize the efficiency with which stockpiled antivirals are used. NIH has been developing diagnostic platforms capable of rapidly identifying a wide variety of pathogens in clinical samples, including specific subtypes of influenza, and we are now working to accelerate development of these platforms to provide improved diagnostics for 2009-H1N1.

Shared Research Resources
When infectious diseases emerge, NIH serves an important role in providing materials, support, and expertise to researchers and the public health community. These resources include blood samples from infected patients, immunological assay reagents, animal models, genomic sequencing and information resources, and isolates of the virus.

NIH intramural and extramural researchers, in turn, depend on materials and information shared by CDC, FDA, and other public health agencies around the world. For example, CDC provided NIH intramural and NIH-supported researchers with samples of the 2009-H1N1 virus, while NIH is making available to CDC researchers archived blood samples from people vaccinated in the 1976 swine influenza outbreak as well as influenza reagents from an NIH research

reagent repository. From my perspective, the coordination and cooperation between government agencies, and with private industry, has been outstanding.

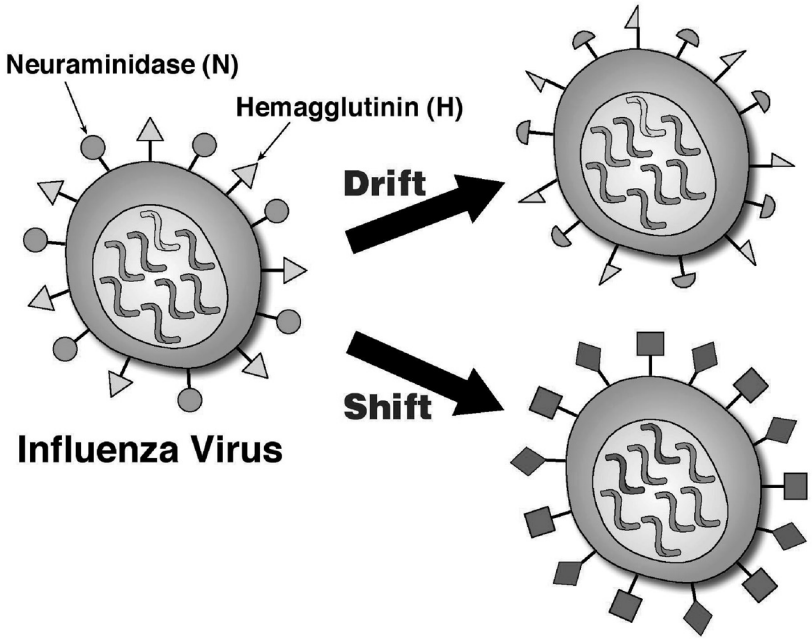
Conclusion

It is important to recognize that we are only in the earliest stages of understanding how the 2009-H1N1 influenza virus emerged and what impact it might have. Influenza viruses are highly unpredictable, and it is unwise to make predictions about how a virus might behave in the future. For example, although the virus at this time has caused mostly relatively mild disease in this country, we do not know whether that might change in the coming months. Nor do we know whether the virus will become resistant to the antiviral drugs we have stockpiled. In short, we simply cannot predict at this time whether the emergence of the 2009-H1N1 virus will prove to be a relatively limited event, or whether it could develop into a major global pandemic either in the immediate future or during a period of seasonal influenza. The NIH and other government agencies are acting to prepare for any possibility.

Our ongoing, collective efforts to prepare for an influenza pandemic—with research, vaccine manufacturing infrastructure, antiviral drugs, public health measures, efficient infection control, and clear public communication—have given us a valuable advantage in the serious situation we face today. I very much appreciate the support that Congress has provided over the years to achieve this level of preparedness.

I would be pleased to answer any questions you may have.

Seasonal vs. Pandemic Influenza



Seasonal Influenza

- Predictable annual occurrence
- Residual immunity in population

Pandemic Influenza

- Unpredictable rare occurrence
- “Naïve” population

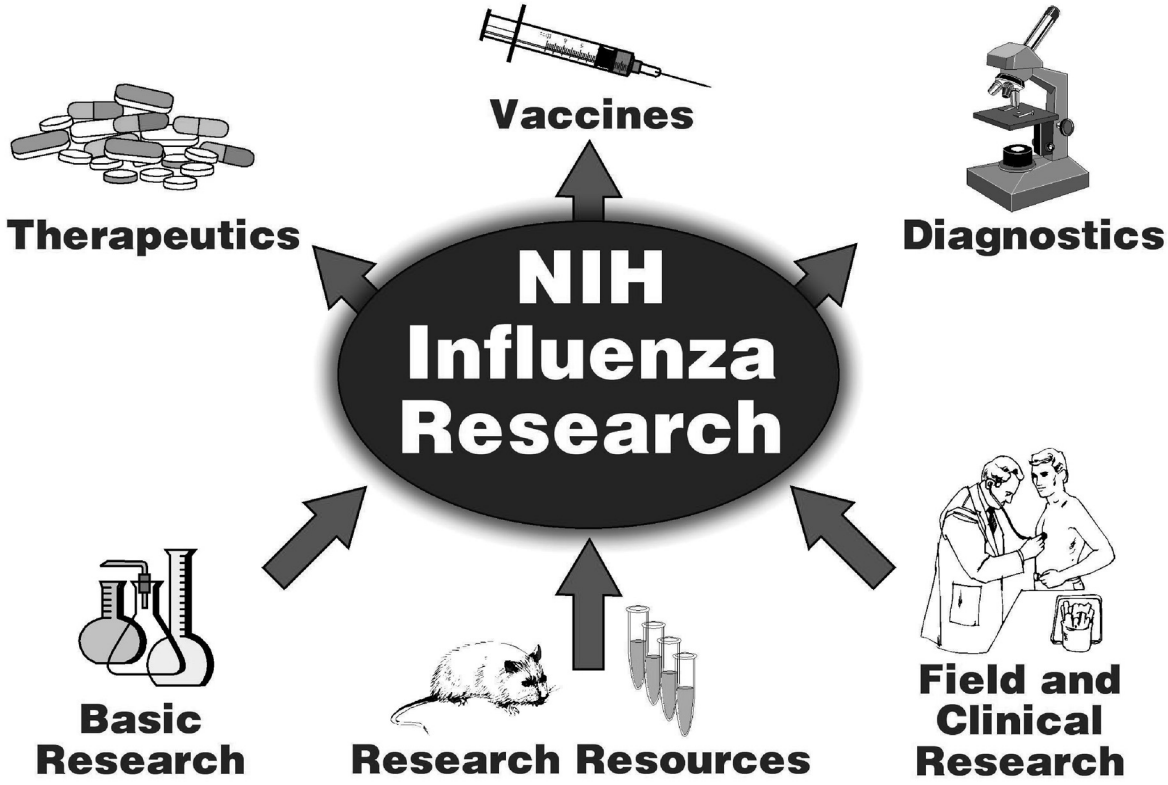
The Burden of Seasonal Influenza

- 250,000 to 500,000 deaths globally/yr; 3-5 million cases of severe illness
- 36,000 deaths and >200,000 hospitalizations/yr in U.S.
- $37.5 billion in economic costs/yr in U.S. related to influenza and pneumonia

Sources: CDC, WHO, Am. Lung. Assoc.

Influenza Pandemics in the 20th Century

1918	H1N1	“Spanish Flu”	>50 million deaths
1957	H2N2	“Asian Flu”	1-2 million deaths
1968	H3N2	“Hong Kong Flu”	700,000 deaths


NIH
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Basic
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Research Resources
Field and
Clinical
Research

