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THE SWINE FLU EPIDEMIC: THE PUBLIC HEALTH AND MEDICAL RESPONSE

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE SWINE FLU EPIDEMIC, FOCUSING ON THE PUBLIC HEALTH AND MEDICAL RESPONSE

APRIL 29, 2009

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THE SWINE FLU EPIDEMIC: THE PUBLIC HEALTH AND MEDICAL RESPONSE

WEDNESDAY, APRIL 29, 2009

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 3:03 p.m., in room SD–430, Dirksen Senate Office Building, Hon. Sherrod Brown, presiding.

Present: Senators Dodd, Mikulski, Reed, Brown, Casey, Merkley, Enzi, Burr, McCain, and Roberts.

STATEMENT OF SENATOR BROWN

Senator BROWN. I call the Health, Education, Labor, and Pensions Committee to order. Thank you all for being here. I want to thank my colleagues, Senator Dodd, Senator McCain, Senator Alexander, and Senator Enzi.

Emerging public health threats, SARS, anthrax, bioterrorism, all of these serve as a wake-up call to bolster our public health capabilities. Chairman Kennedy and Ranking Member Enzi exercised over these years swift and decisive leadership shepherding new legislation to prepare our public safety and public health care systems to respond to these threats. We see how important their actions were.

We see now that the possibility of pandemic outbreak is a very real threat and that if we let our public health infrastructure falter, it is all of us in this great country and around the world that will suffer.

I would like to thank Dr. Fauci and Dr. Besser for taking the time to provide with us an update on the Administration's ongoing efforts to contain and combat the swine flu outbreak. Dr. Fauci, who has just done terrific work over the years on all kinds of public health issues, is with us. Dr. Besser will testify by video.

Earlier this week, the World Health Organization raised the influenza pandemic alert level from phase 3 to phase 4 out of 6, I might add, indicating that the likelihood of a pandemic has increased but not that a pandemic is inevitable.

Domestically we are seeing increases in cases of swine flu. As of this afternoon, the Centers for Disease Control was reporting 91 laboratory-confirmed cases of the swine flu in 10 States, including 1 case in my State of Ohio. This morning it was reported that an infant in Texas died from this flu, the first confirmed fatality in the United States.

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Internationally the situation has become more serious with additional countries reporting confirmed cases of swine flu. Yesterday confirmed cases were identified in New Zealand and Israel, representing the first evidence that this virus has spread to the Middle East and to the Asia Pacific regions. Confirmed cases have also been identified in Great Britain, Canada, Scotland, and Spain.

Today, virtually all cases outside of Mexico have been mild and sporadic but geographically widespread, suggesting that more cases will likely emerge. For these reasons, it is important that Congress examine what efforts are currently being undertaken to ensure the safety of our citizens now and what actions are being taken going forward to limit the spread of this virus and to prevent future outbreaks.

To date CDC and the Department of Homeland Security have taken aggressive and proactive steps to respond to this outbreak and protect our Nation's public health. CDC's Division of the Strategic National Stockpile has already released one-quarter of its antiviral drugs, Tamiflu and Relenza, personal protective equipment, and respiratory protection devices to help States with confirmed cases of swine flu respond to the outbreak.

CDC continues to issue daily guidance to public health departments and individuals and families about how to protect against this disease, what to do if you are feeling sick, and how best to utilize community mitigation strategies in responding to the outbreak.

In addition, earlier this week, CDC issued a travel warning recommending that people avoid non-essential travel to Mexico.

As the scope and extent of the swine flu outbreak become more clear over the next few days and weeks, it is vitally important that Congress stay informed about all efforts taking place to protect our citizens and our families.

It is also important that Congress work to ensure that Federal agencies responsible for leading our Nation's efforts against this outbreak have the resources and the funding necessary to do their jobs and to protect our people.

