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SWINE FLU OUTBREAK AND THE U.S. FEDERAL RESPONSE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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[1] Mr. Vanderwagen did not respond to submitted questions for the record.

SWINE FLU OUTBREAK AND THE U.S. FEDERAL RESPONSE

THURSDAY, APRIL 30, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:10 a.m., in Room 2123, Rayburn House Office Building, Hon. Frank Pallone, Jr., [chairman of the subcommittee] presiding.

Present: Representatives Pallone, Dingell, Eshoo, Green, DeGette, Capps, Schakowsky, Baldwin, Weiner, Matheson, Gonzalez, Barrow, Christensen, Sarbanes, Murphy of Connecticut, Space, Sutton, Braley, Waxman (ex officio), Deal, Shimkus, Shadegg, Blunt, Murphy of Pennsylvania, Blackburn, Gingrey, and Barton (ex officio).

Staff Present: Phil Barnett, Staff Director; Karen Nelson, Health Policy Director; Bruce Wolpe, Senior Advisor; Karen Lightfoot, Communications Director; Earley Green, Chief Clerk; Jennifer Berenholz, Deputy Clerk; Tim Westmoreland, Consultant; Steve Cha, Professional Staff Member; Sarah Despres, Counsel; Naomi Seiler, Counsel; Ruth Katz, Chief Public Health Counsel; Alvin Banks, Special Assistant; Caren Auchman, Communications Associate; Lindsay Vidal, Special Assistant; Elana Leventhal, Legislative Assistant; Mitch Smiley, Special Assistant; Aarti Shah, Minority Counsel; Ryan Long, Minority Chief Health Counsel; and Chad Grant, Minority Legislative Analyst.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The meeting of the subcommittee is called to order. Today we are having a hearing on 2009 H1N1 flu outbreak and the U.S. Federal response.

I have to warn you, I have to get used to this new definition and not use "swine flu" I understand anymore.

The subcommittee is meeting to discuss the ongoing 2009 H1N1 flu outbreak and the U.S. Federal response, and the purpose of today's hearing is to hear from our Nation's lead agencies to learn the what, when and where about this outbreak and also to discuss next steps in the Federal response in reporting and reacting to this potential crisis.

Today we have invited rear Admiral W. Craig Vanderwagen, assistant secretary for preparedness and response; Dr. Joshua

Sharfstein, who is the acting commissioner of the Food and Drug Administration; and Rear Admiral Anne Schuchat, who is interim deputy director for the Science and Public Health Program at the Centers for Disease Control and Prevention.

And I want to thank each of you for taking time out of your extremely busy schedule to come and help educate Congress and the public about this very serious public health emergency and highlight areas where further support may be necessary.

Now let me tell my colleagues that, because the witnesses are on the front line of our ongoing efforts to report and react to the 2009 H1N1 flu outbreak, I am cognizant time is of the essence, and they are needed at their respective offices. Therefore, I have asked all members of the committee to not make an opening statement but instead submit their statements for the record so we can get straight to our witnesses and make the best use of their limited time.

Without objection, Members will have 5 days to submit their written statements for inclusion in the hearing record.

I am going to recognize, though, the committee Chair and subcommittee Chairs and the ranking members for remarks.

And we will begin with Mr. Deal.

[The prepared statement of Mr. Pallone follows:]

CHAIRMAN FRANK PALLONE, JR.

HEALTH SUBCOMMITTEE HEARING

"2009 H1N1 Flu Outbreak and the U.S. Federal Response"

OPENING STATEMENT

April 30th, 2009

Good morning. Today the Subcommittee is meeting to discuss the ongoing 2009 H1N1 Flu Outbreak and the U.S. Federal Response. The purpose of today's hearing is to hear from our nation's leading agencies, to learn the what, when, and where about this outbreak and also to discuss next steps in the federal response in reporting and reacting to this potential crisis.

Today we have invited Rear Admiral W. Craig Vanderwagen, Assistant Secretary for Preparedness and Response, Dr. Joshua Sharfstein, Acting Commissioner,

Food and Drug Administration, and Rear Admiral Anne Schuchat, Interim Deputy Director for the Science and Public Health Program at the Centers for Disease Control and Prevention. I want to thank our witnesses for taking time out of their extremely busy schedules to come help educate Congress and the public about this very serious public health emergency and highlight areas where further support may be necessary.

According to a report released by the U.S. Department of Health and Human Services in 2006, "an influenza pandemic has the potential to cause more death and illness than any other public health threat." Indeed, the potential devastation that a SARS or Avian Flu Pandemic could have on human lives is a frightening scenario.

That is why I applaud the response by our federal, state, and local public health agencies in reporting and

reacting decisively to the current 2009 H1N1 flu outbreak. I have no doubt that years of preparation have paid off as the public health infrastructure is now compelled into action. It is at times like these where every American realizes how important investing and strengthening our public health agencies, infrastructure, and workforce are to our national security and societal health.

I believe our response to this situation will be a direct measure of how much effort and resources we put into our public health system up to this moment. And the response to the next outbreak or disaster will be a measure of how much we invest from this moment on.

That's why we need to empower medical research and innovation so the next generation of vaccines and medicines can be developed. I believe strengthening our public infrastructure - from emergency departments to community

interventions - is an essential part of our ability to handle a surge, should there be a wide-spread outbreak.

Furthermore, improving the public health workforce including nurses, doctors, epidemiologists, and veterinarians to name a few, must be a priority for Federal and local governments because those are the people who are at the front lines of any crisis; who are gathering information, treating patients, and coordinating between all the agencies and organizations involved in keeping our population healthy and safe.

We do not yet know how this situation is going to unfold and what exactly we should expect for now and for the future. But what we do know is that we must move with all due diligence to support our public health agencies during this unnerving time and we must also be prepared for the next outbreak and be ready to respond swiftly and

decisively. I thank the witnesses who are here today as well as all those who are not here and working right now to protect our families from harm. Thank you.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman.

And thank you, distinguished members of our panel.

I think we all want to know how to evaluate and know where we are in the ongoing effort to respond to the H1N1 flu situation, and I appreciate the efforts of the chairman and the members of this subcommittee to give us this opportunity to hear update information on what is truly a dynamic and obviously rapidly changing situation. I recognize the importance of the roles that each of our witnesses play in responding to this public health threat. And so I am going to keep my comments as brief as possible.

I recall, not too very long ago, this committee was having hearings when we were concerned about the bird flu. And many of the concerns and expressions of preparation necessities that we talked about then I am sure are applicable here today.

As our witnesses will attest, the threat of a global influenza epidemic or flu pandemic is one of the greatest public threats that we face today. From speaking with experts in the field, both in this most recent as well as the most recent past experience with this, we have all said it is not a question of if a flu pandemic will hit, it is a question of when, and I suppose now, what strain will it be? And I believe is our responsibility as Members of Congress to ensure that the public is protected from this threat as soon as possible, and that we take the necessary steps to mitigate its spread and of course the heightened risk, and it is certainly something that is high on our priorities.

And there is no silver bullet. We all know that. But we do want to know what is being done? What should be done? What role can we play? I am encouraged by the rapid response of the Federal and State authorities who are working closely in conjunction with the private sector to develop solutions to the flu situation that we are facing. And in addition to these efforts, I think we have to continue to look for the vulnerabilities that leave the American public at risk.

I have been told that this morning Vice President Joe Biden said in an interview that he would advise members of his family to avoid commercial air travel, subways and other locations where transmission of flu from person to person is easy. This seems somewhat contrary to the administration's recent statements, and I hope that we can clarify that in this hearing today. Also I hope that we can see how the administration has looked at all available options in dealing with this matter.

We certainly need to know how to advise our constituents with regard to all of the issues of travel, crossing our national boundaries and all of the things that go with that. This is a very distinguished group, and I feel sure that you can answer these questions and many, many more. Thank you for being here.

And thank you, Mr. Chairman, for the time.

Mr. PALLONE. Thank you, Mr. Deal.

Chairman Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman.

I thank you for holding this hearing.

It seems to me that at this hearing we must accomplish two things. We should get a clear statement to the public about the flu outbreak from the Nation's leading health authorities. And I am pleased that our witnesses are here today to provide that.

We should find out if there are other things, short term and long term, that Congress can do to help in their current and future response. There is much that we cannot know at this point about this flu. We don't know how infectious is the virus or how sick people will get or how widespread it will be, but there is one thing that can be known; we are better situated to face the outbreak now than we would have been 10 years ago. Because of the public health work, the planning, the stockpiles, the building of epidemiological systems, we are better prepared to limit the reach and severity of the epidemic in the U.S. than we would have been.

Fewer people will likely get sick than if this same virus had hit in the 1990s. And there is one thing we can confidently predict. We need to do more. For decades, health professionals have been warning us that we are taking the work of the public health system for granted. The system is generally understaffed, under-equipped and underfunded.

The President has requested an additional $1.5 billion to respond to this flu outbreak. And I am sure the Congress will appropriate these funds. But that should not be the end of our efforts. We should not wait for public health emergencies to come up with ad hoc responses. We should upgrade our public health programs. We should provide them with a firm and reliable foundation of funding, and I hope from this pandemic flu outbreak, we can finally learn the lesson that public health work saves both money and lives.

I appreciate the witnesses here, and I particularly want to thank Dr. Sharfstein for being here. He was an important staffer, not on this committee but on the Oversight Committee. But it is a rare opportunity to have him on the other side of the table. And I am pleased that he is here, and I am pleased he is in the position that he is now holding.

And I thank the other two doctors for being with us as well. We are looking forward to your testimony.

[The prepared statement of Mr. Waxman follows:]

Opening Statement of Congressman Henry A. Waxman
At Hearings on the Pandemic Flu Outbreak
April 30, 2009

Today's hearing should accomplish two things:

- We should get a clear statement to the public about the flu outbreak from the Nation's leading health authorities; and

- We should find out if there are other things—short-term and long-term—that the Congress can do to help in their current and future response.

There is much that cannot be known about the current state of the outbreak: How infectious is the virus? How sick do people get? How widespread will it be?

But there is one thing that can be known: We are better situated to face the outbreak now than we would have been ten years ago. Because of the public health work—the planning, the stockpiles, the building of epidemiological systems—we are better prepared to limit the reach and severity of the epidemic in the U.S. than we would have been. Fewer people will likely get sick than if this same virus had hit in the Nineties.

And there is one thing that we can confidently predict: We need to do more. For decades, health professionals have been warning us that we are taking the work of the public health system for granted. The system is generally understaffed, under-equipped, and underfunded.

The President has requested an additional $1.5 billion to respond to this flu outbreak; I am sure that the Congress will appropriate these funds. But that should not be the end of our efforts.

We should not wait for public health emergencies to come up with ad-hoc responses. Not even counting this recent pandemic flu outbreak, about 35,000 Americans die of regular, seasonal flu each year. That number could be readily reduced with better vaccination programs and public education efforts. But every year these activities are short-changed, as are other important public health measures.

Although we know that "an ounce of prevention is worth a pound of cure," we continue to largely buy only treatments. We know better than that. We should upgrade our public health programs, and we should provide them with a firm and reliable foundation of funding. I hope that from this pandemic flu outbreak we can finally learn the lesson that public health work saves both money and lives.

I look forward to hearing from our witnesses. I'm especially pleased to see Dr. Sharfstein, and I welcome him to the other side of the table today.

Mr. PALLONE. Thank you, Chairman Waxman.

Chairman Dingell.

Mr. DINGELL. You are very kind Mr. Chairman. Thank you.

I would ask unanimous consent to insert my full statement into the record.

But I would like to look back on two things. One, the fact that we have been starving our capabilities of addressing problems of this kind, and we are now are looking at the consequences of that situation. And I would like to observe that the last time we had this kind of serious problem, we had the same kind of potential for a panicky response which I am observing might be the case again today. The result of that was the hideous set of consequences in which the lawyers held swine flu seminars to discuss how it was that they were going to represent plaintiffs and how the situation was going to create the maximum revenue for the plaintiffs and for the lawyers.

I hope that we will have a more measured, thoughtful response, bottom line a more careful approach and that, from the past events, we will learn that we have to do these things in a more sensible, prudent, provident and continuing manner.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Dingell follows:]

Statement of
The Honorable John D. Dingell
Subcommittee on Health Hearing on the "Swine Flu Outbreak and the U.S. Federal Response"

April 30, 2009

Thank you, Mr. Chairman for holding today's hearing on the current swine flu outbreak. It will hopefully give us a greater understanding of the federal government's response during this trying public health emergency. The Administration should be commended on their efforts. We have a rather serious problem on our hands, and it appears as though they are responding appropriately. While much cooperation and leadership has taken place, I expect a heightened level of leadership from the Department of Health and Human Services under the direction of our newly confirmed Secretary, Kathleen Sebelius. This public health threat requires full leadership at every level.

The current swine flu outbreak reminds me of the previous points in our nation's history during which we confronted this disease. In 1976, two recruits at Ft. Dix fell sick from the H1N1 flu strand. Congress responded swiftly. That August a National Influenza Program was introduced and one week later it was signed into law by President Ford. We were later forced to deal with the costly consequences of our

actions. It is appropriate to respond to national public threats, but we need to be deliberate and thoughtful in our response.

As we move forward, our response must be measured and based on the constant changing facts on the ground. In Michigan, we have several dozen suspected swine flu cases with two cases confirmed. The White House has asked Congress for additional funding to help fight the outbreak of swine flu and prepare for the possibility of a wider epidemic. I support this request. Many of our State and local governments, already faced with substantial budget shortfalls and declining revenues, are finding it hard to appropriately respond to this outbreak. It is my hope that some of the additional funds that have been requested will be made available to help State and local governments respond rapidly and effectively. Our efforts must be coordinated at all levels.

While the current outbreak has the potential to have a substantial public health impact, we are also keenly aware of the potential financial impact. The greatest threat to our world economy is fear. On Monday, airline stocks plunged, the Mexican peso devalued, and the price of oil was driven down. On Wednesday, WHO raised the threat level to phase five—one level short of a pandemic declaration. There are concerns that this current outbreak will have the same devastating impact on the American economy as the SARS outbreak impact on the Asian economy

in 2003. If this outbreak turns into a pandemic, the U.S. economy could shrink as much as 6.9 percent as worker productivity and consumer demand decreases.

Additionally, the 2004 Project BioShield Act granted Emergency Use Authorization to the Secretary allowing her, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency. I am aware that this authority has been used for three products—two drugs and one diagnostic test. I think this is a useful authority, however, I will vigilant in ensuring that individuals using these products under these conditions are being monitored to ensure the risks of using these products do not outweigh the benefits.

Finally, I am reminded of sage advice from the then Department of Health Education and Welfare, "[f]or policy decisions and in communication, making clear what is not known is as important as stating what is known. When assumptions are made, the basis for the assumptions and the uncertainties surrounding them should be communicated."

I urge us all to heed this advice as we move forward in addressing the serious issue we are confronted with today. I thank today's witnesses who are working hard to mitigate the swine flu outbreak and I look forward to their testimony.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Dingell.

We will go to the witnesses.

I did want to mention, though, that Congressman Anthony Weiner called me last weekend. I think you had a number of cases actually in a school in your district and asked that we have this hearing. Obviously a number of members requested it. But I did want to acknowledge his quick action, calling me on the cell phone on Sunday and his concern obviously because of the number of cases in the school and his district.

Let me introduce our panel, and this is the order you are going to be speaking. I guess it is a little different from the way you are sitting there. First, we have Rear Admiral W. Craig Vanderwagen, who is a physician and assistant secretary for preparedness and response.

And next is Rear Admiral Anne Schuchat, who is also a physician and interim deputy director for the Science and Public Health Program at the Centers for Disease Control and Prevention.

And last is Joshua M. Sharfstein, who is also a physician and acting commissioner of the Food and Drug Administration.

We are asking you for basically 5-minute statements, and they will become part of the record.

STATEMENTS OF REAR ADMIRAL W. CRAIG VANDERWAGEN, MD, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; REAR ADMIRAL ANNE SCHUCHAT, MD, ACTING DEPUTY DIRECTOR FOR SCIENCE AND PUBLIC HEALTH PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION, ASSISTANT SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JOSHUA M. SHARFSTEIN, MD, PRINCIPAL DEPUTY COMMISSIONER AND ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. PALLONE. And we will start with Admiral Vanderwagen.

STATEMENT OF REAR ADMIRAL W. CRAIG VANDERWAGEN, MD

Mr. VANDERWAGEN. Good morning Chairman Pallone and Representative Deal and thank you for this opportunity to visit with you.

I offer greetings and thanks from our new Secretary Sebelius for this opportunity to assure that both arms of the U.S. Government of the three are working together and that we can share experiences, concerns and strategies for how we will address this opportunity.

Over the past week, you have seen extraordinary efforts on the part of Health and Human Services and the rest of the Federal Government. For the past 5 years, HHS and the U.S. Government made many investments, thanks to the support of Congress, in the Nation's preparedness for pandemic influenza.

Now while the sequence of the events that we have dealt with in the last week, and I will remind you we are talking about essentially a week ago yesterday recognizing two cases in California to now phase 5 in the WHO environment, the events of the past week

have proven the value of the efforts that you supported, which included the development of community plans, the acquisition of medical countermeasures, the development of now diagnostics, and the numerous exercises and response plans at all levels of government.

I would like to take an opportunity also to acknowledge and thank Secretary Napolitano for her continued leadership in this environment. She stepped forward very effectively as the principal Federal official here, and we work under her guidance overall. Our new Secretary engaged immediately. She reported to the office yesterday morning, and in fact, she was briefed in doing press discussions yesterday morning almost immediately. She is actively involved and concerned about these matters and directing our activities as well.