Basic Research on the 2009 H1N1 Influenza Virus

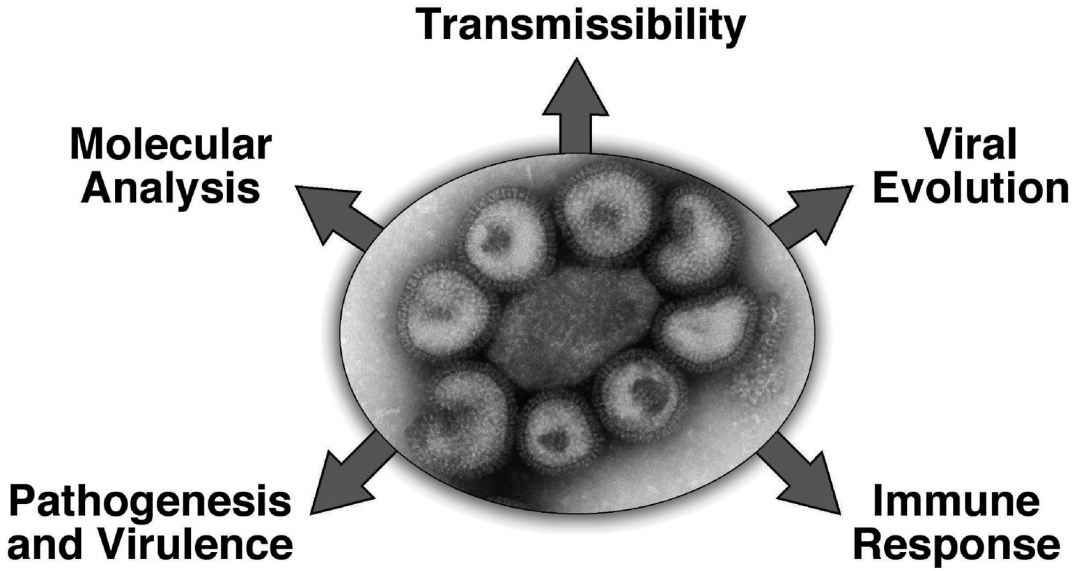
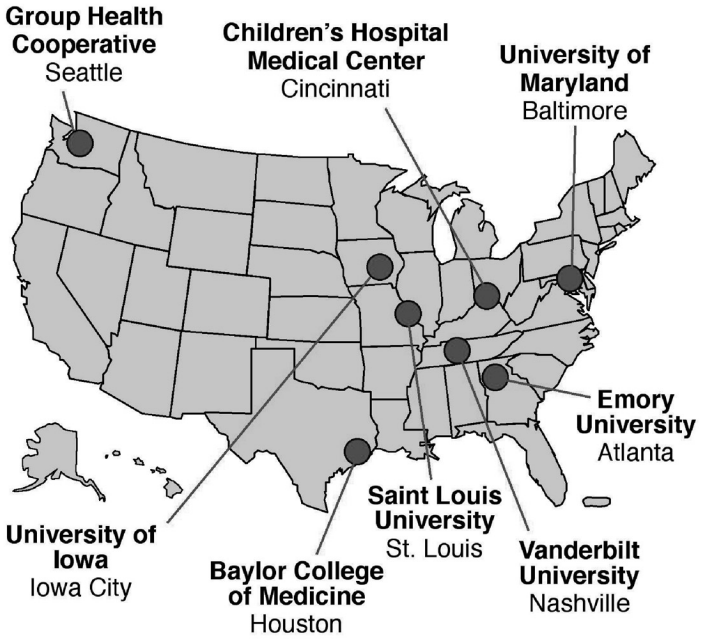


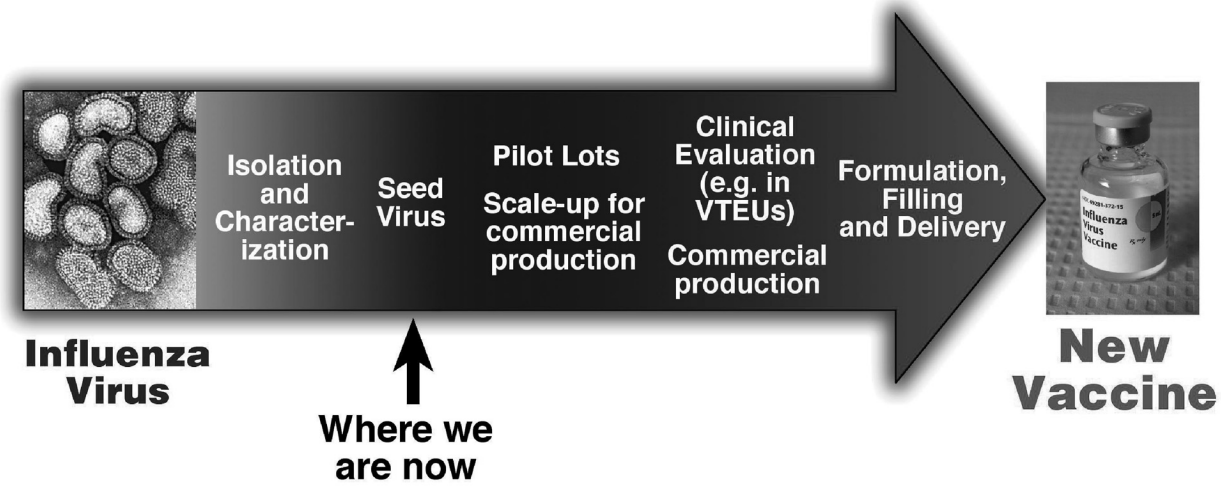
Photo: CDC

NIH's Network of Vaccine and Treatment Evaluation Units (VTEUs)



- Established in 1962
- >160 Phase I, II, and III clinical trials since 1995
- Trials of
  - Seasonal vaccines
  - Pre-pandemic vaccines
  - Antivirals

H1N1 Influenza Vaccine Development: A Collaborative Process



Pandemic
Influenza
Preparedness
Seasonal
Influenza
Preparedness

Mr. PAYNE. Thank you very much.

STATEMENT OF DENNIS CARROLL, M.D., SPECIAL ADVISOR TO THE ACTING ADMINISTRATOR, ON PANDEMIC INFLUENZA, UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT

Dr. CARROLL. Chairman Payne, Representative Smith and other distinguished members of the subcommittee. First off, I would like to thank you for convening this committee. I think we all appreciate its significance and certainly the topic which brings us here today. But I would also like to extend the thanks of USAID to this committee for the strong support you have provided over the years to our global health program. In my written comments, I discuss at some length USAID's response to the recent events in Mexico as part of the larger effort by the United States Government.

In these remarks today I would like to focus more specifically on two aspects of USAID's overall effort to address the threats posed by a pandemic with a particular focus on USAID's primary responsibility as the international response and humanitarian assistance role that we have. USAID has been helping to prepare for just such an event, as we have seen rollout over the last several weeks, over the past 3 years. And as a previous talker have referred to the efforts underway having to do with H5N1 avian influenza, work that we have been doing since 2005 specifically supported by this Congress, have really established a platform which has allowed significant capabilities that otherwise had not previously been available.

What I would like to do is to just talk about some of those capabilities today and how they may play themselves out in the coming months. First off, in terms of a pandemic preparedness program focusing on global response capabilities: USAID has partnered through a U.N. family of agencies, the International Federation of Red Cross and Red Crescent Societies and a coalition of humanitarian response nongovernmental organizations to work with WHO, our colleagues at Centers for Disease Control and other international partners to focus on 30 countries in Asia, Africa and Latin America that have been specifically identified as countries of high risk consequences in terms of a potential pandemic. And with these countries we have been working to mobilize pandemic preparedness planning. Whereas coordinated efforts to respond to disaster such as pandemics usually begin only after the disaster has occurred, the concerns of a global pandemic caused by avian influenza created an unprecedented opportunity to develop planning and coordination for a pandemic in advance of the event.

Because of this work, a developing country's ability to respond to a pandemic today while still far from perfect will be both better and faster than it otherwise would have been possible in years past. While the world remains at Phase 5 USAID is engaged in several critical activities to help monitor the progress of the H1N1 novel virus and assist countries in preparing for a possible Phase 6 pandemic. These activities include testing—first off, testing the appropriate of national pandemic plans. Just last week, USAID supported a regional pandemic readiness exercise as part of our avian and pandemic preparedness program in Addis Ababa, Ethiopia. Country representatives from seven east African countries

were able to draw from their experiences developing national pandemic plans to test them in real-time context of a possible H1N1 pandemic. We have similar exercises already planned for South African countries in June and Asian countries in August. In addition, USAID is working closely with the Department of Defense and its specific and African combatant commands PACOM and AFRICOM to provide direct military-to-military assistance in these 30 countries across Africa and Asia to strengthen their own readiness, the readiness of the military to work in concert with civilian authorities to ensure the military is fully prepared and capable of executing their responsibilities during a pandemic.

And in just 2 weeks as part of USAID's pandemic preparedness program USAID will co-host with AFRICOM and PACOM and the U.N.'s world food program a joint pandemic preparedness exercise in Rome involving 27 countries and their military representatives from Africa and Asia. USAID will also continue to support activities that directly contribute to tracking the circulation of the novel H1N1 virus in both human and swine populations worldwide.

As noted by President Obama, even if it turns out that the H1N1 virus is relatively mild in the front end, it could come back in a more virulent form during the actual flu season. It is important to note that in the 1918–1919 influenza pandemic, which also began the virus emerged first in the spring relatively mild for 6 months until the second pandemic wave revised in a much more lethal version that October. With the advent of influenza season in the Southern Hemisphere now it will be critical that we are able to monitor changes in the virus' virulence and transmissibility and mobilize effective response should it occur.

USAID has also as part of its avian and pandemic influenza program, which we have now adapted to our H1N1 novel virus response, established an emergency stockpile of more than 800,000 personal protective equipment kits, PPEs that include protective gowns, gloves, goggles and masks, 100,000 of which just this past Saturday arrived in Mexico City, the remaining being equivalently ready for rapid deployment as needed. These kits protect health care providers as well as case investigators.

To date USAID has also prepositioned an additional 400,000 kits in 82 countries for use in the event of a pandemic. But even as we mobilize to respond to the threat of H1N1 or the earlier emergence of the H5N1 avian influenza virus, it is important that we appreciate that their emergence is indicative of a broader dynamic that over the past half century has given rise to a steady stream of new and increasingly deadly diseases that originate in animals. In fact, 75 percent of all new emergent diseases that have emerged in the past 50 years their origin are animal.

Having already identified this rising threat as a major new area of focus USAID coincidentally announced last Wednesday at a conference we had organized a new emerging pandemic threats program using Fiscal Year 2009 monies which we plan to have fully launched by October of this year, this program which we will initiate in strong collaboration with our colleagues from the Centers for Disease Control and prevention, as well as our colleagues from the U.S. Department of Agriculture, is intended to support the de-

velopment of a global early warning system for the threat posed by diseases of animal origin that infect humans.