I am anxious to hear from our witnesses about the magnitude and extent of this outbreak, what we should expect in the coming days and weeks, how best our citizens should protect themselves, what efforts are currently underway to fight this deadly outbreak, what plans and infrastructure are in place should the situation worsen, and how we can help you and them do their jobs.

The Senator from Wyoming, Senator Enzi, for his opening statement.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you, Mr. Chairman. Because of the urgency of the information, I was not going to give a statement. I was going to introduce Senator Burr to do one on our side so that there would only be one on our side, but since he is not here, I am going to go ahead and do the statement.

We are facing the early stages of what may become a global pandemic and infection. We are calling it H1N1 so that does not affect the pork market. It is being referred to everywhere else as swine flu, and it has claimed 100 lives in Mexico. Other countries, from

Canada to New Zealand, have confirmed cases. This disease does not know any borders.

While the World Health Organization has yet to declare a pandemic, the early information on the flu bears eerie parallels to the 1918 pandemic. That virus took a devastating toll on the United States and other nations, ultimately killing 50 million people worldwide.

To prevent the flu from becoming the next pandemic and to ensure the health and safety of Americans and individuals around the world, we will respond aggressively to this threat. Our agencies must work closely together and with our global partners to stop the threat of the flu, to help individuals who may be infected find the right treatment as early as possible.

Over the last 5 years, Congress and the previous administration have taken actions to prepare our country for potential disease outbreaks and other public emergencies. In particular, I do want to single out and thank Senator Richard Burr for all he has done to make sure that we are better prepared today for this potential crisis. He and his staff put in months of hard work to craft the Pandemic and All-Hazards Preparedness Act that has put in place the important tools that are now allowing us to respond to the swine flu outbreak. Senator Burr's legislation provided the authority to purchase 50 million treatments of Tamiflu, which has so far been effective in treating swine flu. It also helped promote the development of new diagnostic tools to quickly evaluate to see if illnesses are related. Other countries are now relying on those technologies for quick testing.

In addition to expanding our Nation's supply of flu therapies and increase in global supply of diagnostics, Senator Burr has established the Biomedical Advanced Research and Development Authority, also known as BARDA, which provides Federal coordination for the development and procurement of vaccines, drugs, therapies, and diagnostic tools for public health emergencies.

His legislation also enhanced coordination procedures, and now the Centers for Disease Control and Prevention, CDC, is working closely with the State and local public health departments to train and prepare communities to respond to public health emergencies.

It has been my experience that we in Washington seldom work on a solution ahead of time, and it is even rarer that what we work on turns out to be needed and we got it right. To that extent, I think we are better prepared to deal with this crisis today, and Richard Burr deserves much of the credit. This whole committee worked on it, and I can remember watching the negotiations as we finished it up so that it could actually be signed by the President. A tremendous effort by the people on this committee, and again a bipartisan, very cooperative effort.

Although the United States is more prepared for pandemic flu today than ever before, there are still gaps in the system and we have to fill those to ensure that States are able to respond quickly and effectively. We have to continue to prepare for another pandemic flu outbreak like the one in 1918 but, of course, with better communication, but also more transportation which enhances the problem—by funding research to find newer, better, less resistant treatments.

While I am reassured by the fact that our public health monitoring system was able to catch the outbreak early on, I am concerned about the ability and capacity of CDC and local communities to test and treat for swine flu, should this outbreak continue to spread and come back in the fall even greater.

I welcome our two doctors today to testify, one by high technology and I am looking forward to seeing how CDC and NIH will work together to prepare for the flu and what actions they are taking in response to the H1N1 flu outbreak. We need to be sure we are doing everything in our power to bring attention to the global threat and stop the spread of the flu before it becomes a pandemic. I look forward to the testimony today.

Senator BROWN. Thank you, Senator Enzi.

Senator Dodd.

STATEMENT OF SENATOR DODD

Senator DODD. Well, Mr. Chairman. I will ask consent that a statement be included in the record because I know we have got our witnesses here and a good participation by members.