Today I am joined by my colleagues who currently serve in the HHS leading the response.

I want to say just a thing or two about the assistant secretary for preparedness and response. Congress in 2006 established the authority for this responsibility with the notion that this office would be the principal adviser for the Secretary on public health and medical preparedness and response for health emergencies. And indeed, that is what we are executing at this time.

We are trying to work to assure that there is a coherent HHS approach to public health and medical preparedness and that our response capabilities are coordinated, that the relevant activities of all the operating divisions of Health and Human Services, Centers for Disease Control, Food and Drug Administration, the National Institutes of Health and others are being conducted in a coherent and targeted way on behalf of and subject to the authority of our new Secretary.

Our office also serves as the principal entity that coordinates interagency activities between Health and Human Services and other Federal Departments and agencies, the White House, and State and local officials responsible for public health, emergency and medical disaster response.

In the event of a public health emergency such as the 2009 H1N1 flu outbreak or other medical disasters, Health and Human Services serves as the Federal Government's lead for all of the Emergency Support Function 8, that is the public health and medical response capabilities under the National Response Framework. As the Department's lead for that ESF 8 or Emergency Support Function 8, our office works closely with Homeland Security and FEMA to coordinate all Federal assistance to supplement States, territorial governments, tribal and local resources in response to public health and medical care needs.

We manage the Secretary's Operations Center in the Humphrey building so that the Secretary has moment-by-moment situational awareness and the ability to lead, coordinate and direct, as appropriate, the health assets that are deployed in support of States.

The response and coordination for the H1N1 flu outbreak is going well. You will hear from Dr. Schuchat how our lead operational entity at this point, that is the Centers for Disease Control, is moving forward according to plan, adjusting to reality as it in-

trudes, but doing an exceptionally good job of moving forward to manage this event.

The United States Government is focused on saving lives, slowing the transmission of the disease, and mitigating the consequences of this disease. Those are our strategic objectives. Using the guidelines prepared within our pandemic influenza playbooks and plans, we have been able to more clearly communicate our goals, objectives and strategies to our Federal, State and local partners, so that we understand what they expect, they understand what they can expect from us, and that makes a ton of difference in making operations flow and flow well.

As you know, the World Health Organization raised the world wide pandemic alert to phase 5, which is characterized by confirmed person-to-person spread of a new influenza virus and able to cause community level outbreaks, and Dr. Schuchat I am sure will talk about that in more detail. But prior to that WHO action, we issued several key declarations, including a nationwide Public Health Emergency Declaration and four Emergency Use Authorizations, which I think Dr. Sharfstein will talk about in his discussion with you. These authorizations were issued to make certain diagnostics available to public health and medical personnel, to allow for the use of certainly antiviral products and for the use of certain N95 respirators.

In response to requests received from affected States, HHS recently released antiviral medications from the Strategic National Stockpile to a large number of States. Additionally, Health and Human Services continues to evaluate community mitigation guidelines in those areas where cases have been confirmed through laboratory analysis, and as this outbreak progresses, we will continue to assess these and other guidelines to assure that they are appropriately based on the available science. Over the coming days, we will continue to work with our Federal, State, local and international public health and medical partners to address the needs of this outbreak.

Many assets, and you will hear elements of this from my two counterparts, are working to develop a vaccine for this virus. NIH, CDC, FDA and ASPR are all working together to work this process and to avoid the very dilemma that Mr. Dingell outlined for us.

We will work with several manufacturers to continue to prepare reference strains from which viral seeds for vaccine production and clinical trials can be made. We will not only focus on the immediate response requirements but also those that may lie ahead. As this potentially becomes more of a medical care problem, we will see challenges in the medical care system. We are already actively in communication with our colleagues at the State and local level, in hospitals, in emergency rooms, and in primary care settings to anticipate the implementation of their plans for addressing these matters and how we can support, enhance and fill gaps that may arise in that setting. With that, I will conclude my statement, and you can hear from Dr. Schuchat.

[The prepared statement of Admiral Vanderwagen follows:]

Testimony
Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

ASPR's Emergency Preparedness Role in the 2009-H1N1 Flu Outbreak

Statement of
RADM. W. Craig Vanderwagen, M.D.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 am
Thursday, April 30, 2009

Good morning Chairman Pallone, Rep. Deal, and Members of the Subcommittee. I am RADM. W. Craig Vanderwagen, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). I appreciate this opportunity to discuss the important role of ASPR in responding to the current 2009-H1N1 Flu outbreak. To put the more unique role of ASPR in this outbreak in the proper context, allow me to first provide a brief overview of my office's emergency response responsibility.

Over the past week you have seen extraordinary efforts on the part of the Department of Health and Human Services (HHS) and the rest of the Federal Government. Over the past 5 years, HHS and the U.S. Government made many investments in the nation's preparedness for pandemic influenza. While the sequence of these events has not matched those planning assumptions, the events of the past week have proven the value of those efforts, which included the development of community plans, the acquisition of medical countermeasures, the development of new diagnostics and the numerous exercises of response plans at all levels of government.

I would like to take this opportunity to acknowledge Secretary Napolitano and thank her for her continued leadership and support in this effort. I would also like to recognize our new Secretary, who engaged immediately in this issue upon her confirmation and is actively involved in leading the Department's response. Today, I am joined by my colleagues who currently serve on the HHS team

leading the response, Dr. Anne Schuchat from the Centers for Disease Control and Prevention (CDC) and Dr. Joshua Sharfstein from the Food and Drug Administration (FDA).

The Assistant Secretary for Preparedness and Response is the Secretary's principal advisor on all matters related to Federal public health and medical preparedness and response for public health emergencies. ASPR assures a coherent HHS approach to public health and medical preparedness and response capability by leading and coordinating the relevant activities of the HHS Operating Divisions (e.g., Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health) on behalf of, and subject to the authority of, the Secretary.

ASPR also serves as the principal entity that coordinates interagency activities between HHS, other Federal Departments and Agencies, the White House (e.g., Homeland Security and National Security Councils), and State and local officials responsible for public health emergency and disaster medical preparedness. In the event of a public health emergency, such as the 2009-H1N1 Flu outbreak, or a medical disaster, HHS serves as the Federal Government's lead for Emergency Support Function (ESF) #8 – Public Health and Medical Services under the National Response Framework. As the Department's lead for ESF #8, ASPR works closely with the Department of Homeland Security's (DHS) Federal Emergency Management Agency (FEMA) to coordinate Federal assistance to

supplement State, Territorial, Tribal, and local resources in response to public health and medical care needs.

ASPR manages the Secretary's Operations Center (SOC) located at the HHS Headquarters building. This center serves as the Department's primary location to coordinate the overall public health and medical response effort.

The response and coordination of the H1N1 Flu outbreak is going well. Our investments over the past five years are coming to fruition. The United States Government (USG) efforts are currently focused on saving lives, slowing the transmission of the disease, and mitigating consequences of those affected. Using the guidelines prepared within our Pandemic Influenza playbooks and plans, we have been able to more clearly communicate our goals, objectives and strategies to our Federal, State and local partners.

As you know, the World Health Organization raised the worldwide pandemic alert level to Phase 5, which is characterized by confirmed person-to-person spread of a new influenza virus able to cause "community-level" outbreaks. Prior to WHO's recent action, HHS issued several key declarations including a nationwide Public Health Emergency Declaration, and four Emergency Use Authorizations (EUAs). These authorizations were issued to make certain diagnostics available to public

health and medical personnel, to allow for the use of certain antiviral products, and for the use of certain N95 respirators.

In response to requests received by affected States, HHS recently released antiviral medication from the Strategic National Stockpile to the States of California, Texas, Indiana, Arizona and New York. Additionally, HHS continues to evaluate community mitigation guidelines in those areas where cases have been confirmed through laboratory analysis. As this outbreak progresses HHS will continue to assess these and other guidelines to ensure that they are appropriately based upon the available science.

Over the coming days, HHS will continue to work with our Federal, State, local and International public health and medical partners to help address the needs of this outbreak. Many HHS assets from NIH, FDA, CDC, and ASPR/BARDA are working to develop a vaccine for this virus. HHS will work with several manufacturers to continue to prepare reference strains from which viral seeds for vaccine production and vaccine clinical trials can be made. HHS will continue to focus not only on the immediate response requirements but also those that might exist in the coming days or weeks.

At this point I will conclude my very brief remarks and will welcome your comments or questions.

Mr. PALLONE. Thank you. I assume that I am supposed to reference you as Doctor rather than Admiral. Do you prefer that?

Ms. SCHUCHAT. "Dr. Schuchat." That is fine.

Mr. PALLONE. Dr. Schuchat.

STATEMENT OF REAR ADMIRAL ANNE SCHUCHAT, MD

Ms. SCHUCHAT. Good morning, Mr. Chairman and 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 update you on current steps we are taking to respond to this unique and serious influenza outbreak.

Our hearts go out to the people in the communities within the United States and Mexico and around the world who have been impacted by this new strain of influenza virus. People are concerned, and we are concerned, too. We are responding aggressively at the Federal, State, and local levels to understand the complexities of the outbreak and to implement control measures. Our aggressive actions are possible in many respects because of the investments and the support of the committee and the Congress and the hard work of State and local officials on the frontline around the country.

Flu viruses are extremely unpredictable, making it hard for us to anticipate the course that this outbreak will have with any certainty. We do expect increases in the number of cases, the number of States that are affected and the severity of illness. Amid this uncertainty, we hope to be clear in communicating what we do know and acknowledging the uncertainties, clearly communicating what we are doing to protect the health of Americans and help Americans understand the steps that they can take themselves to protect their own health and that of their families and their communities.

Influenza arises from a variety of sources. And in this case, we have determined that we have a novel 2009 H1N1 virus circulating in both the U.S. and Mexico that contains genetic pieces from four different virus sources. Additional testing is being done on the virus, including a complete genetic sequencing. CDC has determined that this virus is contagious. It is spreading from human to human similarly to seasonal influenza, likely through coughing or sneezing. Sometimes people may become infected by touching something with 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 United States, and there have been no illnesses attributed to handling or consuming pork. There is no evidence that you can get this new influenza virus from eating pork or pork products.

I want to reiterate that, as we look more intensively for cases, we are finding more cases. We fully expect to see not only more cases but also a greater severity of illness. The specific numbers are less important in understanding the outbreak than the more general patterns that we observe that will help us guide our interventions. Aggressive actions are being taken here as well as abroad. We are working very closely with State and local public

health officials around the U.S. on the investigation and to implement control measures. We have provided both technical support on epidemiology and laboratory efforts for confirming cases. And we are working with the World Health Organization, the Pan American Health Organization and the Governments of Mexico and Canada on this outbreak. There is a tri-national team that is working in Mexico right now to better understand the outbreak and to enhance surveillance and lab capacity so that we can better address critical questions, such as why the cases in Mexico appear to be more severe than what we are seeing initially here in the United States. And we are working very closely with HHS and other Federal partners to ensure that our efforts are coordinated and effective.

CDC has issued many health advisories for individuals, health care practitioners, schools and communities, and these continue to evolve as our understanding of the situation changes. On Monday, CDC issued a travel health warning for Mexico recommending that travelers postpone nonessential travel to Mexico. We are also evaluating information from other countries, and we will update travel notices as necessary.

As always, people with flu or flu-like symptoms should stay at home and should not attempt to travel. In fact, a key message that we have for people is that there is a role for everyone to play when an outbreak like this is occurring. At the individual level, it is important for people to understand how each of us can prevent respiratory infections. Frequent hand washing is an effective way to reduce transmission. If you are sick, stay home. I can't tell you how many times I have said that this week. If your children are sick, have a fever or a flu-like illness, they shouldn't go to school. And if you are ill, you shouldn't go on an airplane or any public transport to travel. Taking personal responsibility for these things will help reduce the spread for this new virus as those measures also help reduce the spread of other respiratory infections.

It is also important for people to think ahead to think about what they would do if their outbreak deepens in their community. Communities, businesses, schools and local government should plan now for what to do if cases appear where you live or work.

For example, parents should prepare for what they would do if faced with temporary school closures. We also have additional community guidance so that clinicians, laboratory scientists 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 our regular updates, are posted on the CDC's website at www.CDC.gov.

CDC maintains this Nation's strategic National Stockpile of medications for the eventuality that they may be needed in a situation such as we face today. As part of our pandemic preparedness efforts, the U.S. Government has purchased extensive supplies of antiviral drugs. And our preliminary testing indicates that the virus is susceptible to the drugs we have in our stockpile. We are releasing one-quarter of the States' share of antiviral drugs and personal protective equipment to help States prepare to respond to the outbreak along with the necessary FDA emergency use authorities to facilitate their effective use. Distribution has already begun,

starting with States where we already had confirmed cases and the Department of Defense and individual States have also stockpiled these antiviral drugs.

Whenever we see a novel strain of influenza, we begin the steps to work toward the development of a vaccine in case one is needed. The CDC is working to develop a vaccine seed strain specific to this novel virus, which is the first step in vaccine manufacturing. We have initiated steps so that, should we need to manufacture a vaccine, we can work towards that goal very quickly. And rapid progress is being made possible through the combined forces of CDC, NIH, FDA, BARDA and the manufacturing community.

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 outbreak and for a full pandemic. 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 recognize 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 subcommittee to best address the evolving situation.

Thank you.

[The prepared statement of Admiral Schuchat follows:]

Testimony before the
Committee on Energy & Commerce
Subcommittee on Health
United States House of Representatives

U.S. 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
Expected at 10 a.m.
April 30, 2009

Good afternoon, Chairman Pallone, Ranking Member Deal and other distinguished members of the Subcommittee. 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 in updating you on current 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. People around the country and around the globe are concerned with this situation we're seeing, and we're concerned as well. We are responding aggressively at the federal, state, and local levels to understand the complexities of this outbreak and to implement control measures. It is important to note that our nation's current preparedness is a direct result of the investments and support of the Congress and the hard work of state and local officials across the country.

It is important for all of us to understand that flu viruses – and outbreaks of many infectious diseases -- are extremely unpredictable. We know that as our investigation proceeds, what we learn will change. We expect changes in the number of cases, the number of states affected, and the severity of illness. Our goal in our daily communication – to the public, to the Congress, and to the media – is to be clear in what we do know, explain uncertainty, and clearly communicate what we are doing to protect the health of Americans. An equal priority is to communicate the steps that Americans can take to protect their own health and that of their community. As we learn more, these communications and recommendations will 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. From laboratory analysis already performed at CDC, we have determined that there is a novel 2009 H1N1 virus circulating in the U.S. and Mexico 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 viruses, including a complete genetic sequencing.

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. Currently, there is no evidence that you 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 greater severity of illness. We've ramped up our surveillance around the country to try and get a better understanding of the magnitude of this outbreak.

Let me provide for you an update in terms of the public health actions that are being taken here as well as abroad. On the investigation side, we are working very closely with state and local

public health officials around the country. We're providing both technical support on the epidemiology as well as laboratory support for confirming cases. We are also working with the World Health Organization, the Pan American Health Organization, and the governments of Mexico and Canada on this outbreak. There is a tri-national team that is working in Mexico to better understand the outbreak, and answer critical questions such as why cases in Mexico appear to be more severe than we have seen in the U.S. to date. We are working to assist Mexico in establishing more laboratory capacity in-country; this is very important because when you can define someone as a truly confirmed case, what you understand about how they acquire disease takes on much more meaning.

In terms of travel advisories, CDC continues to evaluate incoming information from the World Health Organization, the Pan American Health Organization, 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. With this warning, we recommend travelers to 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.

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's a role for everyone to play when an outbreak is occurring. 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're sick, it's very important to stay at home. If your children are sick, have a fever and flu-like illness, they shouldn't go to school. And if you're ill, you shouldn't 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.

It is important that people think about what they would do if this outbreak deepens in their community. Communities, businesses, schools, and local governments should plan now for what to do if cases appear in their communities. Parents should prepare for what they would do if faced with temporary school closures, as we are recommending temporary school closures when cases are identified.

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 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 in this outbreak. As part of our pandemic preparedness efforts, the U.S. 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. We are releasing one-quarter of the states' share of antiviral drugs and personal protective equipment to help states prepare to respond to the outbreak, along with the necessary emergency use authorities to facilitate their effective use. Distribution has been prioritized for the states where we already have confirmed cases. In addition, the Department of Defense has procured and strategically prepositioned 7 million treatment courses of oseltamivir.

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 has also identified the needed pathways to provide rapid production of vaccine after the appropriate seed strain has been provided to manufacturers. As this progresses, HHS operating divisions and offices including CDC, NIH, FDA, and ASPR/BARDA will work in close partnership.

In closing, we are simultaneously working hard to understand and control this outbreak while also keeping the public and the Congress fully informed on the situation and our response. We are working in close collaboration with our federal partners including our sister HHS agencies and other federal departments. While much has happened to date, this will be a marathon, not a sprint, and even if this outbreak is a small one, we can anticipate that we may have a subsequent

or follow-on outbreak several months later. 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 Subcommittee to best address this evolving situation.

Mr. PALLONE. Thank you, Dr. Schuchat.
Dr. Sharfstein.

STATEMENT OF JOSHUA M. SHARFSTEIN, MD

Dr. SHARFSTEIN. Thank you Chairman Pallone, Ranking Member Deal, Ranking Member Barton, Chairman Waxman, chairman Dingell and other members of the committee, thank you for having this hearing.

I am Dr. Joshua Sharfstein, principal deputy commissioner and acting commissioner of the U.S. Food and Drug Administration.