The objective of this new program is, in fact, a preempt for combat at their source the emergence of new diseases of animals such as H5N1, H1N1 or even the earlier SARS or HIV that pose significant threats to public health. I need to be very clear that this effort builds on the agency's ongoing work for H5N1. Clearly the platforms which have been supported by this Congress to respond to H5N1 has given us new capabilities and understandings to address these threats and mobilize a global response that should allow us to better predict and respond and in effect put the canary back in the mine shaft.

In closing, let me say that even as we do not yet know how severe the novel H1N1 pandemic will be or how long it will last, as the lead U.S. agency for foreign disaster assistance we will continue to provide emergency support to countries in response to this threat. However, even in the face of the immediate threat posed by H1N1 recent history has been very clear on a core lesson, we must remain vigilant in our response to the larger threat posed by emerging pandemic diseases if we are to be able to ensure a secure future for the world's population. Thank you very much.

[The prepared statement of Dr. Carroll follows:]

TESTIMONY OF DR. DENNIS CARROLL
SPECIAL ADVISOR TO THE ACTING USAID ADMINISTRATOR ON PANDEMIC INFLUENZA
U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

BEFORE THE
SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH,
COMMITTEE ON FOREIGN AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

May 6, 2009

Chairman Payne, Representative Smith, and other distinguished members of the subcommittee. I would like to thank you for convening this important hearing on the 2009-H1N1 influenza outbreak and for inviting me here today.

Since early April, cases of human infection with the Influenza A H1N1 virus have been confirmed in at least 21 countries, as of May 5. On April 29, 2009, the World Health Organization (WHO) raised its pandemic alert level to Phase 5, indicating sustained human-to-human spread of a novel virus in two countries in one WHO region. It is important to note that the WHO phases refer to geographic spread rather than severity. We do not know whether this outbreak will become severe or remain mild. Additional work is underway to determine the virulence of this virus.

Based on the growing threat of an influenza pandemic and in close coordination with other U.S. Government (USG) agencies including the Department of Health and Human Services (HHS), the Department of Defense, and the Department of State, the U.S. Agency for International Development (USAID) has mobilized critical resources to help control the spread of the 2009-H1N1 virus. USAID has provided $5 million in support to WHO and the Pan American Health Organization to bolster disease detection and control efforts in Mexico, where the first 2009-H1N1 cases were detected. Additionally, this past Saturday USAID sent 100,000 sets of personal protective equipment (PPE) to Mexico to help protect disease surveillance workers and first responders from contracting or spreading the virus.

USAID is also providing support to the United Nations Food and Agriculture Organization (FAO) to conduct surveillance in swine in Mexico and other parts of Central America to determine if swine are infected with this virus. In addition, the USAID team in Mexico has been working in close coordination with the Department of Health and Human Services to facilitate the delivery of 400,000 treatment courses of Tamiflu to Mexico.

Even as we have provided immediate assistance for the events in Mexico, we have also been moving aggressively to ensure the rapid mobilization of all necessary Agency resources to address the potential global consequence of a pandemic. On May 1, USAID's Acting Administrator, Mr. Alonzo Fulgham, established an Agency-wide 2009-H1N1 Influenza Task Force to ensure that issues related to the mobilization of all necessary USAID resources are addressed as quickly as possible. We will be focused on assisting countries around the globe as appropriate to:

1. restrict the spread of the 2009-H1N1 virus,
2. reduce the mortality and social and economic impact from the disease, and,
3. respond to emergency needs in countries affected by the virus as needed.

In addition, USAID's Office of Foreign Disaster Assistance (OFDA) and Bureau for Global Health activated a Washington, D.C.-based response management team to coordinate the United States Government's international humanitarian response to pandemic influenza, facilitate information sharing, and provide assistance through international and domestic agencies to limit the spread of the 2009-H1N1 virus. USAID/OFDA has prepared a Pandemic Response Plan targeting the humanitarian needs of 1 billion people in the developing world. This plan builds directly on the Pandemic Preparedness platforms that USAID has been developing in 30 countries over the past two years.

While the current situation regarding a possible 2009-H1N1 influenza pandemic is of concern, it is important to note that due to the work over the last three years, pandemic preparedness measures are in place at the international level. In a statement on April 29, WHO Director-General Margaret Chan noted that the world is more prepared for an influenza pandemic now than at any time in history. This is in large part, she emphasized, due to the investments made over the past several years in responding to the pandemic threat posed by H5N1 avian influenza.

Since 2005, USAID has invested $543 million to build capacities in more than 50 countries for monitoring the spread of the avian influenza virus among wild bird populations, domestic poultry, and humans and to mount rapid and effective containment of the virus when it is found. USAID has also made significant efforts to support more than 30 countries to prepare plans to respond to a possible influenza pandemic. Recent analyses indicate that U.S. Government and international efforts to control the threat posed by the avian influenza virus have contributed to a significant reduction in the number of reported poultry outbreaks and human infections, and a dramatic reduction in the number of countries affected. At the peak of its spread in 2006, avian influenza had been reported in 53 countries across three continents. With the end of the 2008/2009 transmission season only nine countries were affected. Four of the affected countries, three of which were in Asia, accounted for more than 90% of all reported outbreaks. Although these apparent successes are significant, avian influenza remains a serious threat: it continues to spread in poultry, the mortality rate among infected humans

remains above 60%, and the potential for it to again spread rapidly across the globe and cause a human influenza pandemic remains.

As noted earlier, USAID has been helping prepare for just such an event for the past two years. Through a focused partnership with the UN family of agencies, the International Federation of Red Cross and Red Crescent Societies and a coalition of non-governmental organizations, the level of preparedness to respond to a WHO Phase 6 pandemic (if declared) has been significantly improved in 30 countries across Africa, Asia and Latin America. Whereas coordinated efforts to respond to disasters usually begin only after the disaster has occurred, the concerns of a global pandemic caused by the avian influenza virus created an unprecedented opportunity to develop the planning and coordination for a pandemic in advance of the event. Because of this work, developing countries' ability to respond to a pandemic, while still far from perfect, will be both better and faster than what would otherwise have been possible.

USAID has engaged in several critical activities to help monitor the progress of the 2009-H1N1 virus and assist countries in preparing for a potential Phase 6 pandemic. Those activities include:

Testing the Appropriateness of National Pandemic Plans: Just last week, USAID supported a regional pandemic readiness exercise as part of our Avian and Pandemic Preparedness Program in Addis Ababa, Ethiopia. Country representatives from seven East African countries were able to draw from their experience developing national pandemic plans to test them in the real-time context of a possible H1N1 pandemic. We have similar exercises already planned for South African countries in June and Asian countries in August. In addition, USAID is working directly with the Department of Defense and its Pacific and Africa combatant commands, PACOM and AFRICOM, to provide direct military-to-military assistance to 25 countries across Africa and Asia to strengthen their own readiness to respond to a pandemic. In just two weeks, as part of USAID's Pandemic Preparedness Program, AFRICOM and PACOM will co-host with the U.N.'s World Food Programme a joint pandemic preparedness exercise in Rome involving 25 countries from Africa and Asia.

Monitoring for Continued Evolution and Spread of 2009-H1N1 in Swine and Humans: USAID will continue to support our international partners' activities that directly contribute to tracking the circulation of the 2009-H1N1 virus in both human and swine populations worldwide. As noted by President Obama, "even if it turns out that the H1N1 virus is relatively mild in the 'front end,' it could come back in a more virulent form during the actual flu season." It is important to note that the 1918-1919 influenza pandemic virus, which also began in the spring, remained relatively mild for six months until the second pandemic wave arrived with a much more lethal version of the virus. With the approach of the influenza season in the Southern Hemisphere it will be critical that we are able to monitor changes in this virus' virulence and mobilize effective response if needed.

Commodity Support for Response to an Influenza Outbreak: USAID has established an emergency stockpile of more than 800,000 personal protective equipment (PPE) kits, which include protective gowns, gloves, goggles and masks. These kits protect health care providers as well as case investigators. To date, USAID has pre-positioned an additional 394,146 PPE kits in 82 countries for use in the event of a pandemic.

At the core of USAID's planned response to a pandemic is the mitigation of mortality through a package of interventions including disease monitoring, prevention, treatment and assuring food security. Should WHO declare Phase 6, indicating a 2009-H1N1 pandemic is occurring, USAID is ready to support several lines of activity in conjunction with WHO and other international partners, including:

Promotion of social distancing and other appropriate behaviors: As in the U.S., public health authorities around the world will need to get appropriate, technically sound messages to their populations regarding respiratory hygiene, social distancing, and other behaviors that should be adopted during an influenza pandemic. USAID has used its extensive experience in behavior change communications to inform and educate people on the ways in which they can reduce risk and avoid becoming infected with a pandemic virus.