I see Richard Burr, my colleague, has arrived. I remember those long days we spent in Bill Frist's office, you and I and Senator Kennedy—Mike Enzi was there—and working on it. I mentioned yesterday on the floor of the Senate the important work you did in that effort. We appreciate it very, very much, and we are in better shape today because of those efforts, and they deserve to be recognized as well.

Mr. Chairman, in fact, I live in a very small town in Connecticut, and there is a suspected case, not yet confirmed, but just in a small town on the Connecticut River where they closed the high school yesterday. They are going to open up again, soon, after cleaning it thoroughly. This has reached all across our country. While not every State has been affected yet, there are certainly legitimate concerns that it could spread very, very quickly. So it is important we have a good briefing here by our two very distinguished witnesses to share some thoughts on this.

One issue I would like to raise—Ted Stevens and I offered a piece of legislation last year on paid family medical leave and, as many of my colleagues know, spent a long time years ago drafting the Family Medical Leave Act. It became law in February 1993. It is unpaid leave, obviously. Some 60 million Americans have been able to use family medical leave.

One of the concerns we have here is that, obviously, as people stay out of work, the lack of contact could be really very important. I presume Dr. Fauci and others will share with us steps people can take. For an awful lot of people, one out of three Americans, they just cannot take unpaid leave. It is just difficult. They cannot afford to do it. I raise that only because it is an example like this where we need to be thinking. Senator Stevens and I worked on a proposal that involved both employees, employers, and others so as not to be overly burdensome on employers to talk about paid leave.

Nonetheless, I think it is something I would like to see the committee re-examine as we look at an issue like this, where we could be faced with people spending time out of work and not being able

to be there, and to the extent they are able to keep those jobs and not lose the necessary income to support their families is something worth exploring. I just raise that as an issue that we might want to explore at some point.

I thank the chair and I thank Senator Kennedy for his leadership on the issue and Sherrod Brown for taking over the chair on this important matter.

Again, we thank our witnesses.

And again to Richard Burr for those days of working together on that issue in Bill Frist's office. I remember those long evenings very, very well.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Mr. Chairman, thank you for convening this hearing on the continued spread of the H1N1 (swine) flu outbreak.

Today's hearing is especially timely given the apparent rapid spread of human swine flu throughout the United States and the world. One need not look further than any news channel, including those that cover the financial markets, to see the global impact of this outbreak.

I look forward to hearing from Dr. Besser and Dr. Fauci about their ongoing efforts to address this outbreak and I am particularly interested in hearing the status of countermeasures and any plans the CDC or NIH have to fund vaccine development.

As of this morning, the CDC reported 91 confirmed cases of the H1N1 flu in the United States with multiple hospitalizations, and a likelihood that many more cases would be identified in the coming days and weeks. Tragically, one child in Texas has died as a result of this outbreak.

The situation in Mexico, as we've all heard, is more dire. Reports show more than 150 deaths and more than 1,600 illnesses. Additional cases have been identified in Canada, New Zealand, Spain, the United Kingdom, and Israel. Earlier today, the World Health Organization indicated that the spread of the H1N1 virus is moving closer to Phase 5 out of a scale of 6 on its worldwide pandemic alert which would indicate widespread human infection.

In my own State of Connecticut yesterday, two unconfirmed but probable cases of swine flu were identified in adults who recently traveled to Mexico—one in Stratford and one in Southbury. According to authorities in Connecticut, a third potential case has also been identified. All of these cases have been sent to the CDC for further analysis.

Additionally, the Superintendants in East Haddam, CT—the town where I live—and Wethersfield, CT have ordered schools there closed after students and family members became ill upon returning from Mexico.

I have spoken with our Commissioner of Public Health, Dr. Bob Galvin, as well as the Selectman and Superintendant in East Haddam, CT about the situation in Connecticut as it is unfolding. I can report that there is a great deal of coordination going on at the State level and between my State and the Federal Government.