FDA protects the public health in this type of situation by facilitating access to safe and effective human and animal drugs, human biological products and devices. FDA is part of a team led by the Department of Health and Human Services. Working closely with the Department, our sister agencies, other U.S. Government agencies, the World Health Organization and foreign governments, we are responding to this threat.

I appreciate this opportunity to discuss the agency's response, including our approval of several Emergency Use Authorizations earlier this week and the efforts of several internal FDA teams.

Let me turn to the Emergency Use Authorization. Section 564 of the Food, Drug and Cosmetic Act which was added by the Project BioShield Act in 2004 which permits the FDA Commissioner to issue an Emergency Use Authorization following a determination and declaration of a Public Health Emergency. This allows the use of an unapproved product or an approved product for an unapproved use and in a declared emergency.

Mr. PALLONE. Dr. Sharfstein, I think some of the members are having a hard time hearing you.

Dr. SHARFSTEIN. I was talking about Emergency Use Authorizations. And FDA can issue these in an emergency under four conditions: First, we have defined that the agent can cause a serious or life-threatening disease or condition; second, based on the totality of the scientific evidence, it is reasonable to believe the product will be effective against a disease or condition; third, that the known and potential benefits of the use outweigh the known and potential risks; and fourth, that there is no adequate and approved available alternative.

This past Sunday, the acting HHS Secretary did issue a Public Health Emergency declaration and then followed that with declarations justifying the emergency use of certain antivirals, in vitro diagnostics and personal respiratory protection devices.

Let me briefly describe these Emergency Use Authorizations that FDA went ahead and issued as a result or following that declaration. Two of them pertain to drugs. Tamiflu is a drug approved, it is oseltamivir, for the treatment of uncomplicated illness due to influenza and prevention of influenza in patients 1 year and older. Relenza is approved to treat acute, uncomplicated illness due to influenza in adults and children 7 and older who have been symptomatic for less than 2 days and for the prevention of influenza in adults and children 5 years and older.

One of these Emergency Use Authorizations allows for Tamiflu also to be used to treat and prevent influenza in children under 1 year. In addition, under both authorizations, both of these medica-

tions may be distributed with information pertaining to emergency use to large segments of the population without complying with the label requirements that otherwise are applicable to dispensed drugs. They may be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with the State and local laws and public health emergency responses that I know are being planned around the country.

The third one related to a PCR flu panel diagnostic test for the CDC, which allowed the CDC to distribute to public health labs around the country a diagnostic test that can presumptively diagnose this particular infection.

And for all of these Emergency Use Authorizations, the way it worked is CDC applied; we worked very closely with CDC over the weekend to make sure everything was there to get the right information to people; and then we approved them on Monday starting early in the morning. This particular diagnostic test amplifies the viral genetic material. A positive result indicates presumptive infection. A negative result by itself does not exclude the possibility of infection.

The fourth authorization permits HHS to deploy certain disposable respirators in the Strategic National Stockpile for use to reduce exposure to airborne germs. These products, when used properly and in accordance with information that is provided, may help reduce the chances of getting sick. They do not eliminate the risk of illness or death. They should always be used in conjunction with other control measures, such as frequent hand washing, and should done consistently with the advice and guidance provided by the CDC and other public health authorities.

Let me just turn for the last minute to talk about how FDA has organized itself to respond to this challenge. As soon as we became aware of this last week, I asked Dr. Jesse Goodman, FDA's acting chief scientist and deputy commissioner for Scientific and Medical Programs to coordinate and lead FDA's efforts. Dr. Goodman is a world expert in infectious disease. He previously directed the Center For Biologics and has extensive experience in issues related to influenza vaccine production and evaluation.

We have changed the way FDA is managed for this process. We are using an incident management approach with Dr. Goodman as the leader, which includes seven substantive teams that are cross-cutting and include staff from across the FDA and all FDA centers. These teams work with the Department, CDC, other agencies, national and international partners, and they are the vaccine team, the antiviral team, the in vitro diagnostics team, the personal protection team, the blood team, the shortage team, and the consumer protection team. We also, in the incident management approach, have an operations section, a logistics section, and a communication section. We have senior level health, international, and legal advisors.

Let me very briefly explain how these teams work. The vaccine team is working to facilitate the availability of a safe and effective vaccine to protect the public from the 2009 H1N1 flu virus as soon as possible. Now, having that vaccine ready is the goal of the team. There is a completely separate question, and that is going to depend on the status of the epidemic of whether and who that vaccine

would be recommended for. But for FDA, we want to have a vaccine that is safe, effective and available as quickly as possible.

Part of this team starts in the lab. We are growing the vaccine and trying to genetically engineer a reference strain that could be used for vaccine development. We are already preparing a re-agent that will be needed to help manufacturers produce and test the vaccine. We are trying to think through what clinical evidence would be necessary before we can conclude that the vaccine is effective. This team is working with BARDA and HHS to have extensive consultation with the vaccine industry already as this goes forward.

I actually went out and met with the vaccine team earlier this week. They are scientists. They are physicians. They realize how much is at stake for this country.

There is the antiviral team, whose goal is to identify and evaluate antiviral drugs to prevent and treat illness and to facilitate access to these medications. This is the team that led the effort to review the Emergency Use Authorizations with CDC. They are also in extensive communications with manufacturers about other options to treat this infection, particularly if it becomes severe, and is working very closely with other regulatory agencies around the world. This team used its expertise to identify the right dose for kids under 1, and we are hearing from a lot of countries around the world about how they did that.

We have an in vitro diagnostics team that approved the tests that I was talking about that CDC is distributing. It is already working with manufacturers on the availability of other tests as well as current diagnostics just for basic identification of influenza.

The personal protective equipment team did the mask Emergency Use Authorization, and they are also in continuous contact with the key manufacturers to make sure that we can get the appropriate supplies of these products for the American people.

There is a blood team. The blood team is dedicated to the safety and availability of blood products needed for transfusion by the American public during this outbreak. The main focus of the blood team is to make sure there is adequate blood just in general because blood is so important for so many different people and patients around the country in that the response to this just doesn't reduce the number of donors, but they are also starting to think through whether there is any potential risk of the blood supply, and they are engaging other regulatory agencies. So far they are not, there is nothing that they are recommending in terms of particular controls based on their understanding of influenza.

We have a shortage team that is working very closely with manufacturers to, particularly around the issue of how they can expand production of key medications, as well as working with HHS and others about spot shortages that are occurring.

And finally, we have a consumer protection team that cross cuts across all the different parts FDA to monitor for scams, dangerous products, and things that may be marketed that could cause harm to people as they are worried about this situation.

So, in conclusion, FDA is fully committed and engaged in protecting the public's health during this difficult time. Among us are laboratory scientists, medical reviewers, epidemiologists, product

experts and field inspectors. We will bring every skill and every resource we have to this critical mission.

Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.

[The prepared statement of Dr. Sharfstein follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

STATEMENT OF

JOSHUA M. SHARFSTEIN, M.D.

PRINCIPAL DEPUTY COMMISSIONER and

ACTING COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

APRIL 30, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner and Acting Commissioner at the U.S. Food and Drug Administration (FDA or the Agency). Among its other responsibilities, FDA protects the public health by facilitating access to safe and effective human and animal drugs, human biological products, and devices. Recognizing the global nature of public health issues, we collaborate with foreign counterpart regulatory agencies and international organizations to carry out our mission. FDA plays a vital role in the Nation's preparedness for, and response to, challenges such as the one presented today by the 2009-H1N1 Flu virus.

FDA is part of a team led by the Department of Health and Human Services (HHS or the Department). Since the beginning of the 2009-H1N1 Flu virus outbreak last Thursday, FDA has worked closely with the Department, our sister HHS agencies, other U.S. government agencies, the World Health Organization (WHO), and foreign governments.

I appreciate the opportunity to discuss the Agency's response, including our approval of several emergency use authorizations earlier this week, and the efforts of several internal FDA teams.

Emergency Use Authorizations

Section 564 of the Federal Food, Drug, and Cosmetic Act, which was added by the Project BioShield Act of 2004 (Public Law 108-276), permits the FDA Commissioner to issue an

Emergency Use Authorization following a determination and declaration of a public health emergency, provided certain statutory criteria are met. An Emergency Use Authorization allows the use of an unapproved product or an approved product for an unapproved use, in a declared emergency. To authorize the emergency use of a product, FDA must generally find that the agent (in this case, the 2009-H1N1 Flu virus) can cause a serious or life-threatening disease or condition; that based on the totality of the scientific evidence available it is reasonable to believe that the product may be effective against the disease or condition; that the known and potential benefits of the product's use outweigh the known and potential risks; and that there is no adequate, approved and available alternative.

Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act provides that, before an emergency use authorization may be issued, the Secretary of HHS must declare a public health emergency justifying the authorization based on one of three grounds, including "a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents."

This past Sunday, April 26, 2009, the Acting HHS Secretary issued a nationwide public health emergency declaration in response to recent human infections from a newly discovered swine influenza A virus, the 2009-H1N1 Flu virus. On April 26 and April 27, the Acting Secretary issued declarations justifying emergency use of certain in vitro diagnostics, antivirals, and personal respiratory protection devices.

On April 27, 2009, FDA issued four emergency use authorizations in response to requests from the Centers for Disease Control and Prevention (CDC). Three of these emergency use authorizations make available to public health and medical personnel for emergency use two FDA-approved drugs, Relenza and Tamiflu, for the treatment and prevention of the 2009-H1N1 Flu virus, and an rRT-PCR test for diagnosing infection with the virus. The fourth authorizes the emergency use of certain personal respiratory protection devices, specifically disposable respirators certified by CDC's National Institute for Occupational Safety and Health, known as N95 respirators.

These authorizations expire by statute in one year unless previously revoked by the Agency, but they can be renewed if the conditions giving rise to the determination and declaration continue to exist.

Currently, Tamiflu is approved for the treatment of uncomplicated illness due to influenza and prevention of influenza in patients 1 year and older. Relenza is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older.

One of the emergency use authorizations allows for Tamiflu also to be used to treat and prevent influenza in children under one year. In addition, under the authorizations, both medications may be distributed with information pertaining to emergency use to large

segments of the population without complying with the label requirements otherwise applicable to dispensed drugs, and may be accompanied by written information pertaining to the emergency use. They may also be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable state and local laws or public health emergency responses.

The emergency use authorization for the rRT-PCR 2009-H1N1 Flu Panel diagnostic test allows the CDC to distribute the 2009-H1N1 Flu Panel test to public health and other qualified laboratories that have the needed equipment and the personnel who are trained to perform and interpret the results.

The test amplifies the viral genetic material from a human sample. A positive result indicates that the patient is presumptively infected with 2009-H1N1 Flu virus, but it doesn't identify the stage of infection. A negative result does not, by itself, exclude the possibility of 2009-H1N1 Flu virus infection.

The emergency use authorization for certain disposable respirators permits HHS to deploy these products from the Strategic National Stockpile for use to help reduce exposure to airborne germs. These products, when used properly and in accordance with information that is provided, may help reduce the chances of getting sick. They do not eliminate the risk of illness or death. They should always be used in conjunction with other infection control measures, such as frequent hand washing, and other measures recommended by CDC and state and local public health authorities.

The FDA's Efforts on 2009-H1N1 Flu

As soon as we became aware of the 2009-H1N1 Flu outbreak, I asked Dr. Jesse Goodman, FDA's Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to coordinate and lead FDA's efforts on 2009-H1N1 Flu. Dr. Goodman previously directed FDA's Center for Biologics Evaluation and Research and is a world recognized infectious disease expert with extensive experience in issues related to influenza vaccine development and evaluation.

Dr. Goodman leads an incident management approach that now includes seven substantive teams, which are cross-cutting and include staff from across the FDA as needed. All of FDA's Centers are engaged in this important work.

These teams work with the Department, CDC, other agencies, national and international partners. The teams include: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team.

The incident management structure also includes an operations section, a logistics section, and a communications section that coordinates external relations, including media, stakeholders, international, and legislative, and Web site development. It includes senior-level health, international, and legal advisers.

Below is a brief summary of the focus of each team. This management approach is flexible and likely to change over time.

Vaccine Team

Surveillance for novel influenza is ongoing and if epidemiological data suggest the emergence of a novel human influenza virus, we have the infrastructure to begin work in the event that a vaccine needs to be manufactured for the novel strain. The Vaccine Team is working to facilitate the availability of a safe and effective vaccine to protect the public from the 2009-H1N1 flu virus as soon as possible.

Part of the team is growing and genetically engineering the 2009-H1N1 flu virus in the laboratory for possible use in a vaccine. FDA is also beginning to prepare reagents that will be needed to help manufacturers produce and test the vaccine. The Vaccine Team also is working with CDC and other WHO centers on laboratory studies that may help us understand how well the seasonal flu vaccine might protect against the 2009-H1N1 flu virus.

At the policy level, the vaccine team is also fully engaged in discussions with the Biomedical Advanced Research and Development Authority (BARDA), a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS, the National Institutes of Health (NIH), and manufacturers regarding the initiation of clinical trials to evaluate the immune response to vaccines derived from this 2009-H1N1 flu virus and in considering options for production. FDA is a WHO/Pan American Health Organization collaborating center and is already working closely with WHO on vaccine issues, including testing and

development of seed strains in preparation for vaccine development. FDA is also fully engaged with sister regulatory agencies throughout the world.

Antiviral Team

The goal of the Antiviral Team is to identify and evaluate antiviral drugs that can be used to prevent and treat illness caused by the 2009-H1N1 flu virus and to facilitate access to these medications. This team led the Agency's efforts to issue the April 27th emergency use authorizations for Relenza and Tamiflu. In addition, the team is in communication with manufacturers to explore potential investigational options for treatment of the 2009-H1N1 Flu virus. Like the Vaccine team, the Antiviral Team is working closely with sister regulatory agencies throughout the world.

In Vitro Diagnostics Team

In Vitro Diagnostics Team's goal is to identify and evaluate in–vitro diagnostics that can help test for the 2009-H1N1 Flu virus. This team led the Agency's efforts to issue the April 27th emergency use authorization for the rRT-PCR test developed by CDC. This team is in communication with the Biomedical Advanced Research and Development Authority at HHS and manufacturers regarding potential shortages with the FDA-approved rapid influenza A test.

Personal Protective Equipment Team

This team works to facilitate the availability of personal protective equipment that may help reduce the risks from exposure to the 2009-H1N1 Flu virus. This team led the efforts to issue

the April 28th emergency use authorization for disposable N95 respirators. The team is in communication with manufacturers regarding current demand and ability to increase production to meet expected demand. The team is working with CDC on public communications about usage of various forms of respiratory protection.

Blood Team

The Blood Team is dedicated to the safety and availability of blood and blood products needed for transfusion by the American public during this influenza outbreak. Though we have no evidence to date that the 2009-H1N1 Flu Virus has at this time affected our blood supply, we are monitoring the situation for developments, and working closely with HHS, our sister agencies, blood banks, and other experts.

Shortage Team

The Shortage Team works to facilitate the availability of antiviral drugs to the American public. The team participates in daily calls with HHS' BARDA and manufacturers to assess current needs and availability of these products. FDA will be referring private individuals, including health care providers, to their state and local health departments to obtain information about product availability in their locale.

Consumer Protection Team

This team has the goal of protecting consumers from fraudulent and potentially dangerous medical products. FDA is monitoring the internet for sites selling products that claim to prevent, treat, or cure the 2009-H1N1 flu, among other things to protect consumers.

CONCLUSION

FDA is fully committed and engaged in protecting the public's health during this difficult time. Among us are laboratory scientists, medical reviewers, epidemiologists, product experts and field inspectors. We will bring every skill and resource we have to this critical mission. Thank you very much for the opportunity to testify today. I welcome your ideas and your questions.

Mr. PALLONE. Thank you, Dr. Sharfstein.

I thank all of the panelists.

We will now have 5-minute questions from the members. And I will start with myself.

And I wanted to ask, Dr. Schuchat, you mentioned the precautions people can take to protect themselves. But could you elaborate further, and let me just ask, what kinds of symptoms should people be alert to? Naturally, people look to their families, and you get all kinds of things; should I go to a doctor? Should I wear a mask? You don't necessarily have to comment on that. But what are the symptoms that they should be alert to? And what about going to the doctor? Does it make sense to go to a doctor? You don't want to overwhelm the doctors' offices either.

Ms. SCHUCHAT. The symptoms of this new strain of influenza virus are similar to the symptoms of seasonal influenza. And they include high fever, body aches, cough, sore throat. Those sorts of things. Unfortunately, the symptoms of influenza are very nonspecific, and they can be caused by lots of other things. It is important for people to use judgment. If you are really sick, you need to make sure you consult your health care provider. And if your children are ill, the same thing. But it is also important to recognize that this is a time where we don't want the worried well flooding the emergency rooms. We really do need to be careful about that kind of thing.

One of the emphasis areas has been diagnostic tests to help us differentiate this new virus from other illness. And so we are very pleased that this Emergency Use Authorization went forward, and the States are now prepared to differentiate this new flu virus from other things.

But in general, mild illness, you really are able to stay home and self-care. And illness that is a little bit more severe, you want to make sure you contact your health care provider. In particular, in areas where there hasn't been any recognized disease yet, we want people to let their health care provider know if they have these sorts of symptoms and have traveled to one of the areas that is affected.

Mr. PALLONE. You mentioned Mexico. I mean, I do see, well, people mention Mexico; I do see on TV you know people in Mexico wearing masks. That doesn't make, maybe it does in, Mexico but here, that is a little severe, isn't it?

Ms. SCHUCHAT. We think there are a variety of interventions that will help reduce the risk of respiratory infections. And we do feel for the people in Mexico who are in a difficult circumstance now and really doing everything they can think of to try to protect themselves.