Reinforcing hospital and health facility infection control: To date, USAID has oriented most of its activities to the community level, as this is the most effective level from which to conduct most public health control measures. Still, it is estimated that about 40% of ill patients will seek care which will quickly overwhelm health facilities. These facilities should be made safe and secure and not turned into places in which infection can be spread as was the case in the 2003 SARS epidemic. To ensure this, government health facilities will need to institute infection control measures that have already been elaborated by WHO. Through commodity support and technical assistance, USAID can assist countries in the proper methods of infection control in health facilities.

Provision of treatment/management of severe infections related to pandemic influenza: It is important to note that people in developing countries, particularly those who have been displaced, generally have higher morbidity and mortality rates from infectious diseases than people in developed countries due to a variety of factors including crowding, weakened immunity due to other infectious diseases, poor nutrition due to food insecurity and poverty, weak preventive and curative health care services, and suboptimal health education. USAID will support several lines of activity that directly contribute to improving the management of severe infections related to pandemic influenza, and thereby limiting excess mortality, in targeted developing countries.

Food Assistance: In order to prevent people from leaving their homes and communities in search of food during an influenza pandemic, USAID will work with the World Food Programme and other groups to help families maintain continued access to food in adequate quantity and quality. The USG alone cannot provide the funding required to achieve this goal, but together with other donors a large part of the problem can be tackled.

Even as we mobilize to respond to the threat of the 2009-H1N1 virus, or the earlier emergence of the H5N1 avian influenza virus, it is important that we understand that their emergence is indicative of a broader dynamic that over the past half century has given rise to a stream of new and increasingly deadly diseases that originate in animals. Having already identified the rising threat posed by new emergent diseases, USAID announced earlier last month that the Agency will launch of a new Emerging Pandemic Threats Program. In collaboration with other U.S. Government agencies, this program will develop a global early warning system for the threat posed by diseases of animal origin that infect humans. The objective of USAID's new program is to pre-empt or combat, at their source, the emergence of new diseases from animals, such as 2009-H1N1, that pose a significant threat to public health. This effort builds on the Agency's ongoing work to control the threat of the avian and swine influenza viruses and will include four main lines of work: (1) expand our current monitoring of wild birds to more broadly address the role played by wildlife in facilitating the emergence and spread of new pathogens; (2) enhance support for field epidemiological training of relevant animal and human health teams beyond avian influenza to more broadly address the threat posed by other newly emergent diseases; (3) enhance our support for animal- and public-health diagnostic laboratories to more fully address a broader array of infectious disease threats; (4) broaden ongoing behavior change and communications efforts to address high risk behaviors associated with emergent animal pathogens.

In closing let me say, that even as we do not yet know how severe a 2009-H1N1 influenza pandemic will be or how long it will last if Phase 6 is declared. As the lead U.S. agency for foreign disaster assistance, we will continue to provide emergency support to countries in response to the 2009-H1N1 influenza threat. However, even in the face of the immediate threat posed by the 2009-H1N1 virus, recent history has been very clear in its core lesson - we must remain vigilant in our response to the larger threat posed by emerging pandemic diseases if we are to ensure a secure future for the world's population.

Mr. PAYNE. Let me thank all of the panelists for your very insightful testimony. I will yield to the gentlelady from Texas who says she has to leave to conduct a hearing herself. And because of the death of a Texan, I will yield to let her ask a question before she leaves.

Ms. JACKSON LEE. Thank you, Mr. Chairman. I will, in essence, put these two questions on the record and probably will not be able to be here for the response, but I would greatly appreciate the response because I believe Texas has been the epicenter, particularly for its proximity to Mexico in the increasing number of cases that we seem to be determining. One, what will be the reimbursement procedures for health facilities, the clinics and city and county health entities that have been in the midst of this? And I convened a meeting of these individuals last Friday and they do have a long litany. Two, will you continue to provide the, I believe it is the laboratory resource network 1-day testing confirmation which is urgent?

And three, will you as we move into the graduation season our school districts in Texas, universities, are in a flux about whether or not these large venues will be allowed to continue? And I would very much thank you for the answers to those questions. Mr. Chairman, thank you very much and I yield back.

Mr. PAYNE. Thank you. We will now hear from the ranking member, Mr. Smith, and then we will hear from Representative Woolsey who also indicated she has to leave. If you want to go first Mr. Smith said that he would yield to you.

Ms. WOOLSEY. I don't have to go right yet. I have about 5 minutes.

Mr. PAYNE. All right. Then I will yield to the ranking member.

Mr. SMITH. Thank you. Again, I want to thank our very distinguished witnesses for the great work you are doing, but also the insights you are providing to the committee today. First, Dr. Carroll. The USAID reported that the humanitarian pandemic preparedness initiative convened a 3-day conference or exercise to improve the capacity to avert and respond to the pandemic in east Africa. You indicated that some other similar types of exercises are likely to occur. What kind of deficiencies are we gleaning from that exercise as they exist among some of these countries? You talked about some 800,000 personal protective equipment kits being deployed. And I would suspect that is for the health care workers especially so that they can go out and do their work without contracting the disease. But what was learned in terms of any gaps that need to be fixed from those exercises.

Dr. CARROLL. Congressman Smith, thank you very much for this question. And in fact, it is an important one because from a humanitarian response perspective, having the opportunity to prepare for a disaster in advance is a rare opportunity. For tsunamis or earthquakes, we are usually in a reactive mode. And one of the critical challenges and frequently one of the critical failures of an emergency disaster response is poor coordination. One of my colleagues who specializes in emergency response has frequently commented that when they write on the death certificate, the cause of death, more often than not, it should not be malaria or diarrhea, it should be poor coordination.

I say that point because the exercises in Addis Ababa and shortly in Johannesburg, and then in Ho Chi Minh City are intended to bring national authorities together across civilian nongovernmental and military representatives to arc out and clearly identify roles and responsibilities, to establish in advance coordination principles, and to ensure that the lines of authority and the lines of appropriate action are there, understood and that they have an opportunity in these meetings, such as we just hosted in Addis Ababa, to go through a simulation exercise that allows them to test their plans, identify their weaknesses and then to be able to further improve and refine.

The other advantage of these meetings, these regional gatherings is that there also is significant issues having to do with cross-border movement of populations. And these fora also offer that opportunity for national authorities to interact with each other and to identify what might be some of the critical issues which certainly have arisen in our own situation between the United States and Mexico.

So those are the key issues. I can say Addis Ababa certainly benefited by the timing from H1N1. And we look forward to certainly the activities rolling out in Johannesburg and Ho Chi Minh City, and as I mentioned, we have a similar exercise in Rome with respect to the mill-to-mill activities as well.

Mr. SMITH. Just one quick follow-up. I have some more for the second round. Is any special attention being paid to those countries where the system really is broken, particularly in a dictatorship, particularly in a place like Sudan which could quickly find all of its current problems exacerbated and exponentially confounded by—or compounded, I should say, by a pandemic breaking out.

It seems to me that the vulnerable become even more vulnerable. And what provision—we are talking about stockpiling Tamiflu and other kinds of interventions to help alleviate those who contract it. The developing world and the poor, will they have access to those as well.

Dr. CARROLL. Well, let me say two things: Part of the issue that you talked about was the ability to deliver, delivery services. That is one of the reasons we have gone into a partnership for instance with the International Federation of Red Cross and Red Crescents. They frequently act as a parastatal responsible for humanitarian response. And clearly, when you think about Sudan, they have a critical role to play in countries where governance is clearly an issue. In terms of the services that are looking to be provided, we are right now going through our Fiscal Year 2009 budget, and in particular, looking at our avian and pandemic influenza resources, to see to what extent we might be able to free up resources with an eye toward being able to make immediate contributions to the kind of expanded commodity support beyond that related to the protective equipment that we already have.

And so we are working closely with our colleagues at Centers for Disease Control to identify what those resource needs might be and then look at how we might best be able to address both pharmaceutical and nonpharmaceutical as well as delivery competencies.

Mr. PAYNE. Thank you very much. Representative Woolsey.

Ms. WOOLSEY. Thank you, Mr. Chairman. Somebody has to help me with this, and I think you can, because I don't think I am the only one that is looking for the big picture in questioning how when we have for the seasonal flu 3 million to 5 million people getting the flu every year and internationally 250,000 to 5,000 people dying.

In the United States, the average is 36,000 deaths from seasonal flu. And so far this year, 13,000 deaths. Okay, where along this H1N1 line, where do we get to the point, and what are you looking for until this becomes ho-hum seasonal flu. I mean, because it just seems out of context. Go ahead, Dr. Schuchat.

Dr. SCHUCHAT. Seasonal influenza does have a large toll on health in the United States, despite the fact that we vaccinate many people for it, and that many people are immune already because of exposure to similar viruses. The difference with a new influenza virus like what we see right now is that we don't expect very many people in the general population to already be protected.

So it means everybody is vulnerable. Your question of whether this particular new virus is going to look like seasonal influenza in terms of that 36,000 deaths in the U.S. will it look worse than that, substantially worse than that or not that bad, we unfortunately don't know.

We know that this influenza virus can cause severe disease just like the seasonal strains can, and we know that it is easily transmissible, as we have seen in the New York City school outbreak, and so forth. But we don't know whether over the weeks ahead it will just fizzle out or not come back in the fall season or whether it will mutate and become a bit more severe or whether it will have a similar amount of severity as it has right now. If it keeps this similar severity, we are concerned that among the people who are sick and who are becoming hospitalized are younger persons who don't usually get hospitalized with flu, seasonal flu.

So unfortunately, we don't have that crystal ball and with influenza, a new strain in particular, our predictions really need to be cautious.

Dr. FAUCI. Just to add to that, Congresswoman Woolsey, as we have said all along, influenza viruses are inherently unpredictable anyway. When you have a virus that you have never had experience with before, that compounds the unpredictability. So I don't think any of us are going to feel this will become ho-hum, as you said. We have to continue to watch what it is doing and what happens in the fall and winter. So there are a lot of things that we are still uncertain about, as Dr. Schuchat said. So I don't think this will become a ho-hum thing. Even if it remains relatively mild and acts like a seasonal flu, we are going to be watching this very carefully.

Ms. WOOLSEY. Mr. Chairman, just a remark because I do have to leave. I was in Tanzania over the Easter break. The women giving birth have to bring their own gloves to the clinics and their own supplies. How are you going to distribute these kits? I just can't see how that can happen.

Dr. CARROLL. Thank you. Congresswoman, obviously it is a challenge. There is no question about that. Africa has been a remarkable challenge in terms of meeting the infrastructure needs, and

the human resource issues plaguing the health systems there are enormous. Quality control issues are a major challenge. Let me say we have drafted an initial plan about service delivery, part of it having to do with infection control within health facilities, within the various settings that you are talking about. So part of this review we are going through right now is to really focus in on those countries where we feel the vulnerabilities are greatest and what lines of action questions take. Infection control, as you were describing, right now is clearly a major issue. So we will be working with our international and U.S. colleagues to assess how we can most effectively do this in an environment, as you know, that is very, very challenging.

Ms. WOOLSEY. Thank you, Mr. Chairman.

Mr. PAYNE. Thank you. Congresswoman Lee.

Ms. LEE. Thank you very much, Mr. Chairman, and good morning. I want to thank all of our witnesses for being here and presenting your very clear and succinct testimony. Let me ask you, going back to the continent of Africa, noting that there have been no reported H1N1 diagnoses, surveillance we know is an issue on the continent. What health care systems in terms of labs, in terms of health care workers is an issue? Infrastructure. What do you think is going on on the continent? Can we anticipate cases or do we believe that for whatever reason there just are no cases on the continent of Africa, and also what should we be doing?

And I was just reading the President's statement, which I think is a great statement, and I am going to also commend him for his leadership because we all recognize that not only is this a public health emergency and a humanitarian crisis, but also a national security issue that we have to recognize as such. And this is the way to address it within a comprehensive fashion. So in terms of the continent of Africa, what do you think are some of the key investments that we need to make to really begin to address this in a big way in terms of the spread of this disease and other diseases, and also what do you think the real reason is that we don't see any signs yet on the continent? And none of the countries, as I look at this chart, have any cases at all.

Dr. SCHUCHAT. I can start with the issue of what is going on in Africa. One of the values of the investments that have been made in global health is the international network that we have on—the CDC has people in over 45 countries working on a variety of issues, things like PEPFAR, polio eradication, measles, and our Global Disease Detection Program, and we have been holding very frequent phone calls with all of our international staff to both share information of what is going on here and learn from them situational awareness of what is happening. Also they have facilitated our providing these diagnostic kits for the new virus so laboratories in some of these countries will be able to test right there without shipping to one of the WHO labs or here to the U.S. at the CDC. We don't yet have confirmed cases from Africa, but I share your suspicion that that doesn't mean they haven't happened yet. There are lots of variables in terms of temperature and populations and travel.

So where the disease has been confirmed so far, it has been related initially to travel exposure to Mexico. At this point, with dis-

ease in the United States and Europe and New Zealand and many other places, the risk for Africa continues. So one of the issues is how do we find out what is going on, and I think that is through our investments in laboratory capacity, epidemiologic capacity, training, so that the next generation in these countries will be able to detect and respond, communication and information technology, so that we can know what is going on and share that information, and really the governance that allows the different networks to interact. We are working not just with the CDC network, with the WHO network, with Pasteur Institute, of course with the USAID missions.

So I think that—and then the other comment is that some of Africa is in the Southern Hemisphere, where we would expect a reverse season from what we are seeing. In particular, we have a strong collaboration with South Africa, which does have very good laboratory capacities, and that is a place we are going to be looking intensively to understand whether this virus emerges in the summer.

Mr. CARROLL. And if I might add to the answer, I think it is reasonable to assume that this virus will show up in the subcontinent of Africa. The problem of detecting it will be significant. There are steps—your question really had a two-part component, temporal component. What can we do now to make sure we can pick up this virus at the earliest possible moment for the purposes of being able to track it, monitor it, and deliver life saving interventions as needed? But the second part of your question had to do with seeing this as symptomatic of a broader array of challenges within Africa in terms of picking up new diseases and being able to respond.

Specifically, I can tell you two things about that from USAID's side and again with our partnership with Centers for Disease Control. We are looking to have a consultation with CDC next week that will hopefully include WHO and FAO. That will identify immediate actions that we can take and part of this reprogramming of some of our resources will be specifically asking: How can we make investments immediately with resources on hand to increase the likelihood of picking up this virus? So create a better, more focused and coordinated effort toward that end.

The second part of the question has to do with the broader issue of being able to pick up diseases before they become large public health threats within the region. I mentioned to you that we have launched an Emerging Pandemic Threats Program. This is a 5-year down payment program that has as a central part of it investing in a network of laboratories within Africa, specifically intended to increase our ability to diagnose both within animal and human populations new emergent pathogens that we will be in a better position to signal when something novel is occurring and help us to more effectively respond. So that is part of a systems approach toward responding to the larger, more long-term challenges.

So two-part, immediate consultations, reprogramming funds, and creating an opportunity to diagnose now and take simultaneous steps for the longer term.

Mr. PAYNE. Thank you very much. At this time, we will hear from Congresswoman Watson.

Ms. WATSON. Thank you, Mr. Chairman. And one thing I would ask of the witnesses, can you get to the media and ask them to stop identifying this as Swine Flu? I think that educating the general public about this new strain is very, very important. And as I monitor the media, both written, television, and radio, they are referring to it—that gets people in an uproar, and it is not Swine Flu. So if you could help us with that, I would appreciate it.

Let me direct this to Dr. Fauci. I understand there are two vaccines already, Tamiflu and Relenza, that are on the market that are sensitive to H1N1. But how close are we—and all of you can jump in—to finding a particular vaccine that would be specific to H1N1?

Dr. FAUCI. Thank you for the question, Congresswoman Watson. Tamiflu and Relenza are treatments that are used to treat people who get infected to mitigate the severity of disease, and sometimes used as prophylaxis to prevent. Your question about vaccines is one that we have already started the process on, the multi-step process toward developing a vaccine. And as this—I don't think you heard it in my opening statement, but very briefly what happens when you get into a situation like this is you isolate and characterize the virus. The CDC has already done that. They are currently in the process of developing what we call reference strains or seed viruses. Seed viruses are grown up for the purpose of collaborating with our pharmaceutical company partners, to give it to them so that they can start growing it up in large amounts for two reasons, sometimes in parallel. It is to develop what we call pilot lots of a vaccine. We are not there yet because we are still at the process of the seed virus growing up to be able to give to them. Pilot lots are then put into what we call clinical trials by the company themselves or more often than not by the NIH's clinical trial network to determine three things. Is it safe, does it induce the kind of immune response that would be predictive of being protective, and what is the right dosage and number of doses? At that point then you have the option, a decision that has not yet been made, of scaling up a manufacturing, what we call manufacturing scale-up of tens of millions of doses. You then make a decision at an another critical point in that process—what you are going to do with it. Are you going to administer it, what are you going to do? So right now the very earliest of the stages of that step-wide process has already begun.

Ms. WATSON. Thank you for the information. I am a bit confused as to who is most susceptible. Is this H1N1 a flu or strain of flu running across age levels or young people, middle age, older people? I have heard several different things over the media.

Dr. Schuchat.

Dr. SCHUCHAT. Sure. Of the cases that we have confirmed here in the United States, they are primarily in the age groups of 5 to 50. This is different from the usual influenza season where we see a lot of disease in seniors as well. We don't know yet whether this disease will become quite common among older persons or whether people over 50 may have some protection against this virus, perhaps because of viruses they saw when they were young or perhaps because of other factors. But it is also possible that in the U.S. the virus first emerged in teenagers and young adults and their social

networks are such that they are spreading to each other before we eventually see disease in older age groups.

So right now we don't see the pattern of lots of hospitalizations in very older people and very young people. Even the hospitalizations that we have primarily are in that group of 5 to 50.

So it is confusing because the seasonal flu doesn't look that way in terms of the risk groups we talk about. I would say, though, that we do have some information already that people with underlying medical problems might be at higher risk in terms of our hospitalization data. It is very preliminary, but as we review those data we do note that some of the people who are requiring hospitalization have underlying medical problems that would be classical risk factors for influenza.

So unfortunately, I gave a really long answer, unfortunately it is early and things may change. But right now we have a little bit of difference with the seasonal flu and a little bit of similarity with the underlying diseases.