Here we have issued guidance for the mask use, for different circumstances. And we update our guidance as we get new information on our Website. But I think it is important to say that guidance is going to be different in different areas. The New York City area was having an outbreak in a school that was fairly large, and their guidance was really targeted at the circumstances on the ground.

CDC is trying to issue guidance and updated guidance very frequently for the country. But we recognize that the local authorities

have the best information on their circumstances. And we really want people to know what is going on in your own community; what do your local authorities say? And really use us as a technical support to those local entities.

Mr. PALLONE. Let me ask Dr. Sharfstein about the vaccination. I seem to recall, I don't know if it was at the briefing yesterday or that they said that it probably wouldn't be available for everyone until maybe November at the earliest, possibly not until January. I remember in 2004 when we had a major shortage of the seasonal flu vaccine, and at the time, the public health officials were saying, if we faced a pandemic, we wouldn't have adequate vaccine capacity. Can you explain what the government has done to increase the vaccine manufacturing capacity, and where are we now?

I mention that I don't know where I heard that November to January. It might have been at the briefing we had yesterday but——

Mr. SHARFSTEIN. I am happy to answer that. In 2004, there were only about 60 million doses of vaccine for the flu that year because of the problem that one of the manufacturers had. And in addition, the infrastructure was relatively weak, and there wasn't the capacity if there was a pandemic to be making another vaccine. But because of the committee's efforts and the Federal Government's efforts and FDA's efforts, there has been a tremendous shift since that time. I will go through a couple of issues.

One is that there was funding appropriated to strengthen the vaccine infrastructure, and one way to talk about that is eggs. Flu vaccine is made in eggs. And in 2004, there weren't extra eggs. There was just the eggs for the regular flu vaccine. But HHS has gone out and contracted. They have extra flocks. And we have gone to a year-round egg availability. So there aren't any months where eggs aren't available. So that reduces most of the time that people were worried about in 2004 would be the delay.

On FDA's side, FDA aggressively went out and solicited other companies to be making the flu vaccine for the U.S. market and used an accelerated approval approach to bring online three new manufacturers. So, this year, I think the capacity is around 130 or 140 million doses instead of just 60 in 2004, with additional manufacturing capacity potentially out there. And all the companies already engage with us in how to make the vaccine and the eggs available.

I was hearing that we now have the capacity where we had 200,000 eggs a day only during the flu vaccine season; that that has gone up considerably, maybe as much as 500,000 eggs a day year round. So right now, the capacity in the system and the availability of the manufacturers to make vaccine is so much better than 2004.

The challenge is, and why people are talking about different dates to when it could become available, has to do more with the virus than anything else. There are several steps to make a vaccine and test a vaccine, and each of those has its own uncertainties. If everything goes extremely well, we will all be happy. But we don't know if everything will go extremely well. You could have a problem creating the virus initially, a problem growing the virus. And then when you make the vaccine, you have to test it to see if it gen-

erates the immune response you are looking for, or else it may have to be reformulated.

So I think the position is, to explain, is that the infrastructure we are building on is extremely strong, particularly compared to where we were in 2004. But we are dealing with an unknown virus, one that hasn't been turned into a vaccine before, and there is a lot of uncertainty about how that will go. But it is really a scientific uncertainty. I think the basic infrastructure to succeed is there.

Mr. PALLONE. Okay, thank you.

Mr. Deal.

Mr. DEAL. Dr. Vanderwagen, first of all, I would like to ask you, how did the administration arrive at the $1.5 billion as the figure that the request was made for? How would that money be distributed? To which agencies? What would those agencies be allowed to use that money for? And are there other funds that HHS can currently draw on to deal with this matter?

Mr. VANDERWAGEN. Thank you, Mr. Deal. Good question.

When we analyzed the potential demand for additional antivirals, we looked at the cost of production of vaccine. We looked at the cost of potential medical supplies should we have a wider, more severe event in the medical environment. When we look at a number of those issues, the cost requirements can be fairly significant. I think the President's intent was, given that there are all those potential uses, depending upon how this thing progresses, that this was a place to start.

I think the majority of that would be looking at such things as additional medications, additional development costs associated with the vaccine and getting it to the point where we have a safe and effective vaccine, and providing some support to local and State requirements for preparedness. I think those are the kinds of issues that we are looking at in terms of where that funding would go.

Mr. DEAL. You are not allowed to cough during this hearing. I am joking. You are not allowed to cough during this hearing.

Mr. VANDERWAGEN. Oh, well, it is allergies in my case.

So the universe of need could be quite large, much larger than that figure in fact. But this is a way for us to look at some of the known things that we think we are going to need to take care of. We are currently replenishing our stockpile for those amounts. And we are considering that. We have funds inside the Department we might be able to use to cover that, so that is a decision point that we are examining right now.

If we want to cover so those antivirals that we already sent to the States and replenish that, we may have funding available to us internally to do that. But beyond that, if we are going to start talking about wider support antivirals, it will be a very difficult challenge to find funding within the existing HHS appropriations for that.

Mr. DEAL. So part of it would go to facilitate FDA's more rapid response to approving vaccines, for example, for this particular thing, is part of what I hear you say. Is that right?

Mr. VANDERWAGEN. Well, the short answer is yes. NIH will conduct clinical studies for safety and efficacy in partnership with

FDA. That takes funding support. We would be looking at beginning to develop the pilot lots. That costs money to do that particular clinical trial. In series, we would be looking to try to ramp up vaccine commercial production capacity while those tests are undertaken. Those all have costs associated with them.

Mr. DEAL. Dr. Sharfstein, from the FDA point of view, I have been told, and I think the chairman alluded to this as well, that if we are developing a vaccine specifically for the H1N1 virus, that it could be done as a separate vaccine for that. And I have been told it would take maybe 4 months to get that, from the time you arrived at what you think the formula needs to be, about 4 months to get it to its production stage. Is that generally about right?

Dr. SHARFSTEIN. First of all, let me follow up on what you said before. There may be extra funds FDA needs, but I want to assure you that everything we think needs to be done is being done. And the management structure we have in place is really pushing the staff, and everybody is completely committed to doing everything we need to do to meet these different goals on each team as quickly as possible.

Four months is one possible scenario. But what it really depends on is how this virus behaves in a vaccine. I will just give you an example. We have to combine it with other viruses in order to get it to grow fast enough. Then it has got to eventually be grown in bulk. And then it has to be tested in people to see how much of it produces an immune response. If you do the first test, and it doesn't show the right—it may be the first test as a couple different options, but based on that data you have to look at it, because our goal is both an effective vaccine and a safe vaccine. So it is going to depend. Since we are not going to be waiting for eggs, that was actually one of the biggest problems in 2004——

Mr. DEAL. I hate to interrupt you, but my time is about out. I want to ask you one other thing.

My understanding is that, each year, in the seasonal vaccines, that you choose up to maybe three different strains. I assume this was not one of the strains that was anticipated to be included in the seasonal vaccine simply because you didn't, first of all, anticipate it; secondly you have not had the time to ramp up for it. Are you so far along I assume in the seasonal vaccine process that, if you were to be able to come up with a vaccine for this, that it would not be allowed to be included in the seasonal vaccines but would have to be a separate vaccination program? Is that a correct assumption?

Mr. SHARFSTEIN. That is an excellent question. You are right that it was not in the flu vaccine that had been prepared because people weren't aware of the virus's existence. And right now, we are basically developing with the manufacturers the ability to make a vaccine. And then there has to be some strategic decisions made over the next few weeks. One of those decisions is going to be whether to make this as a stand-alone vaccine, to combine it with other vaccines, and that in part has to do with the manufacturing capacity. If you make a single stand-alone vaccine, you can make more of it. And in part that is going to depend on how much of it you need to develop the immune response.

So there are a lot of factors out there. And what FDA does is it works with the CDC, the World Health Organization and an advisory committee of experts to look at all the evidence, look at what we know about how this vaccine looks to us as well as what we know about the manufacturing capacity, and then there will be a recommendation about how this integrates with the seasonal flu.

So it might, you know, it is too early right now to have an answer. But it is an excellent question. And I think probably within a few weeks, we will be able to know more and be able to give a better answer.

Mr. PALLONE. Thank you, Mr. Deal.

Chairman Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Schuchat, I would like to explore with you how this virus is different from other flu viruses. Most people are familiar with the fact that we have an annual vaccine to deal with the flu that might be in the flu season. And we are in the middle of all this where the flu season is pretty much over.

Every year, millions become ill, about 36,000 die from the regular seasonal flu in this country. But this new H1N1 flu does appear to be different. And I still recognize we have a lot to learn. But I am hoping you can clear up a few questions. Can you explain what the H1N1 flu is, and how it is different from the seasonal flu? Is this virus easily transmitted from person to person? And do we know how dangerous this virus is?

Ms. SCHUCHAT. Thank you.

This is a new virus that humans have not had before. There are H1N1 A influenza viruses that we get every year as part of seasonal flu. But this is a new H1N1 strain that we hadn't found before in all of the banks of strains that we have looked at. It is a very unusual one. It has four genetic components in it: one that comes from swine from north, from North America; one that comes from swine from Europe and Asia; a third part that has human origins; and a fourth part that has bird origins.

So it is a very unusual virus. And we don't believe that humans have experienced it before until these cases that we are seeing.

It does appear to be easily transmissible in terms of the information we have already here in the United States as well as in Mexico. But we don't have good information about how dangerous it is. It is a very important issue. In Mexico, we are getting more data about the severity. In the U.S., we are in early days, but really trying to understand how severe it is. We are taking it very seriously.

Mr. WAXMAN. On the news shows, there is a constant comparison to the pandemic flu in 1918 which did such devastation. And it is worrisome when we hear about this comparison because that virus affected not just the very young and very old but also affected otherwise healthy adults. Early reports suggest that many of these people who are being hospitalized in Mexico were apparently young and otherwise healthy as well. I know it is early, but can you tell us in what ways this might be similar to 1918?

Ms. SCHUCHAT. A worrisome sign from the early reports in Mexico was the age of the patients and the apparent young, healthy adults. That did ring a bell from the circumstances back in 1918. So far the cases we have had here in the United States that have

been laboratory confirmed are relatively young also. I think our median age is 22 right now.

But, again, we are beginning to collect more information and these things could change quite a bit. There are some very different circumstances from 1918. Today we have antiviral drugs that treat flu. We also have the antibiotics or antibacterial drugs that treat the kinds of secondary bacterial pneumonias that we think played a role in the 1918 devastation. We have better health-care circumstances. We have much better communication, and hopefully more skilled leadership who is doing the communication.

One of the really important things in addressing something like this is making sure that people have good information and that our interventions are not worse than the virus itself.

Mr. WAXMAN. Even if we assume that this virus is as bad as that one in 1918, these modern medical advances will be helpful in treating patients, we are not going to see the same kind of death and terrible results that we saw then when we didn't have vaccines, we didn't have antivirals, we didn't have the whole infrastructure of communication that we now have.

Ms. SCHUCHAT. I think the circumstances are much better today to respond to this kind of thing. I also want to introduce the uncertainty that every new strain is different and we really need to learn as we go about how this one will behave. We also are mindful of circumstances in other parts of the world which may not be as fortunate as ours.

Mr. WAXMAN. Would this virus possibly mutate in the next several months?

Ms. SCHUCHAT. Influenza viruses can mutate frequently, and we need to keep our eye on them. During the regular seasonal flu, we test strains throughout the season. Often we find changes in the resistance patterns of the virus. We are very happy that the original strains that we have tested are sensitive to the Tamiflu and Relenza that is in our stockpile, but we need to keep looking at that and also look at the antigenic or immune properties, because that will feature into what vaccine will be useful. So they do mutate and we need to keep our eye on that.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Waxman. Mr. Gingrey.

Dr. GINGREY. Mr. Chairman, thank you. First of all, let me just associate myself with the comment that our Chairman Emeritus, John Dingell, made in his opening remarks in regard to not overreacting to the point that we create a pandemic of panic. And I want to thank our panelists. I think already some comments have been made to that regard.

And yesterday when Secretary Sebelius and Napolitano and, Dr. Schuchat, you were there as well—it is very reassuring to Members of Congress to get the feeling that we indeed are prepared. The remarks that we heard from Dr. Sharfstein, of course, just add to that. I feel good about it.

I think what occurred in 2003, 2004 in regard to the fear of an avian influenza pandemic led to a $6 billion emergency appropriation. And as you have pointed out, a lot of that money went toward making sure that a stockpile of Tamiflu and Relenza was beefed up to something like 50 million courses, not just one dose, but courses

of treatment. And also the three or four pharmaceutical companies who had maybe been in the domestic business of manufacturing vaccine, but because of liability and no reimbursement for the vaccines that were never given, it was not a very cost-effective business for them. We helped with that, with grants and some of that money was spent in that way.

And then it is my understanding—this goes with what Ranking Member Deal mentioned as far as the $1.5 billion, Dr. Vanderwagen—that 1.3 billion of that original 6 is still available.

And I want to ask this question about that particular amount of money. President Obama, I think, had no choice because he doesn't want to get Katrina'd, you know; the media frenzy about this issue leaves him no choice but to say, well, look, we are not going to go to sleep at the switch and we are going to appropriate this money. But if, Dr. Sharfstein, if we decide that it is not really appropriate, not really necessary to go forward with the development of that vaccine specifically against this H1N1 flu—we won't call it swine flu—then maybe at some point when this is all said and done, it turns out to be a mild disease and people kind of go back to their normal living and they are not shutting down schools because one child is sick, and they are not avoiding the subways and taking commercial airline flights—I mean, you know, we are getting to the point where I fear that we are getting ourselves in a frenzy and it is inappropriate. So if this thing turns out not to be the real bad pandemic that everybody fears it could be, then I would hope that the money that is not spent to develop this vaccine will go back to John Q. Taxpayer, go back into the general Treasury or whatever, and not just stay there for the next 10 years when it is really not needed.

I don't want to underplay this. I am a physician member. I don't want to have egg on my face a month from now. But I do agree with Chairman Emeritus Dingell, we don't want to overreact here. And I think Dr. Schuchat mentioned that yesterday, and again today, and I would like for all of you to comment on that a little bit, if you would.

Ms. SCHUCHAT. I think it is really important to recognize the uncertainty that we have, that influenza can be very unpredictable, that evolution of the situation in the past week has had many worrisome aspects, but that we are acting aggressively. And I think that we really do need to make sure that we are able to aggressively respond.

An important issue, I think, is that the investments that were made in the past few years for pandemic preparedness have greatly strengthened our response to seasonal influenza. And as was mentioned, 36,000 Americans die every year from seasonal influenza. So it is likely that flexible programming of emergency funds would be flexibly applied to strengthening our work against the seasonal flu, which is such a killer in America.

Dr. SHARFSTEIN. I think that your point is very well taken, and we heard about the analogy of the 1918 flu, but some people have also been discussing the 1976 swine flu situation. And in looking back on that, some historians said that might have been an instance where people overreacted. And the lessons, I think, that were drawn from that experience was that you have got to separate

out the preparation for the possible worst-case scenario from actually implementing it, and that people in looking back felt like maybe because they had a vaccine, they had to use it. And I think it is very clear now that those two things have got to be separated.

In the end, it is going to be okay if we have a vaccine but it turns out not to be a pandemic. We just don't want to be in a situation where we have a pandemic and we don't have a vaccine.

Mr. VANDERWAGEN. And the last comment—just to finish out your threesome here, sir—I think that we are now down to about 600 million remaining. And most of those, as you know, we received special milestone payment authority under the Pandemic and All Hazards Preparedness Act for acquisition of materials and so on. That balance is really already sort of precommitted as part of those milestone payments which are going for diagnostics, new antivirals in case we develop resistance to the existing antivirals, and to support some other vaccine analysis that is ongoing. So it is committed in the milestone payments stream for those products that are in development.

Mr. PALLONE. Thank you. We just have one vote. I am going to try to proceed with questions. I am going to see if there is some way we can work it out so that we don't have to break, but I don't know if that is possible. But in the meantime, we will proceed to Chairman Dingell.

Mr. DINGELL. Mr. Chair, I thank you for your courtesy and I commend you for the hearing. I have several questions I would like to have for the record. And I would ask unanimous consent that the responses be inserted into the record at the appropriate place and fashion.

The first one: Who is going to be the lead agency? Is it going to be HHS or is it going to be the Department of Homeland Security?

Mr. VANDERWAGEN. The simple answer is for public health and medical activities, it is Health and Human Services; for the wider response, if it involves energy, transportation, security, et cetera, that is all in the hands of DHS. We all work as a coherent team under their leadership.

Mr. DINGELL. Do you have a memorandum of understanding to finding how that is going to be done?

Mr. VANDERWAGEN. Yes, sir. There is a National Response Framework.

Mr. DINGELL. Would you please submit that for the record?

[The information appears at the conclusion of the hearing.]

Mr. DINGELL. How is this budget going to be expended? Would you submit to us a statement of how the money is going to be expended, if you please?

Now, the States are going to have a very severe problem. My home State of Michigan has a budget deficit which it has been announced is going to go to a billion dollars after some very savage efforts to cut back on the expenditures. How much of this money, this billion and a half dollars, is going to go to the States to be expended through their agencies, for what purposes?

Ms. SCHUCHAT. I think these matters are being evaluated and the Office of Management and Budget is intending to submit something soon with those types of allocations.

Mr. DINGELL. So the answer is we don't know?

Ms. SCHUCHAT. Exactly.

Mr. DINGELL. I am assuming that the answer is you do not yet have a defined budget structure?