Ms. WATSON. And finally, some of the schools—I am out in Virginia—are opening back up. Parents are very confused and they want to be able to plan their lives, and I know that is kind of improbable at this particular time. But some of the smaller schools, the private schools are staying closed.

What does that indicate?

Dr. SCHUCHAT. This is a challenging time for families and communities because information is changing quickly and of course when our children are involved that hits right to the heart. The CDC has been working with the State and local public health officials on the response. We issue guidance to—always saying that local and State decisions really are important because of the circumstances in the community, the locals have so much more information than we do. Yesterday we announced updated guidance that the schools that were closed could reopen and that people could really focus on making sure sick children stay home and that the teachers and parents are attuned to whether their children are ill and we try to keep the ill children out and let the other children benefit from school and school lunches, and so forth.

So I think it is a challenging time and each of those school authorities are making decisions hopefully in conjunction with the local public health officials. There are other circumstances, like whether the teacher has left town and is able to be back and reopen. So I do think in the next several days there will be variability. And we want to make sure that as we find information we get it out and people can react appropriately.

Ms. WATSON. Thank you. Thank you, Mr. Chairman.

Mr. PAYNE. Thank you. Dr. Schuchat, you mentioned in your testimony that CDC funds over 30 countries in pandemic preparedness to improve their ability to detect and respond to pandemic flu. Would you be able to tell us generally what countries these are that you are funding?

Dr. SCHUCHAT. Yes. We actually—I believe for influenza we either directly or indirectly support more than 50 countries. Some of that is through a person assigned to work in the country, either with the World Health Organization or the Ministry of Health. Some of that is through cooperative agreements where we provide

funding for the countries and some of it is through networks that we are part of. We can provide the committee a list of the countries. Originally we had some priority countries related to where the H5N1 virus, the avian flu virus, was emerging, primarily in Asia and some in Africa. We have actually expanded to make sure that we have support really to all of the developing country regions, often through the World Health Organization regional offices, sometimes through PAHO.

So even though our eyes were really keenly pointed toward Asia, we have been working with Latin America on the pandemic preparedness. But we will be able to offer you a list of the individual countries. We do have a number of countries in Africa, and we have 11 countries in the Southern Hemisphere that have gotten support from us.

Mr. PAYNE. In Europe, what organization do you work with? Is it through the EU or individual countries? What is their CDC/NIH component? Is it the European Parliament?

Dr. SCHUCHAT. There are a number of organizations, and of course that is one of the important aspects of this, is coordinating across the governments. We work with the World Health Organization working in all regions. We also work with the European CDC. Our CDC in Atlanta has secunded an influenza expert to the European CDC in Stockholm, and we have been working very closely with our colleague there over the situation in Europe. We also have liaisons assigned to the FAO and the OIE related to all of this human-animal interface work and understanding what is going on in the animal populations around the world as well as in the wildlife.

So I think that we are trying to stay connected. A lot of the leadership globally comes from the World Health Organization in Geneva with the Director General Margaret Chan.

Mr. PAYNE. I think I heard you mention some of the military-to-military, AFRICOM, and so forth. Is there any component in NATO since that tends to be a quasi-political although military organization? Have you worked with them in this area?

Mr. CARROLL. Thank you, Chairman. We have not worked with NATO. The reason we are working with AFRICOM and PACOM is that we did essentially a risk analysis. Were there a pandemic virus similar to the one that emerged in 1918, and I can say we did this with the Central Intelligence Agency, we basically identified how that might play itself out around the world in terms of mortality and morbidity using a variety of modeling factors. Those countries largely fall within the Africa and the Asia region. Our focus is clearly going after where the risk is greatest, the burden is maximum.

So where we entered into the agreements with PACOM and AFRICOM is with a focus toward those countries in that region where the vulnerability is greatest. With respect to NATO, that is not something we have direct engagement with.

Thank you.

Mr. PAYNE. Now, with H5N1, everyone was expecting it to come back. And in Egypt, where I think there was a real problem with that, it seems that they went and killed 350,000 pigs. Do you think

it is an overreaction or is it tied into their fear of the H5N1 and whether there could be a connection between H1N1 and H5N1?

Mr. CARROLL. Again, thank you, Mr. Chairman. Let me first off say in terms of the Government of Egypt, we have a very strong and very good program with them, specifically with respect to H5N1, and they have shown extraordinary leadership and effectiveness in their program over the last couple of years. The events over the last week where swine throughout Egypt have been targeted quite frankly is an unfortunate one. There has been no documentation of H1N1. It clearly is an overreaction at this point. And there is no apparent public health value.

We have been in direct consultation with the Government of Egypt with respect to this issue, and we will continue to do so. But our focus remains strengthening their H5N1. And even as we talk about H1N1, this is an issue of H5N1 that we need not lose focus on. It remains a very dangerous virus, mortality rates continue to be in excess of 60 percent. And if I may just add, H5N1 has been one of those success stories over the last couple of years. Were we sitting here 3 years ago in 2006, we would be talking about 53 countries with reported, confirmed outbreaks of H5N1. We have just finished what is in effect the H5N1 transmission influenza season end of April. This past 2008–2009 influenza season, that number has gone from 53 down to 9 countries, and of those 9 countries, 4 countries account for 95 percent of all outbreaks involving animals or humans. So there has been a tremendous progress in terms of moving this virus back, and the platforms that have been invested in for surveillance, for coordinated response, for communications, for laboratory strengthening, those are the very platforms we are looking now to adapt in other parts of the world where the H5N1 is less of a risk now to this broader agenda of dealing with other emergent disease threats.

So the support you have provided quite frankly has been hugely successful, led to huge success with this respect and the U.S. Government across the board has played a disproportionate leadership role in delivering support for this global effort. Egypt continues to be a point of concern.

Mr. PAYNE. Thank you. My last question, and I will yield back to the ranking member. Dr. Fauci, I am just curious. The 1918 flu had just come out and, you know, 50 million deaths resulted. There was nothing like it before and nothing like it after. Is there the potential for another Spanish flu type? Or what was so peculiar about 1918? Do you know—I mean, it was just unbelievable that it caused more deaths than the war going on.

Dr. FAUCI. Well, the answer to that is it gets back to what we had been saying just a little bit ago about the unpredictability of pandemics, the unpredictability of influenza, particularly when you have a brand new virus to which the community has never been exposed. That was the scenario in 1918 when you had the first H1N1. And as you know, historically it came in the spring and was acting in a way that was not substantially different than what you would expect from a flu. But then it came around in the following fall and winter, came back with—as we say, with a vengeance and was very devastating. We don't know the reason for that. We have studied from a molecular biological standpoint how some of the sig-

natures that might be related to virulence or not are spread. But it still remains a mystery how and why that happened, which is always the case with potential pandemics, which is one of the reasons why we are so vigilant now and we take this seriously and continue to take this seriously. We don't want to get anyone alarmed that it is a 1918 type at all, and I don't think we should even be talking about that. But the fact is when you are dealing with brand new viruses, influenza viruses, to which the population does not have any experience with, no background immunity, you have to have an overabundance of diligence and caution, which is what you are seeing right now in how we are responding right here.

Mr. PAYNE. And just the last point, how was the breakdown of the 50 million here in the United States and Europe?

Dr. FAUCI. There were 500,000 people in the United States who died. The 50 million, 40–50 million were distributed throughout the rest of the world. But in the United States, there were at least 500,000 people who died in the 1918 pandemic.

Mr. PAYNE. Thank you. And we won't talk about it anymore, like you said. We will try to go forward. Thank you.

Mr. Smith.

Mr. SMITH. Mr. Chairman, thank you very much. Dr. Schuchat, if you could with regards to the Global Disease Detection Program, the GDD centers in Kenya, Guatemala, Thailand, Kazakhstan, Egypt and China, do they operate in a regional mode? And are there any countries that are outside of their reign of influence?

Dr. SCHUCHAT. Yes, the intent of the Global Disease Detection Centers is to both work with a country through the Ministry of Health and also to provide regional leadership for training, for laboratory and epidemiologic capacity development. At this point, there are six full GDD centers. There are a few other sites that are carrying out some of the components, but we don't really have the entire globe covered. We are making sure that where we do have these integrated centers, they are able to provide services way beyond the national borders. But there are some gaps probably around the world.

Mr. SMITH. For the record could you provide what countries to date have not been included in that regional coverage? It seems to me an opportunistic infection if all a sudden something breaks out and it goes less than it could have been detected had we had that kind of surveillance. If you could provide that for the record, I would appreciate that.

With regards to our operations in China, what protections—and this would be for all of the countries of course. But I spend an enormous amount of time working on human rights issues, vis-a-vis China, and have grown increasingly alarmed about their—I even had a hearing in this room on the transplantation of organs, which is done routinely in China through the death of the prison or the inmate population. And there is great concern that Falun Gong, political prisoners, other political prisoners become fodder for experimentation. And I am wondering with regards to China in our interface with them, what protection, what kind of best practices, ethical and otherwise, do we insist upon—and this would go for any of our distinguished witnesses—so that human subjects are pro-

tected and the most vulnerable, someone who is a prisoner, is not compelled into signing a disclosure or an informed consent when he or she had no ability to resist and then they become the subject of an experimentation? How do we protect human subjects?

Dr. SCHUCHAT. The CDC has quite a number of collaborations in China, including our Global Disease Detection and Response Program there. And when we are involved in activities, the international standards for human subjects research are always followed. The NIH also probably wants to comment on this, but this is a U.S. Government-wide requirement. We are not allowed to provide funding to entities that don't follow the appropriate institutional review board.

Mr. SMITH. But are we able to exercise a kind of oversight? We know that when it came to drugs, there were some serious problems with drugs that were manufactured in China, even baby toys and children's toys were laden with lead, which raised serious problems about quality control. But the record on human rights in China is an abysmal record. It is beyond poor. It is among the worst in the world. And it would seem to me if we are not checking that ethical standards are being consistently and aggressively applied, human subjects, especially if we get to the point of another Spanish flu-like situation where panic sets in and we have got to find an answer to this becomes the modus operandi, human subjects could very quickly become utilized in experimentation.

Dr. SCHUCHAT. Yeah. The ethics of what we do is vital, and I would say that the exchange in collaborations that we have with China are a very positive step in terms of ability to influence each other and work in a transparent way. We have probably advanced this quite a bit in the past several years.

Mr. SMITH. Could you as a result of this question maybe look into it even further? And I raise that again. Again, we had a guard testify here who Harry Wu smuggled out of the country, who told how they would not kill the prisoner, but then they would kill them, he or she, through a capital punishment regimen, only after they took the desired body parts, mostly internal organs, and we had an enormous amount of collaboration for that. And I would hate for us to be less than vigilant in ensuring that no human subjects are abused, particularly the prison population, political prisoners especially.

Dr. Fauci, did you want to—okay.

With regards to Russia, are they involved with the GDD center? How do we interface with Russia, which could be experiencing——

Dr. SCHUCHAT. One of our centers is in Kazakhstan, so that is the regional place. So some of the places we have established centers are ones where enhancing capacity would be very valuable and other times it has been a place of strategic importance. So our work in Russia is not necessarily through our Kazakhstan center but more bilaterally at this point.

Mr. SMITH. Just briefly because we are running out of time. Dr. Fauci, you mentioned that the H1N1 virus is sensitive to Tamiflu and Relenza. But experience tells us that resistance to influenza and to viral medications frequently emerges. What other potential treatments are in development?

And finally, Dr. Carroll, refugee populations, the 25-plus million who are of interest to the UNHCR High Representative, any special concerns being expressed by the UNHCR working with WHO, with us, to ensure that we don't get a massive outbreak in the close confines of a refugee camp or something like it?

Dr. FAUCI. Let me answer the first question about resistance. That is one of the reasons we have a very active and aggressive program of drug screening and drug development. There are already a number of compounds that are in the pipeline, some of which are being tested, some of which are in preclinical development to try and, as we say, keep a pipeline of drugs available in the eventuality that we might see resistance. And we have seen resistance, on and off, to various anti-influenza drugs through the regular pandemic flu season. Fortunately, we have not been in a situation where there has been resistance to all of them. There has been resistance to one or the other. But the precise answer to your question is that is the precise reason why we have a very active drug development and screening program.

Mr. CARROLL. Congressman Smith. Thank you very much for the question about the vulnerability of refugee and migratory populations. It is clearly a major one. And I mentioned in my comments that part of our strategy for pandemic preparedness was to enter into an alliance with the family of the United Nations that includes, in fact, UNHCR and IOM. In addition to the 30 countries that we are working with to develop pandemic preparedness plans and test those out, we have been working explicitly with UNHCR and IOM to make sure that the large populations of refugees that fall within the world have adequate planning capability and identification of needs. So we have been working very aggressively with them, and it is a major part of our effort and they are a major recipient of support from us.

And I might just add that today in Paris, yesterday and today in Paris, all of our U.N. and international partners are in fact, including UNHCR and IOM, are explicitly addressing the issues of refugee populations and migratory populations.

Mr. PAYNE. Thank you very much.

Representative Lee.

Ms. LEE. Thank you, Mr. Chairman.

Dr. Schuchat, at the end of your testimony—let me just read you one paragraph. You said the government cannot solve this alone and, as I have noted, all of us must take constructive steps. If you are sick, stay home. If your children are sick, keep them home from school, wash your hands, take all of those reasonable measures that will help us mitigate how many people actually get sick in our country.

I read this and I said, okay. Is this a teaching moment? And I say that because these are standards that we should follow each and every day in terms of public health, in terms of prevention, in terms of making sure that transmission of infections and diseases are reduced.

And so one is, is this a teaching moment? Can we mount a public information campaign so that people understand how to prevent the transmission of other types of infections and diseases? And

also, secondly, is there anything else we need to do as it relates to H1N1?

Dr. SCHUCHAT. Thank you for that comment. The advice about hand washing and these sort of basic guidances are prudent for this particular virus, but as you say, they are also helpful for other respiratory infectious diseases, and we are very pleased that the Harvard poll results came out a few days ago and said that 59 percent of Americans say that they are washing their hands more than they ever did in the past. I think it is going to be important to sustain that type of behavior, not just when you are fearful because you are bombarded on TV, but over the long haul because it can really help a lot of infectious disease transmission.

I think there is another thing we can do long term. It is really important for people to know that seasonal influenza is an important public health problem. We hope this new H1N1 strain will not become more severe and cause lots of problems, and, of course, we are working aggressively to attend to what needs to be done in the short term. But year in and year out, 36,000 people die from seasonal influenza in the U.S., and we do have a better vaccine manufacturing capacity than ever and we really want people to know they can protect themselves from that infectious disease year in and year out. A lot of steps in play for vaccine development work against this new strain. But that is the kind of long-term guidance that we think is important.

Ms. LEE. But with this new strain, are there any additional precautionary measures that people should take?

Dr. SCHUCHAT. The other thing that is important is to plan ahead. The behavioral advice we have made about washing hands and stuff will help with reducing respiratory infections, but if we do see a substantial increase in illness, hospitalizations and social disruption, we think people need to be prepared for how they are going to manage that kind of disruption in the family or the workplace. We are also reminded we are coming into hurricane season, tornado season, these types of things and knowing how to handle the types of disruptions with your family, the family communication plan, the provisions that you have, the way you are going to stay in touch with people, those are important steps, whatever the disaster or emergency is.

Ms. LEE. Thank you very much. Could I ask one more question of Dr. Fauci? Dr. Fauci, good to see you again.

Of course concerns many of us have regarding the impact of H1N1 now and in the future on underserved communities, particularly communities of color, the uninsured here in our own country, and of course outside of the country. So what steps are we taking to ensure that individuals who are not insured are educated properly with regard to prevention but also have access to the preventive types of measures and the type of treatments, if, in fact, they are uninsured, no insurance and end up in the emergency rooms. You know what I am talking about. So, you know, we have an additional problem here in our own country with 47 million uninsured.

Dr. FAUCI. Well, I am always happy to answer your questions. That is not an area at the NIH that we are involved in. One of the things that has been done, and I think very well, by the CDC is to get the message out broadly to everyone that you possibly can

get to. We always are faced with a system of health care issues in this country and people who are underserved and any disease generally, particularly people in poverty tend to do more poorly than others, and we have seen that with virtually every disease that I have ever testified before this committee for and other committees, and that is just something that hopefully that will improve as we get the health care delivery system better.

Ms. LEE. Thank you very much, Mr. Chairman. Because I think as we look at H1N1 and all these other diseases, within the context of developing a universal health care system, we have to look at how we rev up in communities that are left behind.

Thank you.

Mr. PAYNE. Representative Watson.

Ms. WATSON. Yes. At the end of this month a codel is going down to South Africa to take a project to our library in Soweto, an information center. Possibly if we have a CDC location down in that area, we might take some time. We are going to fly into Johannesburg, and we are going to look at a PEPFAR program relative to USAID's. Since there seems to be no reported cases on the continent, we might want to go to a CDC center and get an update. Do we have a CDC center in that area?

Mr. SCHUCHAT. The CDC has a large program in South Africa based in Pretoria and——

Ms. WATSON. We are going to Pretoria.

Dr. SCHUCHAT. Most of the activities are PEPFAR, TB related. But there is actually influenza work going on as part of the CDC cooperation with South Africa. And if you are in Johannesburg, you would be able to see it right there.

Ms. WATSON. Very good. Thank you.

Mr. PAYNE. Thank you. Overall would you say the CDC's work focuses on building capacity of health systems, particularly in Africa and Latin America? Is that one of your goals?

Dr. SCHUCHAT. We certainly think that improving capacity is vital to the long-term protection of populations in Africa as well as in the United States. So the strategies that we have for our investments and collaborations in Africa are not just one-time interventions but really with a mind toward sustainability. Part of our PEPFAR strategy is to work directly with the ministries of health and really improve their ability to long-term strengthen the health services, the evaluations, the ability to improve policies and such.

So I think that it is a huge mission, but we do try to do our technical support in a way that will be capacity building.

Mr. PAYNE. Thank you very much. How about USAID's work in this area also focusing on capacity building in particular but not just to combat pandemic influenza but overall to combat HIV/AIDS, tuberculosis, malaria, neglected tropical diseases and things of that nature? How does USAID work in this area?