Ms. SCHUCHAT. [Witness nods in the affirmative.]

Mr. DINGELL. There is no nod button on the reporter's response. The answer is yes; is that right?

Mr. VANDERWAGEN. Yes to what, sir?

Mr. DINGELL. What is the potential for this flu outbreak to reach pandemic levels?

Ms. SCHUCHAT. The World Health Organization elevated the phase yesterday to Phase 5, which is the second highest phase. But here in the United States, we have already been acting as if it were a full-blown pandemic in terms of our response, aggressively preparing for widespread disease in many communities. We don't know if that will actually happen. But we are seeing sustained transmission in a few communities. We don't yet have severe illness, or lots of severe illness, but we fear that we may have additional severe cases as we have with seasonal flu.

Mr. DINGELL. I would like to have you submit to the committee as soon as you can, what assistance the Federal Government is going to be providing the State and local units of government to enable them to address their responsibilities in this matter of flu. I ask unanimous consent that be inserted into the record at the appropriate place.

Mr. Skelton. I note that FDA is currently using three products whose use is being vigorously monitored. The Secretary was granted emergency use under the 2004 Project Bioshield law to clear the unapproved use of particular products in the event of an emergency. The Secretary is exercising this authority for two drug products and one diagnostic test. What are the considerations in deciding to clear the products for use of young children and adults? This is for Dr. Sharfstein.

Mr. SHARFSTEIN. Sure. Thank you for the question. The basic considerations are set out in the law. And then I will tell you how we applied it in this case: that, first of all, there is a serious or life-threatening condition. We know that is the case.

Second, that the totality of the scientific evidence makes it reasonable to believe that the product may be effective.

Third, that the known and potential benefits of the use outweigh the money in and potential risks.

And fourth, there is no adequate approved and available alternative.

Now, for kids, the only thing that is done differently under the emergency use authorizations is for Tamiflu, where it permits the use under age 1. And it is an excellent question because you think how did FDA decide that that was okay, how did you figure out a dose? It was not in the original label. And it turns out FDA has been looking at this for a couple of years and has been working very closely with NIH and the company to get data on under age 1.

And there was actually a study that was done, FDA reviewed the study, and even over the weekend got additional data from the company involving more than 750 infants from Japan and also

some German data. There was a study that was organized out of NIH which was specifically for kids—

Mr. DINGELL. Please submit the rest of our question for the record.

Mr. SKELTON. I would like to know if your agency has a regular on-the-shelf plan to address these kinds of problems when they arise; yes or no?

Mr. PALLONE. Chairman Dingell, if I could just interrupt and tell the members what we are going to do is continue because of the time constraints of our public health witnesses here. And then Mrs. Capps, as our vice chair, is going to come back and replace me so I can go vote. So you will have about 8 minutes left if you want to leave now and come back—I don't mean the witness, I am talking about the members. We are just going to continue.

I apologize for interrupting, Mr. Chairman.

Mr. DINGELL. I will repeat the question. I would appreciate you submitting for the record, one, the answer: Do you have an on-the-shelf plan. You are nodding yes?

Mr. VANDERWAGEN. Yes is the answer.

Ms. SCHUCHAT. Yes, all of us do.

Mr. DINGELL. All three of you?

Mr. VANDERWAGEN. Yes.

Mr. DINGELL. Does that include working with the Department of Homeland Security?

Mr. VANDERWAGEN. Yes.

Mr. DINGELL. And do they have one?

Mr. VANDERWAGEN. Yes.

Mr. DINGELL. Would you submit those plans to us for the record, please?

Mr. VANDERWAGEN. Can do.

Mr. DINGELL. Mr. Chairman, I thank you.

Mr. PALLONE. Next is Mr. Murphy.

Mr. MURPHY of Pennsylvania. Thank you, Mr. Chairman. I want to thank all the distinguished panelists. I am learning a great deal here. I am not a physician. I am a psychologist and I understand panic. And I need to ask you some questions, and I am not meaning to embarrass anyone, but I think it is very important that you get some official statements out for this.

Is anyone from any of your departments recommending that any American citizens avoid airplanes, buses, elevators, confined spaces; or do you think that perhaps we should not be saying that right now?

Ms. SCHUCHAT. We are recommending that people defer non-essential travel to Mexico. We are recommending that people who are sick not get on airplanes or public transportation, and I think there may have been a misstatement.

Mr. MURPHY of Pennsylvania. Do you all agree with that? We will let it stand at that. But I do think it is important that we let people know this. Every year when there is a flu in this country, many people die, sadly, from that. But the main thing is to understand that you are working this issue very hard, and I appreciate what you are doing.

However, it is a concern about anytime people will use transportation. And I am wondering as part of your plan, we have the

transportation security system set up. Every airport has lots of poachers and lots of issues, and I am wondering if you are recommending people not travel if they are sick, stay home if they are sick. The airports are a particularly important area because that is where you have people who may be ill traveling across the country and spreading this.

Is this part of your plan to also include that as a location for other public information posters perhaps at airports? And added to that, anything you are advising airlines with regard to if they see passengers come to the airport that appear to be sick?

Ms. SCHUCHAT. Yes, we have been issuing both guidance as well as developing materials. We have also started to hand out the yellow card, the travel health alert notices, at airports and other ports for people who are traveling to know what signs to look for and what to do if they do become ill. And we are certainly—we actually just recently issued guidance for airline crews if they were caring for someone who was ill, what are the steps they need to take. And we will continue to update those kind of guidances.

Mr. MURPHY of Pennsylvania. Will this include information that airport security or airline workers, if they see someone who appears to be ill before they get on the plane, perhaps tell them not to fly?

Ms. SCHUCHAT. Yeah. That is right. We actually do already have quite a bit of intervention in terms of education for the travel worker, the customs and border protection personnel, as well as a good relationship with the airline industry. We have developed a greater collaboration during the SARS problem to really be able to make sure people working in that profession could recognize the issues and address them.

Mr. MURPHY of Pennsylvania. And one other thing, and open up to other comments as well, certainly we are aware of those things that our parents taught us: You cover your mouth if you sneeze; if you are sick you stay home; you wash your hands. I see you have your little bottle there. You have been using that very effectively, Doctor.

But are there things that you advise people not to do? For example, should people go out and get Tamiflu and just start taking it? Should people start taking antibiotics if they have some in their medicine cabinet? What kind of things are not a good idea for people to do? I wonder if you could comment on that.

Ms. SCHUCHAT. At this point we are recommending that drugs like Tamiflu, which is an anti-flu viral—or antiviral drug against the flu, or antibiotics against bacterial infections, be taken under a doctor's advice.

Mr. MURPHY of Pennsylvania. Are antibiotics useful at all with the flu?

Ms. SCHUCHAT. Influenza is a viral infection and antibiotics treat bacterial infections. Some people suffering influenza can later develop a secondary or late-onset pneumonia caused by a bacteria. So there are circumstances laid on following influenza where antibiotic treatment might be necessary, but this would all be under a doctor's advice.

Mr. MURPHY of Pennsylvania. Again I am asking the panel this. Some people may call their doctor now and say, can you give me

a prescription for antibiotics? I have got some in the medicine cabinet when I was sick last year, should I start taking them? What would you all advise?

Mr. VANDERWAGEN. We would advise people not to self-medicate; that they should seek consultation with their physician before they take any medical intervention. And we are advising them that this is a doctor-patient relationship that has to be worked through, rather than just arbitrarily deciding to medicate yourself.

Mr. MURPHY of Pennsylvania. Do you agree with that, too, Doctor?

Mr. SHARFSTEIN. Yes.

Mr. MURPHY of Pennsylvania. I appreciate that it is important that—I don't want people to take this too lightly nor too seriously, as we had the SARS issue, as we had the avian influenza issue. These are good important issues that people need to be addressing, and I do appreciate the important medical comments and information we would be sending out to Americans. Thank you so much.

Mr. SHARFSTEIN. I would just add that people can contact their local health departments also to understand what things may be accessible.

Mrs. CHRISTENSEN. [presiding] Thank you. The Chair now recognizes Congressman Green for 5 minutes.

Mr. GREEN. Thank you, Madam Chairman. And again, I want to thank you. I have a district in Houston, a very urban district, and people go back and forth to Mexico literally every day. But I appreciate the measured response, but also the planning, because our Governor just announced a disaster declaration because of the issues.

We have two schools now, public schools, Hamilton Middle School and Harvard Elementary School. Because of a child, they have shut down the schools. So they are being very cautious. And that is the encouraging—all of our directors are planning to do that, I think.

One of the concerns I have is that because of the experience a few years ago when we didn't have the development of the regular flu vaccine—and I think Congressman Deal may have mentioned it. You are not recommending slowing the production of the flu vaccine that we know we typically would be receiving in the fall. This would be a separate injection, if we get to that point?

Mr. SHARFSTEIN. Right now there is no recommendation to slow the production. However, as we understand more about the virus, the threat of the new virus, that could potentially change, but it will be a decision that is made with a lot of external input from a lot of very smart people thinking about what the best balance is going to be.

Mr. GREEN. I know HHS is releasing 25 percent of the strategic reserve of the 50 million treatment course of antiviral drugs, Tamiflu and Relenza, in the strategic national stockpile. It is my understanding these will be available to all States, prioritizing distributions to the affected States; is that correct?

Ms. SCHUCHAT. Yes, that is right. We have released 11 million of the 44 million doses that were designated for the State or project areas, and all of the States will be receiving those. Already 11 have either received or are en route, I think.

Mr. GREEN. I guess my concern is that in Texas we are seeing actually pharmacies who are running out because of prescriptions. And I am glad that is happening.

Mr. VANDERWAGEN. Recall that the principles under which we established that stockpile was a partnership with States and that the goal was for we in the States to be able to cover 25 percent of the population for treatment of active disease. That was the principles under which that acquisition was really driven. And most of the States bought their share. There are a half dozen States or so that did not. But we are still providing a pro rata share to all the States in that event. But it is about treatment for people who are sick.

Mr. GREEN. Okay. I know Texas has 840,000, 7-day course of antiviral medication, and I heard we qualify for an additional 650,000. Is that generally correct? Do you know on a State-by-State basis?

Ms. SCHUCHAT. I guess actually I want to correct what I said. What I know is that we have completed the shipments to nine States and six of the States completed receipts of shipments in the last 24 hours, but we are continuing to work through the listing. So I don't know the doses.

Mr. GREEN. Okay. If you could get that information back to our office. I know Congressman Gonzalez from San Antonio would share the same concern, my colleagues on the Republican side.

Mr. SHARFSTEIN. There is one thing I want to mention, to be clear. You said some pharmacies were having shortages. And the medicine going into the States is going through the public health side, not directly to the pharmacies, and it will be up to the local and State public health plans how that medicine gets distributed.

Mr. GREEN. Well, I guess—I have a daughter who is an infectious disease fellow at the University of Texas medical branch, and she told me Galveston—which is not our district—all the pharmacies in Galveston County were out of the prescriptions. But I don't know about in Harris County, which is Houston, where Galveston is separate.

What role should the State play in the distribution of these drugs? It is going through the public health like we have and that is where I am getting my information, is from the State Health Commission.

Ms. SCHUCHAT. Each of the States has a plan for how they are going to do their distribution. So we look to them to let local folks know how it is going to work. But that has been part of the States' pandemic efforts.

Mr. GREEN. In my last 49 seconds, I know the answer to the question on the H1N1 vaccine and how quickly we can get a development is a couple of months. Two months seems a fairly short time frame for a vaccine to both be tested and it is safe for individuals, whereas Tamiflu was recently labeled to show adverse psychological effects. What precautions is the FDA taking to monitor adverse effects from this new vaccine that we are developing now?

Mr. SHARFSTEIN. Just on Tamiflu, there is a team that is looking specifically at Tamiflu adverse effects. For the flu vaccine, it depends if it is—you know, from the manufacturing standpoint, there is a chance that this will just be produced according to the regular manufacturing approach; in which case, you know, every year it

has to be done pretty quickly because every year the flu vaccine is different. If a different approach has to be taken, that will raise different types of oversight issues. But in all those things, assuring that the risks are outweighed by the benefits and that we think it is a safe vaccine is really the point of our involvement.

Mr. GREEN. Okay. Thank you, Madam Chair.

Mrs. CHRISTENSEN. Thank you. Mrs. Blackburn of Tennessee is recognized for questions.

Mrs. BLACKBURN. I want to again thank you all for your patience for being with us yesterday, Dr. Schuchat, and then for you all being here this morning to help answer these questions. We are concerned.

In my district in Tennessee we now have a Williamson County case and a Shelby County case. So as you can imagine, as this started to make its way into the news last evening and this morning, I am hearing from parents and from constituents and medical care providers and health care providers with some questions. And one of the questions that has been asked of me—and if you can provide some guidance on how best to answer this, I think it would be helpful.

The way the process, the way we understand the process, when a doctor takes a culture, that goes to a State lab. When a State lab suspects that this culture has either the H1 or the N1 and they decide that there is probable cause that it could be the H1N1 strand, then it comes to the CDC for confirmation.

Then my question is: Number one, how many of those cultures do you have waiting for confirmation? And number two, once that culture makes it to you, how long does it take for you to provide that confirmation?

Ms. SCHUCHAT. Part of our planning has to be make sure that we have adequate staff day and night for something like this. And the laboratory staff in the influenza division have been doing—we have had shifts throughout the night, throughout the weekend. But we have also taken steps to increase the capacity at the State public health labs with these kits that were recently approved for shipment and started to be shipped on Monday. It was incredibly quick, so that more and more State and local areas will be able to do that, confirmatory testing on site.

We are not working with a backlog. We are really working around the clock to make sure that information that is so critical for local decision-making is available. We have made many contingency plans for the surge idea so that the State and locals have some capacity through the public health laboratory network. And also we have got some agreements with commercial labs to help with surge of specimens for sort of——

Mrs. BLACKBURN. Is it fair to say you all turned this around in a day, or a matter of hours? What is the time frame there?

Ms. SCHUCHAT. There are several steps. You know, a doctor will take a test and make it a positive rapid result or make it a suspicious result; forward that onto the State or local laboratory where the strain needs to grow and additional things happen, although now they have these PCR tests that are more rapid. At that result, things get sent to us.

Sometimes the shipping is even one of the longer steps, although we have been really expediting that, and then it is several hours upon receipt in the CDC lab before results would be available. Things may change over the days ahead as increasing numbers of cases are detected, and we really need to make some triage decisions. But at this point, with new States wondering do we have this or not, we are really prioritizing that kind of question that is going to make a difference for a school district, for instance.

Mrs. BLACKBURN. Dr. Sharfstein.

Mr. SHARFSTEIN. Just to follow, CDC just did an unbelievable job basically inventing a lab test for this, that could be shared with the States within a couple of days, and FDA worked with them so that all the instructions were there, all the quality assurance procedures are there. And now the State public health lab network, which was sort of created to be ready for exactly this, they have the kit. So for somebody in your county, really it should go to—to the State lab and they are the ones making the diagnosis. Those samples shouldn't even have to go to CDC anymore. And that was all done so quickly to be able to give them that capacity.

Mrs. BLACKBURN. That is great. So individuals should know within a day, 2 days? What would be the answer?

Mr. SHARFSTEIN. That is probably going to depend on the policies of the State. But the test itself doesn't take more than a few hours. It is a question of how they are handling the—

Mrs. BLACKBURN. And you have both the public labs and the private labs involved in this process?

Ms. SCHUCHAT. It wouldn't be the hospital labs. The public State labs or some of the bigger city labs are part of this public lab network. There are a couple of commercial laboratories that aren't doing that special testing, but they are ready for surge of the original testing.

Mrs. BLACKBURN. I have got one other question and we may not have time for you to answer it. But we have had questions from several people. This is not flu season in the U.S., and this seems to be a very strong strand; and as we move into the warmer months, it may naturally dissipate. But your expectation for when we move into flu season in November, how do we best prepare for a resurgence? Do you think it will come back? Will we have a vaccine by that time? What is the preparation strategy for next year's flu season?

Ms. SCHUCHAT. These are really important issues. We are mindful that things may look like they are getting better, but we might have a resurgence in the fall. There are many steps being taken to anticipate that, and part of the efforts of evaluating production of a vaccine is with that in mind. Also looking to the southern hemisphere for what happens there, because they typically have a reverse season from us, and then also understanding the evolution of the virus during the next bit of time.

While flu season is pretty much over in most communities here in the U.S., it is not completely over everywhere. But you are right that we usually don't see cases in the summer, except in people coming back from the southern hemisphere, and then we will be mindful in the fall.

Mr. SHARFSTEIN. I would say we would like to have a vaccine as soon as we can get one, and even if it—let us say you have a vaccine and it doesn't come back in the fall, that is okay. We don't want to be in a situation where you have a serious problem and you have stopped making the vaccine for some reason. So the plan is to prepare for the worst.

Mrs. BLACKBURN. Thank you so much. Thank you, Madam Chairman.

Ms. CHRISTENSEN. Thank you. The Chair now recognizes the vice chair of the full committee, Ms. DeGette, for questions.

Ms. DEGETTE. Thank you, Madam Chair. I want to congratulate all of you and your agencies for the aggressive efforts and smooth preparations you are taking here. I have been on this committee now for 12 years and remember quite well the hearings that we had in 1993, 1994 and 1995. In fact, I have been urging our leadership to have additional hearings so that we can see the progress. And I am gratified to hear that we have made progress.

I do have a few questions, though, about what will happen. My first question is: Do we have a sense of what the incubation period of this virus is?