Mr. CARROLL. Thank you, Chairman. First off, I think it is worth noting that the efforts in these countries are all part of a very well-coordinated U.S. Government response. So as we speak about what USAID is doing, I think we also are reflecting what CDC and other colleagues are doing as well. PEPFAR, the President's Malaria Initiative, the TB programs that we are all supporting clearly have at their center the investments in local capacities. These are insidious

diseases. They are only going to be solved if—solved for the long term if there are the local capacities at national, provincial, district, local levels to be able to carry out these activities.

So there is a major investment, and I think it was reflected yesterday in President Obama's announcement. The whole issue of health systems that has been a major area of challenge over the last decade as we have rolled out other programs and understanding and investing in the system capacities to deal with HIV/AIDS, to deal with malaria, that is a centerpiece for our work, for Centers for Disease Control's work as part of these larger programs.

So I think the answer to your question is, yes, capacity building and indigenous strengthening is a part of our program, but I think it is the U.S. Government's program at large.

Mr. PAYNE. Dr. Schuchat, in your testimony you mentioned the CDC's Global Disease Detection Program, the GDD centers in Kenya, Thailand, Kazakhstan, Egypt and China. And Mr. Smith mentioned it also. Do each of these centers have the capacity to detect this H1N1 strain and what other diseases, if they do, can they detect at the center, such as MDR and XDR–TB? And what are we doing to build lab capacity in general as we dealt with MDR and XDR–TB. Once again as you mentioned earlier in your testimony, South Africa had the capacity to have labs. We found out that there are 20 labs in all of sub-Saharan Africa that could detect MDR and XDR–TB and 19 of the 20 were in South Africa and one in the rest of the other 52 sub-Saharan African countries. So there is definitely a disparity and a very lack of ability to really detect. And so when we were trying to determine the severity, we knew the damage that MDR and XDR–TB were doing in South Africa. Archbishop Desmond Tutu sent a letter to me about 2 years ago where he mentioned that at a hospital in Cape Town there were 53 patients that were HIV positive and the MDR strain of tuberculosis was detected in that particular ward. Out of the 53 patients, 52 died within 2 weeks from either MDR or XDR–TB. We got a $50-million additional appropriation—overnight really and then a large amount I think, 400 million or 500 million, to deal with MDR and XDR. But how do we stand in that area?

Dr. SCHUCHAT. One of the strategies for the Global Disease Detection and Response Centers is to strengthen laboratory capacity for the known, but it is also to strengthen the ability to detect the new or unknown. So, yes, we have had respiratory infectious syndromes as a priority for the GDD centers and they have been trained to recognize the typical and then the unusual respiratory infections, including unusual influenza strains, and of course we have recently shipped out these new kits for the novel H1N1 strain. But the centers also work in an integrated way, the laboratory strengthening with epidemiologic and rapid response teams, to really respond when there is an unusual cluster and we don't actually know what it is, so that their investigation will permit us to find the new. One of these sites in Thailand was very helpful in the SARS epidemic in assisting in other countries in that region and understanding what that new particular virus was.

So with infectious diseases, certainly something like MDR–TB is a major concern and a priority. But we also need to be ready for

the new and unpredictable and have high quality, trained laboratory staff who can adapt some of the molecular techniques for one infection and look at others and really know how to work in partnership with reference support.

So I would say that there is lots more readiness that we could have for a long list of important infectious diseases, but it also a strategy of ability to respond to something new and potentially concerning.

Mr. PAYNE. Thank you very much. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman. Just one final question. It was reported that the woman who died this morning apparently attributed it to H1N1 influenza. She was pregnant. She had a cesarean section and her baby was born apparently healthy. Every year, about 4 million babies are born in the United States. If this comes back especially more virulent and our worst nightmare, what thoughts are being given and what precautions are being taken? What special protocols perhaps are being devised to ensure that pregnant women who may need a different kind of case management, if they get sick, are protected as well as their unborn child? We are talking about two patient, mother and baby. I am not sure you could tell us, our committee, is this like HIV/AIDS where HIV contagion can be transferred during the birthing process, and we know that certain drugs can mitigate that which are now mother-to-child transmission has been cutting significantly. So I don't know that answer and I really would like to know. Again this baby was born via C-section. But 4 million kids and their mothers could be at risk if this comes back and depending on how long it does last.

Dr. SCHUCHAT. We know from seasonal influenza and studies in the past that pregnant women are at higher risk for complications of regular influenza, and they are one of the groups that we have always recommended get influenza vaccines each year to help protect them and their babies. The preliminary information that we have right now on the cases in the United States doesn't as of today suggest that pregnant women are at greater risk than the general population. But it is an important issue that we are monitoring. We have also issued interim guidance for care of pregnant women, the ways to diagnose and treat pregnant women, because as you know many medicines are not necessarily tested as fully in that population and yet physicians and their patients need guidance.

The third comment is that the anti-viral drug, Oseltamivir, had not been licensed for use in young children under 1. And one of the things that happened in the past 10 days was an emergency use authorization was approved through the FDA and CDC and HHS so that use of that drug for younger age, not for newborns, but for older babies would be available under certain circumstances.

So I think, though, the vulnerable infants, newborns, the pregnant women are always a concern and influenza is a particular challenge in those populations, but we are trying to stay focused on it.

Mr. SMITH. Does the virus go through the umbilical cord or is it stopped? If the mother has it, does the baby get it?

Dr. SCHUCHAT. Yeah. I am not familiar with that as a route of infection. But with a new virus we always are mindful that there are lots of things to learn. So this particular H1N1 influenza virus I am not aware of that we have any mother-to-baby transmission. But with viruses, that can happen for many of them.

Mr. SMITH. But we are looking for that to see if that is a possibility?

Dr. SCHUCHAT. We are looking actively at all routes of transmission right now.

Mr. SMITH. Thank you, Mr. Chairman.

Mr. PAYNE. Let me certainly thank each of you for your very important testimony. It is something that we are proud that we are able to be prepared. As you have indicated there, years ago we would not have all of these various procedures in place. And so I really commend the work that CDC, NIH, USAID and all of you that work in government agencies are doing. Also once again, I commend President Obama for the $63 billion over the next 6 years that will really continue our vigilance in working to try to eliminate HIV and AIDS and tuberculosis. Malaria is really getting a tremendous amount of attention; we are seeing very good results in other tropical diseases that have not gotten the attention, river blindness and other kinds of tropical diseases. So we are very, very pleased.

Congresswoman Jackson Lee has additional questions, which we will forward to our witnesses and we will ask that you respond to these in a timely manner so that we can get the answers back to her, and we certainly greatly appreciate your participation.

Before closing I want to ask for unanimous consent for members that have 5 days to revise and extend their remarks and submit questions for the record. Without objection, so ordered.

Once again, thank you. We had such a distinguished panel here testifying this morning and with kind of short notice. Thank you again, and the meeting stands adjourned.

[Whereupon, at 11 o'clock a.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

SUBCOMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH
Donald M. Payne (D-NJ), Chairman

May 5, 2009

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend the following OPEN hearing of the Subcommittee on Africa and Global Health, to be held in **2172 of the Rayburn House Office Building.**

DATE:	Wednesday, May 6, 2009
TIME:	9:00 a.m.
SUBJECT:	Global Health Emergencies Hit Home: The "Swine Flu" Outbreak
WITNESSES:	Anthony Fauci, M.D. Director National Institute of Allergies and Infectious Diseases National Institute of Health Rear Admiral Anne Schuchat, M.D. Interim Deputy Director for Science and Public Health Program Center for Disease Control and Prevention Dennis Carroll, M.D. Special Advisor to the Acting Administrator on Pandemic Influenza United States Agency for International Development

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee as noted above.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON *Africa and Global Health* MEETING

Day *Wednesday* Date *5/6/09* Room *2172 RHOB*

Starting Time *9:07 a.m.* Ending Time *11:00 a.m.*

Recesses [ ] (to)

Presiding Member(s) *Donald M. Payne*

CHECK ALL OF THE FOLLOWING THAT APPLY:

Open Session [✓]
Executive (closed) Session [ ]
Televised [✓]

Electronically Recorded (taped) [ ]
Stenographic Record [✓]

TITLE OF HEARING or BILLS FOR MARKUP: *(Include bill number(s) and title(s) of legislation.)*

Health Emergencies Hit Home: The Swine Flu Outbreak

SUBCOMMITTEE MEMBERS PRESENT:

Payne; Jackson-Lee; Lee; Smith; Watson; Woolsey; Boozman

NON-SUBCOMMITTEE MEMBERS PRESENT: *(Mark with an * if they are not Members of HIRC.)*

HEARING WITNESSES: Same as meeting notice attached? Yes [✓] No [ ]
(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: *(List any statements submitted for the record.)*

ACTIONS TAKEN DURING THE MARKUP: *(Attach copies of legislation and amendments.)*

RECORDED VOTES TAKEN (FOR MARKUP): *(Attach final vote tally sheet listing each member.)*

Subject	Yeas	Nays	Present	Not Voting

TIME SCHEDULED TO RECONVENE _____
or
TIME ADJOURNED *11:00 am*

Subcommittee Staff Director