Ms. SCHUCHAT. We are looking at these new cases and the numbers change day to day. Recently, I would say conservatively, 2 to 5 days or maybe 1 to 5 days. The idea is that it is a relatively rapid transmission from one person to another.

Ms. DEGETTE. One thing I think is that—you know, I have a high school freshman in Denver, and I think at high schools and colleges all around the country, many of the students are concerned that if they or someone they knew went to Mexico some weeks ago, that that could still be incubating. I think that is important to say. Although, of course, it can be transmitted from person to person here.

My second question is: I am concerned about the fact that while we have come a long way over the last few years, as Dr. Sharfstein was describing about developing the egg-based vaccines, I am concerned that we still have not been able to move to a cell-based production. And I am wondering if you can talk about what the status is of development of a cell-based vaccine?

Mr. SHARFSTEIN. Sure. There has been a tremendous investment in cell-based technology, so that was done in parallel with getting the eggs up to—capacity up so that the seasonal—so that the egg-based vaccine could be produced relatively quickly. There are companies that make cell-based vaccines and FDA is working very closely with them.

Ms. DEGETTE. Are you working closely with them to develop cell-based vaccines around this new H1N1 virus?

Mr. SHARFSTEIN. Yes, in the sense that we are discussing that with them. But I think the sense that I am getting is because we have a licensed process for the egg vaccine and because we have the eggs, that we have a terrific potential capacity to make plenty of vaccine with the traditional approach, rather than have to—and that would be our preference, because we know all the steps in the process.

Ms. DEGETTE. Except for the fact, Doctor, that if it truly does turn into a pandemic, then having 160 million doses by next Janu-

ary, or whenever, is not going to be sufficient even for the U.S. population, much less around the world. And so it is great in the short term, but ultimately we are going to need to move to that cell-based vaccine?

Mr. SHARFSTEIN. Your point is very well taken. I think a couple of things to say, that is why we are having the conversations with them, and that is the future and that is why there is such an investment.

Ms. DEGETTE. But it is not going to be the future for this particular strain, correct?

Mr. SHARFSTEIN. I don't want to rule that out. That is under discussion. What I have heard from the vaccine team is that they believe there is a tremendous potential. And it is probably—the potential is larger 160 million doses. That 160 million doses are trivalent vaccine, meaning that three strains—so it is actually probably somewhere around triple that. Plus—

Ms. DEGETTE. But efforts are being made to move to the cell vaccine, even with this—

Mr. SHARFSTEIN. Right.

Ms. DEGETTE. My next question is: Is there some potential that this virus could mutate in the summer months, between now and the fall, when we think we might see a resurgence? Dr. Schuchat.

Ms. SCHUCHAT. Yes, that is possible. And that is why we will be continuing to look at it. Just to clarify, the planning assumptions were to have capacity to be able to produce enough vaccine for 300 million people, assuming two doses. And there are lots of things to be sorted out about how much quantity we are going to need that will influence what the real capacity is.

Ms. DEGETTE. Right. But, again, I am concerned because if, with this old egg-based technology—like I say, I think we have come a long way. I am not trying to be critical. But heaven forbid, the virus mutates between now and the fall, then we have to develop a new vaccine and keep with the egg-based technology. We may not have a vaccine developed until next spring, and I think that is worrisome to all of us. Dr. Vanderwagen.

Mr. VANDERWAGEN. Let me add one or two things to what Dr. Sharfstein has offered you. We think 600 million doses is achievable in a 6-month time frame. We think that is achievable both in egg-based, with some cell-based augmentation. Part of Congress' investment, all the money that was talked about in flu investments, 1.3 billion went to the development of cell-based cultures. We have two large plants that are in very late stage of construction. They are close to inspection. And we have made significant progress with them. Will they be ready by January? I don't know that they will exactly be ready by January, but we know from the existing infrastructure we could probably generate a monovalent—600 million doses in a 6-month time frame.

Ms. DEGETTE. Thank you. Mr. Chairman, I would hope these witnesses and their agencies would continue to keep this committee apprised of their development of the cell-based vaccines and their development of the doses as we move forward in the coming months.

Mr. PALLONE. [presiding] I would appreciate that and I am sure they will.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Our vice chair, Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman. And thanks to each of you. You have been spending a lot of time in the last couple of days here on Capitol Hill, and it is very valuable for us to have your expertise and to be kept abreast of what is going on.

A different set of questions from me, please. The recommendation for people—and I will address this to you, Dr. Vanderwagen. All of you have comment—but I want to just sort of go from topic to topic. I have three. The recommendation is if you have the symptoms, call your health provider. Forty-seven million Americans don't have regular access to health care. It seems likely that if this progresses and becomes worse, emergency rooms and hospitals, other public places, are going to be on the frontline of receiving all of these patients, because they would be the first place and the only place many people could turn.

Our emergency rooms are already overflowing and it is clear that responding to a pandemic would be more than they could handle under existing circumstances. Our goal now, simultaneously, is to work toward providing health care for all Americans, access to health care.

In the meantime, I want a comment from you on what kind of emergency coverage—do you recommend a particular plan that we could speedily enact to provide coverage in this case of an emergency?

Mr. VANDERWAGEN. Well, ma'am, I really appreciate your linkage between preparedness and health security and health reform, because I think they intertwine in a way that people don't always realize, and I appreciate that. Medical surge is a function of people, facilities, supplies, equipment and systems. And what we have seen with investments that Congress has appropriated to us in hospital preparedness is the emergence of systems that rely on the fact that no one place is going to be able to manage the flow.

So how do we work collectively to share that flow in a way that takes the burden off? We have seen extraordinarily good examples of this in a wide variety of states: Illinois, Minnesota, North Carolina, et cetera. These are best practices that have been put in place, that these States have already done a significant job of analyzing people, equipment, facilities. Those are the kind of best practices we would extend to communities that are still trying to find the answer to that problem. The emergency assistance impacts between States also offers us ways for hospital care, not so much emergency department evaluation, but for hospital care. There are good models out there and best practices that we can share with communities.

Mrs. CAPPS. Thank you. And, Mr. Chairman, I would hope that we could keep this discussion going as the days go, in case there is a way that we should be responsive to you as well.

Now, another challenge, Dr. Schuchat, for the provider in the household. You are calling on people to stay home if they are ill to prevent the spread of the H1N1 flu. But millions of people work every day but don't have any sick leave, don't have any time that they can take; and with this economic uncertainty, they are very reluctant to stay home from work, and to work with symptoms and

have to send their kids to school because there is no one to stay at home. This is going to be difficult to contain the flu.

We do have legislation in the works. Senator Kennedy and Congresswoman DeLauro are planning to reintroduce the Healthy Families Act. I am cosponsoring it. And that would guarantee 7 sick days a year.

First of all, you could help us with support of that kind of legislation for the next event, and maybe if you have any thoughts of what you or we could do together to respond to this crisis.

Ms. SCHUCHAT. Just a few comments. Health in the workplace and health in the family is very important. It is a central component of public health. And we did see during the SARS epidemic that in Canada some of the hospitals were really taxed trying to figure out how to make sure that health care workers, including contract employees would stay home, whether furloughs needed to be used. And it was a very difficult circumstance to make sure that health was taking a front seat and that the rules could be worked out. So we would just be supportive in making sure that health is addressed.

Mrs. CAPPS. Thank you. I have one final question and there is not a lot of time for it, and maybe some ongoing conversation about this. It is to any of you, because workforce shortages are something that you are experiencing in every one of your agencies and all of our local and State public health facilities. Eleven thousand public health workers are due to be laid off because of State budget cuts, attrition over the past year. This is exactly who you are depending on, even as we speak for solutions. Do you recommend any suggestions for us to help you do this or to recruit more or to implement anything?

Mr. SHARFSTEIN. A month ago I was the local health officer in Baltimore, Maryland, working with Congressman Sarbanes and others. And I think your point is very well taken that a lot of the things that are being planned at the Federal level really depend on the State and local public health authorities to implement. The emergency use authorizations that we granted have a very clear role for State and locals and how they hand out medicines that may be important to people. Eventually if there is a vaccine that will be delivered through the public health infrastructure, and ensuring that that infrastructure is strong is extremely important, and I know it is very important to the administration.

Mrs. CAPPS. My time is up, but there is more to talk about. Thank you very much, Mr. Chairman.

Mr. PALLONE. Thank you. Mr. Blunt.

Mr. BLUNT. Thank you, Mr. Chairman. I have a couple of questions here. One, I got an e-mail from my daughter late last night who lives in Kansas City and it involves her, but even more importantly—just as importantly, involves my grandchild. I guess I ought to think about how I say that. And the e-mail from her is a confirmed case of swine flu in Kansas City. On a scale of 1 to 10, how concerned should we be? Anybody want to give an answer to that?

Ms. SCHUCHAT. People like your daughter are concerned and so are we at CDC and so is the government. But we are taking ag-

gressive steps to address the challenges and we do feel that we have been exercising and planning for this kind of circumstance.

There are lots of things everybody can do in the community and the family, as well as in schools and workplaces. So I think that this is a serious situation and we all really need to get ready for some uncertainty, to stay aware. It is great that your daughter knows exactly what is going on where she is and that guidance from the local and State authorities will probably help her understand what is going on there and what the next steps are if your grandchildren's school is closed, for instance, or really what are the plans.

Mr. BLUNT. It is called swine flu, but is there any concern about the food supply at all? I think it is important to clarify that, and you may have already. But if you wouldn't mind repeating that for me.

Ms. SCHUCHAT. Sure. There is no evidence that swine in the United States have this new virus. There is no evidence that eating pork or pork products gives you this infection. The USDA is aggressively looking at the issue both here and working with Mexico as well. And I would say that we don't have any reason to believe that eating pork gives you this particular infection.

Mr. BLUNT. We have no reason to believe we have any problem in any part of the U.S. food supply?

Ms. SCHUCHAT. No. This isn't an infection that we think is foodborne.

Mr. VANDERWAGEN. Our veterinarian colleagues over at Agriculture call this human flu, because it doesn't occur—they don't see it in pigs, so they are calling it human flu.

Mr. BLUNT. I think that is a good thing to understand because there is some reaction at the grocery store to what they think.

The other question I would have: On Amy Blunt's scale of 1 to 10, assuming 10 is the most concerned, it seemed to me that the Vice President was there this morning at the 10 level when he said he would advise people not to get on planes, his own family, or even on subways. I am sure that is not the official position of the government.

Would somebody reiterate what must be, for a repetitive response, the official position of the government on that topic?

Ms. SCHUCHAT. We have advised people to defer non-essential travel to Mexico. We have advised people who are ill with respiratory symptoms and fever not to go to work or school or not to get on an airplane or public transport. But we do not have recommendations to stay away from those transport methods if you don't have respiratory symptoms, and I am looking forward to getting on an airplane later today to go back to Atlanta.

Mr. BLUNT. Well, most of us will get on airplanes later today, too, to go back to Atlanta or Missouri, as I will—or other places—and I would hope that the commerce and the travel of the country don't shut down based on advice from the government. I yield back, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Blunt. Mr. Weiner.

Mr. WEINER. Thank you, Mr. Chairman. Let me just pick up on that a little bit. You know, I think you will forgive our constituents for being a little whip-sawed by the news and images that they get.

And I represent the district that has half of all of the confirmed cases in the country. And, you know, to watch some to the imagery on television, to listen to even official channels. To listen to the head of the health policy at the European Commission, in theory someone who is supposed to be pretty level-headed say it is not a question of whether people die, but more a question of how many. Will it be hundreds or thousands or tens of thousands? You will forgive some of my constituents for wanting to get into the fetal position and bathe in Purel after hearing things like that.

And let me say that it is in contrast to the way you all have presented yourselves. So, too, the health officials in New York City who may have made a more sober assessment. But just to put a finer point on the question Mr. Blunt asked, focusing on subways. Just to instruct New Yorkers to avoid the subways is to in many cases to instruct them not to make a living, not to travel around their hometown. It is the very way that we communicate with one another and the way we get to and from.

If you are not one of the 96 confirmed cases, if you don't feel like you have got the flu, can you just say with clarity about subways, it is safe to get on a subway? We would encourage you to get on a subway, and if there was a subway to Atlanta, you would take it?

Ms. SCHUCHAT. The only people we are saying should avoid crowded circumstances or airplanes, for instance, are people with fever and respiratory symptoms. We also think it is important for local authorities to be giving the guidance for the community. They understand the way the—the ground truth. And we know that the New York City Health Department is fantastic it is and really is providing good guidance.

Mr. WEINER. Can I ask you, how good a job did the Mexicans do on letting you know what was going on? There was a report in today's Washington Post that lays out the tick-tock of notification that seems clear that the 24-hour rule was violated by a magnitude of a couple of weeks. Apparently, our Department of Health and Human Services, which oversees the CDC, found out about the Mexican outbreak about the same time the rest of us did, on the television on the 24th.

It strikes me that that window of time is valuable and it strikes me that in fact it could have helped—well, maybe prevented some or at least gotten us a couple of weeks or a few days at least jump on this. How would you grade the Mexican response up to now?

Ms. SCHUCHAT. The Mexican community and government are coping with a very difficult circumstance right now. And the focus of our attention is providing technical support to help them respond to the situation. I can say that I don't have all the information—I don't think anyone does yet— about all the circumstances leading up to where we are. But it is important to note that increases in respiratory illness happen quite frequently, and they can have lots of different explanations.

And as I understand it, the original increases that they were seeing were believed to be due to regular influenza. Most respiratory infections don't actually get a specific diagnosis, and we see lots of changes in the numbers that don't pan out to be anything quite serious.

Here in the U.S., because of our investments, we promptly recognized these very unusual strains of influenza and issued an MMWR dispatch after the first two that we had seen. But I think the circumstances in Mexico right now, the focus really needs to be on helping with the response.

Mr. WEINER. Could I say, you know, it is—traditionally the influenza outbreak happens in cold weather. And I know there is some disagreement on why exactly that is. Maybe we are all together much more.

Are we rooting for a particularly hot stretch here? Would that help us? Should we be trying to be outdoors more? Is the coming summer months, is it helpful to us? Is it not clear that it is helpful? If there is a high pollen count, does that mean perhaps we should be more careful? Are there any weather-related indicators, since this is kind of a counterintuitive strain, it is hitting younger people more. Are there things about it that we have learned so far that give us an indication that the weather might be on our side here?

Ms. SCHUCHAT. We think from the past and from seasonal flu, that we don't see much influenza in the summer months, and so we hope that will be the case. But every influenza expert that I hear from really cautions me in anything I say to remind people how unpredictable influenza can be, and especially a new strain. So we do optimistically hope that things will get better because of the season. But we need to be attentive for the fall afterwards.

Mr. WEINER. Thank you. Thank you, Mr. Chairman.

Mr. SHARFSTEIN. I would just say, if we can get time, that really helps with the vaccine production. And the point about how each virus is different is extremely important about vaccine production. And I think just to clarify, I think the idea that a certain amount of vaccine will be ready in a certain amount of time—those predictions really can't be made now until we understand more about this particular vaccine, this virus.

Mr. PALLONE. Thank you. Next is the gentleman from Maryland, Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman. First I want to say how impressed I am with the response that you and your staff have made to this situation. There has been a calmness and professionalism to it that I think is having the desired and appropriate effect on the public, and I know that will continue. So thank you for that.

I also want to echo those who are welcoming Dr. Sharfstein to his new position. As he indicated, we have worked together closely in Baltimore. We suffered a great loss that he is now here, but the country is certainly gaining by his appointment.

Dr. Schuchat, you mentioned—and I was intrigued by this—that the number of cases is not something you are so much interested in as the patterns that you see emerging. And I wondered if you could describe a little bit more what you mean by that? What are the patterns that you are looking for and what do those patterns tell you about the progress of this disease?

Ms. SCHUCHAT. We are working closely with some of the State and local health—public health officials who are on the frontline of responding to this, to really understand the epidemiology: who is more likely to become ill; what are the clinical characteristics of ill-

ness; how does it look like the infection is spreading; and how transmissible is it? So those are things we are evaluating in some of the on-the-ground circumstances in the U.S. as well as with our Mexican and Canadian partners.

Those types of investigations can help us understand what kinds of interventions will be most effective. We would love those investigations to show us that disease is becoming milder. But we need to be ready for the idea that the disease is becoming more severe. So rather than focus too much on individual numbers, we know that numbers are going to be varying, that information is in flux, that we have just decided at the CDC, once a day we will update the numbers, and we are really focusing on the actions and activities. So the patterns are really at an early phase, understanding which populations are at the greatest risk, how transmissible is the virus and then the severity.

Mr. SARBANES. Is it a combination of the patterns and numbers that would also advise as to when a community ought to be taking a particular action, shutting the schools in a community and so forth?

Ms. SCHUCHAT. That is right. We have guidance about when there is illness—a confirmed illness in a school, that we recommend that that school be closed temporarily while things are being reevaluated. But there could be triggers that would prompt a more aggressive approach beyond that. There are other community interventions, such as eliminating mass gatherings or really implementing social distancing, asking people to work from home and to really avoid crowds.

I was in Beijing during the SARS epidemic and they intensively instituted those, and they really helped. But that was a very different circumstance. So I think the pattern will tell us whether more aggressive measures are needed. We are really trying to strike a balance in making sure the interventions are not worse than the virus, because there is a balance in all of these interventions.

Mr. SARBANES. Let me ask you a different question. There has been a lot of discussion and focus on sort of tracing back this virus to a specific geographic origin. Is that the right perspective to have? I mean, is it the case that this disease will be appearing, as it were, spontaneously in a lot—in a number of different locations, or does it make—because when I hear people discuss they found new cases, and the next question always is, did you have contact with somebody who recently traveled to—but that can't be the only intention of the inquiry, right?

Ms. SCHUCHAT. Yes. That is right. I think in the initial day, there was an intense focus on contact with animals and then a little bit after, contact with Mexico. We are at a different point where there are lots of exposures that are being looked at. And, really, the intense look for cases is so that interventions around those cases, and where they work or at school, can be imposed.

So for those other sectors that are focusing on tracing back and where did this all start, that can be important information for future planning. But I think the public health community here in the United States is really focusing on what we can do to reduce illness and death and slow spread, giving time for more definitive inter-

ventions like vaccine, should we go that route. And, really, the focus of our goal is to reduce illness and slow transmission, not to find the source.

Mr. SARBANES. Mr. Chairman, can I ask Dr. Sharfstein? It will be a 15-second question.

Mr. PALLONE. Sure.

Mr. SARBANES. I appreciate it. My understanding is that the flu strains we experienced this past winter did not respond particularly well to Tamiflu; is that correct?

Mr. SHARFSTEIN. Yes.

Mr. SARBANES. But that we are seeing at least initially this strain is responding. So I guess that is a lucky thing in a sense, right? Because it could very well be that this strain also would not be responding, and so I am just putting that in the happy coincidence category. Is that fair to do?

Mr. SHARFSTEIN. Yes. But there are always a few qualifiers. We know, I think, looking at it genetically and in the lab, that it looks like there is activity against the virus. That doesn't necessarily mean that every patient, as soon as they get it, gets better. In fact, it is more effective the earlier you get it in treatment. In people who are quite ill it can set up all sorts of problems in their body that even getting rid of the virus can't help anymore. So there is a qualifier there.

The other qualifier is that it is possible that a resistance may emerge, and that is something I know the CDC is very interested in, is watching very closely. That could have recommendations for treatment that could change, could change recommendations for treatment. So we are starting off with some—a little bit of good news there. But it is going to depend on how this whole thing unfolds.

Mr. SARBANES. Thank you. Thank you.

Mr. PALLONE. Thank you. The gentleman from Iowa, Mr. Braley.

Mr. BRALEY. Thank you, Mr. Chairman. I want to thank all the witnesses for being here. But, Dr. Schuchat, I want to start with you and follow up on your answer to Mr. Blunt's question about the reality of this virus and its impact on our food supply. You said there is no evidence that swine in the United States have this virus, which is a standard answer on the CDC Web site in response to concerns about food safety issues. And if you go to the CDC Web site there is a specific question: Can people catch swine flu from eating pork? And the answer says there is no evidence that swine influenza can be transmitted through food. And yet your Web site is the Web site of all of the organizations here, including the WHO, that continues to identify this as swine flu. And on the Web site, it also makes reference to the fact that this is a new strain of flu that consists of a mixture of genetic material from swine, avian and human influenza virus.

I come from a State that is a leading pork producer in this country and in the world, and this outcry over the alleged connection between food safety and this virus is having an enormous economic impact on pork producers in Iowa, North Carolina, and all over this country.

So is there a plan to change the Web site and refer to this by its appropriate scientific name, Influenza A, substrain H1N1?

Ms. SCHUCHAT. Our new information will have the new terminology. Our communication teams are focusing on critical information for health care providers, for families and so forth. So we do intend to make sure that the many, many thousands of Web site pages that we have already put up in the past week become amended. But the critical focus of the people in place right now is developing the new information that people need.

We understand the concerns and are very mindful in our communication going forward, and really need to—people are working 24 hours a day. There are communication experts in there. It is really—I mean, I don't want to be impolite, but I just want to say that our priorities are the public health information being out there quickly and accurately. And going forward, we will do the best that we can.

Mr. BRALEY. I appreciate that. No one appreciates that more than I do. But I am also concerned, because I was at the congressional briefing yesterday, and when you go to the CDC's Web site, what you find is a page, the first page, that says swine influenza. And on that page, there are probably at least 10 references to swine influenza. And when your agency is one of the most critical public information dispensers in the Federal Government, it feeds this misperception if you don't address this issue immediately.

And my point is that these other agencies are not using that terminology, and it is for a reason. So I would just encourage you, knowing that you are not in charge of the communications division at CDC, to emphasize to them the importance of making that change as quickly as possible. Would you agree to do that?

Ms. SCHUCHAT. We will do the best that we can.

Mr. BRALEY. Now, one of the other concerns I have is the impact on workplace safety, because one of the things that OSHA has done is prepared a handbook guidance on preparing workplaces for an influenza pandemic.

Have any of the three of you had an opportunity to review that pamphlet to determine whether it consists of the most up-to-date information to help prepare workplace environments to deal with the potential influenza pandemic? Dr. Sharfstein.

Dr. SHARFSTEIN. I haven't personally looked at it, but we have an employee health part of our team on personal protective equipment, and I know they have been talking to OSHA. The FDA part that oversees devices because that is really what it is, the mask and that kind of thing, relates directly to OSHA and I know that our team and OSHA have been talking about the different authorizations that the FDA has made, how that intersects with what OSHA needs to do to protect workers.

Mr. VANDERWAGEN. Mr. Braley, I think most of the elements of HHS have worked closely with OSHA. Most specifically NIOSH, the National Institutes of Occupational Safety and Health, which is part of the CDC, has been working extremely closely with OSHA to assure that we are aligning any health guidance that we are bringing forward out of our department and gets accounted for in their documents. We have worked very closely on with them on masks. We have worked very closely with them on a variety of things over the last 2 or 3 years.

So I tell you we are lashed up pretty good with the OSHA folks vis-a-vis assuring that we have a common message and a common set of principles.

Mr. BRALEY. Thank you.

Mr. PALLONE. Thank you. Next is the gentlewoman from Wisconsin, Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman. Thank you to our panel of witnesses today. I want to join in the sentiments that have been expressed by some of my colleagues about the very good job that has been done identifying and tracking this outbreak and the communications to the Congress as we are trying to learn more and work hand in hand with you in your mission. I think an outbreak like this exposes the strengths and weaknesses in our public health system.

Dr. Vanderwagen, you talked about the system as sort of people, supplies, equipment, facilities, and systems, and I have been working with a number of my colleagues on both sides of the aisle on trying to address our public health system and strengthen it in some areas where I think that there are some weaknesses. I want to probe into two of those areas. One is relating to our State lapse of hygiene, and I guess I would start with you, Dr. Schuchat, and would like to hear your feedback on how it is these days working with the States to track and monitor this disease.

And I ask the question because in my examination of the issue, and this is based on a 2007 survey by the Council of State and Territorial Epidemiologists, showing that 16 States are still completely paper based, 20 States are still using manual reporting that is Web based, and only two State public health laboratories in the country have bidirectional data flow that can both send and receive laboratory messages.

I understand also that technology is not yet deployed that would support new pathogen discovery and rapid electronic exchange of public health information, national bacterial and viral databases for DNA fingerprinting of infectious disease organisms, things like that. If you tell me how things are going and how those technological upgrades being deployed in our labs might help.

Ms. SCHUCHAT. You know, the promise of information technology is huge and unfortunately it hasn't gotten applied to public health infrastructure as rapidly and as in some of the business community, and I think we are not where we would like to be in that area. You know, in doing this investigation we have just yesterday I think got electronic reporting from the States coming in, which was exciting for us because it has been a long time coming but that is just for this investigation but not for everything. You know there are huge opportunities in that to really increase the efficiency of how public health works.

Mr. VANDERWAGEN. And ma'am, the comments I made to the member from California apply here as well, that as we think about health reform and we think about preparedness, it is not just a matter of hospital services concerns here. I think these issues are going to need to be thought through as part of that context as well.

Ms. BALDWIN. Let me follow up with some of the personnel challenges we are dealing with. Certainly as States and local governments have real budget squeezes I know that they have had to

shift around staff in order to deal with this outbreak. I don't have the specific question right now on the staffing of labs of public hygiene. As I said, I am working on bipartisan legislation. We have introduced a bill called Strengthening America's Public Health Systems Act, which deals with the technology and the personnel there.

I want to focus quickly on another area of personnel workforce shortage, both present and looming, and that is with regard to public health veterinarians. While we have probably, I want to say, about 85,000 veterinarians in the Nation, I think my figures say only a little over 4,000 are food animal predominant, some with a mixed practice. The number of veterinarians in public, corporate or federal positions, which includes teaching, research, military, inspection and food safety, is just under 15,000. And the projections are that we will have a significant increase in demand as we move forward for these professionals and a significant shortfall now and as we move forward.

Dr. Vanderwagen, could you talk to us a little about the role of public health veterinarians with regard to this outbreak and are you seeing that the shortage of public health veterinarians in the U.S. and around the world is having an impact now?

Mr. VANDERWAGEN. Yes, ma'am, and you read my eyes. My dad was the chief veterinarian for the State of California, and so I grew up in a home with a public health veterinarian, large animal practitioner to start. I think it is critically important that we think in terms of one medicine. There are many more species with health issues than humans and even though we focus heavily on humans, and I think appropriately so, it is our species, notwithstanding that we are at extreme risk from a variety of diseases that emerge from the animal environment, and without the kind of knowledge that public health veterinarians bring with regards to animal-based diseases that have zoonotic; that is, transmissibility from animals to humans, as an underlying principle, we end up flying blind on a significant number of challenges that our health security may be confronting.

So I think it is critically important that we think about that workforce and that we embrace the notion that there is more to health than simply that of humans alone.

Mr. PALLONE. Thank you. The gentlewoman from the Virgin Islands, Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you Mr. Chairman. Dr. Vanderwagen, you can't get away from me. You know this, right?

My first question is to Dr. Sharfstein. On the food panel diagnostic tests, are those available to the Territories like my own and those in the Caribbean and those in the Pacific? Do we have the assurance that we have the availability of those tests?

Dr. SHARFSTEIN. I am also actually going to ask Dr. Schuchat to answer that. FDA made that available to the group of labs that CDC requested, which is this network.

Ms. SCHUCHAT. Yes. I was just trying to verify. We have been shipping the test kits to public health laboratories that are either part of the laboratory response network or similar public health labs. And so I don't actually know. I believe it is likely, but I will need to check, and we can get you that information. The idea is that the public health laboratories be able to, that have gone

through the appropriate training and are part of this system, be able to perform these tests.

Mrs. CHRISTENSEN. I would suspect that ours is in Puerto Rico. But the Pacific is much more difficult.

Ms. SCHUCHAT. Absolutely.

Mrs. CHRISTENSEN. They shouldn't have to go all the way to Hawaii. And so that is my concern. Would you pronounce your name for me?

Ms. SCHUCHAT. It is Schuchat.

Mrs. CHRISTENSEN. So Dr. Schuchat and Dr. Vanderwagen, and you know this already but all during my time on the Committee on Homeland Security I have been concerned about the inequities and the deficiencies in the public health system in certain parts of our country, communities that are rural, Indian reservations, poor communities, communities of color, and they are very vulnerable. And it is often said that when the rest of America gets a cold, we get pneumonia.

So my question is knowing this, what special efforts are being made to ensure that these communities have what they need given that their infrastructure, the poor health infrastructure in terms of hospitals have closed, less labs, less providers? What is being done to reach to these vulnerable communities?

Ms. SCHUCHAT. You know, this is a huge issue in health in general. In terms of the new influenza virus investigation and response, one of the teams that we have stood up is a vulnerable populations team that is really trying to address the appropriate outreach and planning for communities that may be harder hit.

Mr. VANDERWAGEN. Well, Mrs. Christensen, it is so good to see you again really because I think we have a great dialogue that is important. With regards to Indian Country because you know that is—

Mrs. CHRISTENSEN. I see your watch and your ring.

Mr. VANDERWAGEN. With regards to Indian Country, at least for those Indian people that are provided service funded or directly provided by Indian Health Service, they are on our daily policy calls. They are on our ESF 8 calls on a daily basis so that the most recent and clear communication can be transmitted through that system to people who are dependent on those health systems.

The tribal leaders are actually here in town today to talk to HHS about budgetary considerations and concerns, and we will listen and respond the best we can.

Mrs. CHRISTENSEN. Thanks. Great. And Dr. Schuchat and Dr. Sharfstein, you said that this virus is a new virus but it has genetic material from four known viruses, various origins. What, if anything, does this mean in terms of the severity of the illness, what you would predict, our possible level of prior immunity and the development of the vaccine? Are those four pieces of genetic material make it any easier to deal with?

Ms. SCHUCHAT. The virus is new, and we don't—although it is H1N1, it is different from the human H1N1s that are part of seasonal flus that many of us have been exposed to or vaccinated against with the seasonal flu vaccine. We can't predict with certainty what this virus will do. So the four components only tells us really—it just tells us it is new. There is a possibility there might

be some cross protection in certain subpopulations. And it is the kind of thing we are looking into. But you know since we have tested many, many thousands of strains and have never seen it, it is novelty that is the most concern.

Mr. Sharfstein. And I agree completely, and the only thing I would add is the question has been raised is whether people who got the flu vaccine this year have any extra protection against this. And I don't think that question has fully been answered. It is one of the things that the CDC is looking into. The initial tests which test one type of immunity did not show any cross reactivity, but there is a potential there and I think it is going to be an important question to answer about it. I think in general the answer is you can understand what the virus is but to understand how it behaves you just have to watch how it behaves. It is just hard to determine that just from the genes alone.

Mrs. CHRISTENSEN. My time is up. Thank you. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I want to add to the chorus of thanks. I think that the response has been really comprehensive. And we have on our Web site now a link to yours so that people can get the best and the latest information and we, I think a lot of Members, are doing that right now.

We now have in Illinois 19 suspected cases, is it? 17 probable cases in Illinois. The one school that was closed in Illinois is in my district at the Kilmer School. I don't know if any of those have been confirmed. Do you know that?

Ms. SCHUCHAT. No, I don't have the details of that. And I certainly feel for the folks in your district who are coping with such a challenge.

Ms. SCHAKOWSKY. I wanted to ask you about if and when we have immunizations and vaccinations for, if not immunizations but vaccinations, most States' Medicaid programs provide some coverage for adult beneficiaries in situations like this. And some States have exempted some populations from the nominal copay, pregnant women, children. I realize that this is impacting a somewhat different population.

Do you think that in certain public health problems like the current one it would be good policy to exempt all Medicaid beneficiaries from cost sharing for vaccines and maybe for other things as well, but are related to this outbreak? And I am just wondering how that might impact the numbers of people who are able to access the care that they need.

Mr. VANDERWAGEN. I think, and I can't answer you definitively, ma'am, but I would suggest that the considerations are that when we have this kind of an issue, it is about our population and our citizens as a whole and less about individual benefits and services. We need to think about what can and should we do to serve our whole population. That is a little different mode than the way we think about medical care and health services in the country generally, which is about care for that one-on-one patient. Here we have to assure that our whole population is protected in the face of the challenge.

Does that mean we should promote a waive policy? That is for people above my pay grade. But I think there is a real public health argument that says we have to think about population and not just think in terms of limited individual benefits, which would suggest that we should cover everyone for those threats.

Ms. SCHAKOWSKY. Right. Individuals, however, when seeking care think about their own situation and whether or not they are covered and whether or not they should be going to the doctor and whether they can afford to go to the doctor. And so I think we have to think about how we convey that people who may have it should seek the care that they need.

Ms. SCHUCHAT. It is important in this kind of circumstance to eliminate the barriers to people presenting who need to be either cared for or whom interventions would need to be initiated. It has been a challenge in a lot of infectious disease outbreaks where communities sort of go underground and are fearful about presenting for care or the ability to pay. So it is very difficult with infectious diseases which don't respect what insurance card you have, and I think we really want to have a public health approach that will help the communities.

Mr. VANDERWAGEN. I echo what she said.

Ms. SCHAKOWSKY. Let me ask another question. I wonder if someone can describe the process for data sharing between Mexico and the United States. My understanding is that we have a number of unanswered questions, whether Mexico is in the first or second wave of illness, the percentage of people dying from the flu compared to the percentage of people who are infected, et cetera.

Ms. SCHUCHAT. I am happy to say that we, the CDC, are part of a trinational team that is on the ground in Mexico, Mexicans, U.S. workers, and Canadians who are working on the epidemiology and laboratory aspects of investigating and responding to this concern. Information is getting better now, but information in this kind of outbreak is really difficult even in the best of circumstances. Information can be sketchy at the beginning, and we need to hone in on the details.

And in particular, before you have a good laboratory test, it is hard to tell what is going on with people with pneumonia or severe respiratory illness. And so one of the goals of the trinational team is to strengthen the laboratory capacity in Mexico so they can detect this new strain right there without having to shift to the U.S. or Canada or elsewhere.

So I think we are getting much better information and cooperation. I mean the cooperation has been good, but the information quality is improving by the day.

Ms. SCHAKOWSKY. Thank you.

Dr. SHARFSTEIN. I can just add that FDA is collaborating with the FDA equivalent in Mexico around some of the recommendations that have been made in the United States that would be applicable, like what the right dose is for young children.

Ms. SCHAKOWSKY. Thank you.

Mr. PALLONE. Thank you. Ms. Eshoo.

Ms. ESHOO. Mr. Chairman, thank you for having such a timely hearing on such an important subject. I have so many things that I want to say and ask, but this is my—these are—first of all, thank

you for the magnificent work you do at each one of your agencies. I think they are all parts of the jewels in the crown of America's health system that needs help in so many ways but, boy, do we depend on the work that is done out of these agencies.

Here is my sensibility that people are being, and it may have been said earlier by members when I wasn't here when the hearing began, the American people are inundated by the blaring, glaring headlines and, as one of the staffers said behind me, that the only break that they had from swine flu was Senator Specter switching parties. That was the news break and now we are back to swine flu. I am not diminishing what all of this represents, the seriousness of it. But I think that what people need to hear over and over again are the really commonsense steps of responsibility that they need to exercise, washing our hands 1,000 times a day, the coughing, the sneezing, making sure that we cover our faces.

I think on this issue of air travel in the United States, I am pretty sensitive about this. I have commuted across the country now every single weekend for 16-1/2 years. And as my mother would say, I don't know who has raised some people, but they don't cover their faces when they sneeze or they cough. Now this is voluntary for the airlines to say something. But if they can remind everyone to fasten their seatbelts in the eventuality that something can happen to us if there is a drop, I think that that should be part of the text and that our government ask in very strong, firm tones, we don't need to pass a law on this, but I think the director or the Secretary of Transportation, along with health officials, should get on the phone and have a conference call with all of the airlines and say, please, we are asking you to make this public health announcement at the beginning of every flight. Because the proximity of human beings one to another on a plane is far different.

Now I have been told that walking down the hall one of the house doctors was telling me that if someone coughs or sneezes, it is 6 feet. I sit pretty close to people on the plane. So do all of you. So I would ask that you do that. Get that ball rolling, and I think that that is in terms of prevention really important.

I wanted to ask the following, and that is in the 109th Congress Representative Rogers of Michigan and myself introduced legislation, and we were successful, because it became law, it was the Biodefense and Pandemic Drug Development Act, it is called BARDA, to create—you are all nodding—a new office within HHS. What is the nexus between that office, the work that it has done, and this swine flu that evidently really doesn't come from pigs?

Mr. VANDERWAGEN. Ma'am, I will answer that fairly simply. BARDA has always worked across the Department to assure that the NIH discovery research and the FDA oversight responsibilities get brought into the mix as we do advanced development. Over the last 4 years, what has happened is that BARDA, through their funding, brought us the first licensed H5N1 vaccine. They brought about the kind of vaccine production changes that Dr. Sharfstein referred to where we have a warm base, if you will, that will allow us to ramp up—

Ms. ESHOO. That is very good news. The good news is that the House, in our economic recovery package, included increased funds for this. But the Senate took them out. I don't think they are going

to be feeling so good about that right now with what is going on. Maybe one of them is tuned into this hearing tonight when they are home sitting on their sofa.

So let me ask this question. We just have 4 seconds left. Can you explain how the CDC and the Federal Government plan to administer a flu vaccine and, given that many of those who, so far, from what I have read, that are infected are children, is this going to be performed in schools and will it be a mandatory vaccine?

Ms. SCHUCHAT. There is an answer to only some of those questions. But the States have been planning around countermeasure response assessments and they have done exercise drills with seasonal flu vaccine in terms of how will they administer promptly, get the kind of information——

Ms. ESHOO. You are saying they will probably use that same model?

Ms. SCHUCHAT. Correct. And they are also making sure they have ways to find out who has gotten one dose because there is a good chance you will need two doses of this. So there are State-based planning efforts around those models.

Ms. ESHOO. Well, again, Mr. Chairman, this is a timely hearing. I thank all of you, the great professionals, health professionals of our country, and we have learned a lot today. And I think we really have to be very sensible about this as the science and the scientists and the medical community take the lead. But we just have to hammer home what people can do to be responsible all day long every day, and I think that is going to equip them with a sense of a little, some sense of reassurance on this.

Thank you.

Mr. PALLONE. Thank you, Ms. Eshoo. The gentlewoman from Ohio, Ms. Sutton.

Ms. SUTTON. Thank you, Mr. Chairman. And thank you very much for your testimony and even more importantly for what you are doing to try and deal with this situation and keep the public safe. I come from Ohio. We have one confirmed case, and it is in my district. The case arises in a child who traveled with his family to Mexico over spring break. And the situation is that the school has been closed, and I know that the CDC, Dr. Schuchat, recommends that—the language I see here recommends strong consideration of school closure of the schools with a confirmed case or a suspected case that has been epidemiologically linked to a confirmed case.

The first question I have is, why do you stop short of saying close the school?

Ms. SCHUCHAT. I do think that we are evolving our guidance over time and some things may become clearer or stronger over time. At the time of the initial drafting of guidance, there was quite a bit of debate because illness that we had been seeing was fairly mild, and there was a question of balance. I think it is really—I think it is in there, but we meant to have in the guidance information about the local authorities having the best information or respecting their ability to make decisions that were either more stringent or less stringent than ours. But I do think at this point we think it is very prudent to close schools where a case has been con-

firmed or is highly suspect until we have more time to understand what is going on.

So we are probably a little bit more aggressive than when that was written.

Ms. SUTTON. And to follow up, I should say that the superintendent in the school district did close the school. So I commend him strongly for doing that. This is a case that, as I say, a child traveling with their family, there are other siblings who go to other schools who are not, you know, exhibiting the symptoms of the swine flu. What is the recommendation there in that situation?

Ms. SCHUCHAT. At the present time what we have suggested is that the intervention be targeted at the school where the child with illness is, that additionally that gatherings associated with that facility be closed, but recognizing that there is a lot of variation in local realities. A school district in New York City is very different than a school district in a small town, and really respecting the ability of the local authorities to assess the situation and the practicality, the issues of what is possible. We really want to make sure that our interventions are not having more adverse impact than the virus itself. But we also are being mindful that we don't know as much as we want to know so far about this particular virus and we are probably being more aggressive than others would think we should be in order to protect people.

Ms. SUTTON. And isn't it correct that unless a person is exhibiting the symptoms themselves that the danger of transmission is not present?

Ms. SCHUCHAT. Unfortunately there are no absolutes. And what we think about from seasonal flu is that you may be able to spread infection a day before you have symptoms yourself and so, you know, it is one of those circumstances where we wish it were simple and we wish there was a very specific symptom and we wish that everyone who is infectious knows they are infectious and can stop from spreading to others. But we are at early days with this virus. It is a new one. And we don't know whether it will be most infectious later on in illness or what.

With the SARS epidemic we were really fortunate actually that most of the spread occurred when people were really, really sick, not in those early days. But when you have infections that are transmissible before they are symptomatic, before a person is symptomatic, those are really tricky, and that is the case with measles in fact. People think if I don't vaccinate my child it is okay and my child can't spread the infection to somebody else, I will know when they are sick and keep them home. But you can actually spread measles before you even know you have it. So this is one of those challenges with infectious diseases and why we are being pretty aggressive in our interventions now.

Ms. SUTTON. Okay, and I could, and this goes back to a lot of what we have heard here about common sense about people staying home when they are sick and the like, but the people I represent, they are hard-working people and they are not, they don't stay at home with a sneeze because you just, it is very difficult. But could you just explain and stress the importance of people who aren't feeling well staying home, their kids staying home and,

frankly, you know, the implications to employers, too, and why it is to their benefit that obviously those folks stay home?

Ms. SCHUCHAT. Some of the interventions that we are recommending are inconvenient. We actually did an effort in our planning a couple of years ago to address the public. We did public engagement in several communities to understand what people, average citizens were willing to do, if there were risks of something like a pandemic happening what was the trade-off in terms of personal flexibilities in the social protections. And through that we learned that there was support for many more aspects, I think, of this community mitigation strategy than I think some of us would have expected. But there is a balance. And we would really like to understand what is the severity, what is likely to be happening, before we really reduce people's lives.

Ms. SUTTON. Thank you. I appreciate it.

Mr. PALLONE. Thank you. This completes our questioning. But I just really want to thank again for being here. I thought it was very helpful to us. You have heard several members say that they would like you to keep in touch with us, but certainly I will express that as well. Hopefully things do not, you know, really get to the pandemic stage but obviously we might at some point ask you to come back again. I hope that is not necessary.

We also have a policy where probably within the next 10 days you could get additional questions from members to answer in writing, and so we would appreciate a response. But again thank you very much and Godspeed in what you are doing. And without further objection, the subcommittee hearing is adjourned.

Thank you.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement of the Honorable Anna G. Eshoo
Committee on Energy and Commerce, Subcommittee on Health
Hearing on Swine Flu Outbreak and the U.S. Federal Response
April 30, 2009

Thank you, Mr. Chairman. We are all acutely aware of the importance of today's hearing on the recent outbreak of swine flu. We all want to hear how much our country is dealing with this health emergency.

We live in a time where millions of people fly across the world every day and millions more cross national borders daily. As we've seen in the last week, a virus that originates in a small town in Mexico can spread across the world in the blink of an eye. As more Americans are falling ill to swine flu, we must act quickly but cautiously in determining a federal response to prevention and treatment.

According to Bruce Gellin of the National Vaccine Program Office at HHS, we have until June to decide if we're going to produce enough swine flu vaccine for every American by September. With that decision come difficult questions:

- Who gets the vaccine first? Those with vulnerable immune systems? Healthcare workers on the front line? Public safety officers and the military?
- Will the swine flu vaccine require two doses since many individuals may need an additional booster if they've never had the vaccine before?
- Should we include the swine flu vaccine as a cocktail with the normal influenza vaccine?
- How do we ensure vaccine safety so we don't have a repeat of 1976 where people died from side effects of the swine flu vaccine and Guillain Barre Syndrome?

In the 109th Congress, Rep. Rogers and I introduced and successfully passed the Biodefense and Pandemic Drug Development Act (BARDA) to create a new office within HHS to be the single point of federal authority for the development of medical countermeasures for these situations. The House also included funding for BARDA (and pandemic flu specifically) in the economic recovery package but unfortunately, the money was stripped out during compromise negotiations with the Senate. Now is the time to rectify that unfortunate undoing and ensure that we do everything we can to protect the American people from this grave threat.

I look forward to hearing from our witnesses.

Statement of U.S. Rep. Ed Whitfield
Before the Subcommittee on Health
"Swine Flu Outbreak and the U.S. Federal Response"
April 30, 2009

Mr. Chairman, thank you for agreeing to hold this timely hearing on an issue impacting not only our country, but the entire world.

As we have learned over the past week, a new strain of flu is impacting our country. "Swine Flu," as it has been labeled by the media, has already infected over ninety Americans in eleven different states. While the symptoms of Swine flu have been relatively mild in the U.S. so far, I think it is critically important that we continue to look closely at the goals and strategies behind our preparations. It is essential that we start preparing now in order to combat any widespread pandemic.

Vaccination is the primary strategy for protecting people who are at greater risk of serious complications and death from a pandemic virus. The Food and Drug Administration (FDA) is prioritizing efforts to speed the entry of all willing manufacturers into the vaccine market. Currently, the FDA is doing that to the manufacturing process by providing vaccine companies with vaccine reference strains as the starting point for large scale manufacturing. This will allow vaccine companies to start producing vaccinations almost immediately with the hopes that one will be made available in four to six months.

I also believe we must consider the manner in which we communicate important swine flu information to the public. It is essential that our nation's leadership communicate, clearly and concisely, accurate and up-to-date information to the American people, so that we do not cause unnecessary concern or confusion. For example, many people are confused about the consumption of pork, but swine flue cannot be spread through cooked and properly handled pork. As a Representative from a major agrarian state, I am concerned that we not start a fear that pork is not safe, which will only hurt our pork farmers and not help the problem at hand. It is imperative that the FDA and the Centers for Disease Control (CDC) work closely together so they can send out the same pertinent and reliable information to the American public.

Finally, we need to ensure collaboration between our public health and private sector partners. If an outbreak should occur, we need to be prepared to treat these illnesses at the front lines in doctor's offices, health clinics, grocery stores, and pharmacies. The CDC has established a planning team comprised of staff from across CDC, as well as representatives from state and local public health agencies that meet weekly. In addition, they have worked with the Advisory Committee on Immunization Practices to develop more refined vaccination priority plans that can be used should there be another critical vaccine shortage.

I look forward to hearing from our witnesses today and continuing our efforts to ensure steps are in place to protect the American people from any pandemic.

Statement of Representative Michael C. Burgess, M.D.
Committee on Energy and Commerce: Subcommittee on Health
Swine Flu Outbreak and the U.S. Federal Response
Thursday, April 30, 2009

Mr. Chairman,

Thank you for holding this hearing in a prompt fashion.

The threat of a pandemic outbreak of swine flu cannot be underestimated.

Philadelphia once found itself in a similar situation. At first unnoticed and then ignored, a similar disease swept through the crowded inner-city neighborhoods.

First a few cases, much like today, but then the numbers began to rise – quickly.

Some leaders refused to act. Others who tried found it was too late to prepare themselves for the worst case scenario.

Philadelphia went on to see roughly 13,000 residents die. The year was 1918 and Philadelphia was about to become the American city with the highest death toll in one of the worst epidemics in recorded history.

The point of me recounting this story is simple. I encourage the Administration to take every action possible to restrict and mitigate the spread of this outbreak.

If closing the border hinders the spread of this strain, even by the smallest amount, we must do it. If a vaccine is needed because we anticipate the scope to continue to grow, we should start the process. Not a week from now – TODAY.

When we are talk about a viral strain that can easily spread between humans – which this strain clearly has the ability to do – there should be no concern about overreacting.

I will not criticize *anyone* in this Administration for being overprotective of our citizens' health when the threat is as real as the one which we currently face.

If we do too much and this threat dissipates I will not lose any sleep.

But, I cannot stand by the notion that complacency in the face of a realized threat to public health is the answer. I understand no one wants to start a panic, but with two American deaths confirmed, responsibility to our people warrants action.

I pray that this Committee is not convened a year from now to ask how we *could have prevented the deaths of any Americans from inaction.*

As Benjamin Franklin said, an ounce of prevention is worth a pound of cure.

Under the National Response Framework, the Department of Health and Human Services (HHS) has the lead for public health and medical services, which include assessing public health and medical needs, conducting disease surveillance, providing public health and medical information, and managing health, medical, and veterinary equipment and supplies.

CDC

As part of HHS's response, the Centers for Disease Control and Prevention's (CDC) responsibilities include identifying and tracking the spread of the disease, conducting epidemiological investigations and laboratory tests, managing the Strategic National Stockpile (SNS) and providing SNS medicines and medical supplies to states, and communicating health-related information to the government, the media, the public, and other groups.

CDC provides support and technical assistance to state and local health departments that are tracking and investigating cases in their jurisdictions. CDC has a network of quarantine stations throughout the country that coordinate their efforts with Customs and Border Patrol and the Transportation Security Administration.

FDA

As part of HHS's response, the Food and Drug Administration (FDA) issues emergency use authorizations following the declaration of a public health emergency by HHS, subject to certain conditions. This allows the use of unapproved products or use of an approved product for unapproved uses in a declared public health emergency.

FDA has also formed a number of teams to focus on the specific tasks in addressing the 2009-H1N1 flu outbreak. The missions of the teams are to collaborate on the development of new vaccines, antiviral medications, and diagnostic measures as well as address consumer safety and other concerns. These teams include: the vaccine team, the antiviral team, the in vitro diagnostics team, the personal protection team, the blood team, the shortage team, and the consumer protection team. This team effort is a new approach taken by the Agency in applying an interdisciplinary model to addressing serious public health challenges.

ASPR

The Assistant Secretary for Preparedness and Response assures a coherent HHS approach to public health and medical preparedness and response capability by leading and coordinating the relevant activities of the HHS Operating Divisions (e.g., Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health) on behalf of, and subject to the

authority of, the Secretary. ASPR manages the Secretary's Operations Center (SOC) which serves as a central location to coordinate all HHS emergency response efforts and is the focal point for synthesis of critical public health and medical information on behalf of the U.S. Government.

ASPR also serves as the principal entity that coordinates interagency activities between HHS, other Federal Departments, Agencies, and offices, including the White House (e.g., Homeland and National Security Councils), and State and local officials responsible for public health emergency and disaster medical preparedness. As the Department's lead for Emergency Support Function #8, ASPR works closely with the Department of Homeland Security's (DHS) Federal Emergency Management Agency (FEMA) to coordinate Federal assistance to supplement State, Territorial, Tribal, and local resources in response to public health and medical care needs identified by the affected State and local authorities.

BARDA

ASPR/BARDA has managed $4.6 billion in pan flu preparednesss money. This has led to advanced diagnostics, including diagnostics used in this event, significantly expanded vaccine production capabilities, and development of useful new medications. Many, if not all of these are or will be used in this event."

NIH

NIAID influenza experts are working with colleagues at the Centers for Disease Control and Prevention and throughout the government to provide advice, knowledge, and support in the response to this outbreak. This includes working with our partners at the CDC, FDA and in industry on the next stages of making a vaccine against this novel virus. An immediate priority is the development and testing of a seed virus strain that could be produced in pilot lots by the private sector. The development of these seed viruses has already started as part of a pre-arranged plan. The NIAID clinical trials infrastructure -- called the Vaccine and Treatment Evaluation Units -- is at the ready to quickly evaluate pilot lots of vaccine candidates to determine safety and immunogenicity of the candidate vaccine.

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June 17, 2009

RADM W. Craig Vanderwagen, MD
Assistant Secretary for Preparedness and Response
Department of Health and Human Services
200 Independence Avenue SW Rm 638-G
Washington, DC 20201

Dear Dr. Vanderwagen:

Thank you for appearing before the Subcommittee on Health on April 30, 2009, at the hearing entitled "Swine Flu Outbreak and the U.S. Federal Response".

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions and include the text of the question with your response, using separate pages for responses to each Member.

Please provide your responses by July 8, 2009, to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

The Honorable Mike Rogers

1. What is the status of BARDA's funding for new antivirals against influenza?

2. When does the Agency plan to award funding for new drugs or combination drugs under its October 2008 RFP?

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