The traditional flu season recently ended but in Connecticut, our public health lab reports an unusual spike this week in the number

of positive rapid flu test specimen from all over the State. The State lab is preparing for what it anticipates being an onslaught of additional positive specimen in the coming days and weeks.

I am concerned about the capacity of our State and local public health labs to conduct surveillance and detection during this swine flu outbreak given their current resources and workforce shortages. These are the same labs that conduct food-borne illness surveillance and detection as well as newborn screening and many other critical public health functions.

In Connecticut, these vital functions are performed by a staff of 100 which has been cut in recent years. Nationally, I am told that over 500 public health lab staff out of a total workforce of 6,500 have been laid off in the past year. That includes approximately 10,000 State and local public health positions in the United States that have been lost due to budget cuts and other factors.

I am also concerned about the capacity of our Nation's hospitals to handle a sudden surge in sick patients and whether the right countermeasures will be available at the right time to patients of all ages.

I understand that President Obama has submitted a request for $1.5 billion in additional funding to address the swine flu outbreak. Although funding is not within this committee's jurisdiction, I hope the Senate will move quickly to get the President and Secretary Sebelius the funding they have requested. I know my colleague Senator Harkin is hard at work at making that happen.

I suspect we are only at the beginning of our understanding of this global outbreak. The American public—and I include myself here—is full of questions about the swine flu outbreak: How can I protect myself and my family? What should I do if I or a family member becomes ill? Is the danger of the situation likely to grow?

One question that I suspect will grow in significance is what will happen to my job if I have to stay home to care for myself or a family member?

The CDC has recommended that those sick with the flu "stay home from work or school and limit contact with others to keep from infecting them." Workers will need access to leave from work to recover and protect others from contracting the illness. In order to limit the spread of this virus, we will need workers to stay home and limit their contact with others.

The Family and Medical Leave Act provides 12 weeks of job-protected, unpaid leave in a 12-month period for eligible workers. The FMLA has helped millions of workers take much-needed time off of work to attend to a new child, their own health, or a family member's health.

However, for every employee who can take advantage of leave without pay, there are three more who cannot afford the loss. I believe they deserve paid leave, and the need for this will only become clearer if the swine flu becomes a pandemic. I introduced legislation last year, and will do so again this year, that would give eligible employees 8 weeks of *paid* leave over a 12-month period.

Our country is in the midst of a public health emergency. The FMLA allows workers time off from work to take care of themselves and their family members when they need to, often unexpectedly. The Federal Government's policies must reflect employ-

ees' need for paid family and medical leave, especially as a growing number of Americans deal with this outbreak.

I want to commend the Obama administration for its handling of the swine flu threat thus far. It is clear that the various agencies of government are working closely and collaboratively.

As a result of the work of the HELP Committee and many of my colleagues in the Senate to write and fund the Pandemic and All-Hazards Preparedness Act and predecessor bioterrorism legislation, the country as a whole has made great improvements in surveillance, coordination, communications, and treatment capabilities. The U.S. response to this current global threat is evidence that those preparedness efforts are paying off.

Now we have a Secretary confirmed at the Department of Health and Human Services. I am confident in Secretary Sebelius and her ability to lead the public health response to this outbreak.

Above all, I think it is important that people stay calm and not panic, but it is equally important that they take the necessary precautions and remain vigilant. Federal, State and local public health officials have issued recommendations to the public for how to protect itself from the spread of the flu through some simple steps.

I thank Dr. Besser and Dr. Fauci for being here today on such short notice. I look forward to their testimony and hope they can address some of the issues I have raised.

Senator BROWN. Thank you, Senator Dodd.

Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, I would also ask unanimous consent that my opening statement be a part of the record.

I just want to thank my colleagues for their very kind remarks and to also publicly thank Chairman Kennedy for his help and support.

I also want to thank Tony Fauci. Tony was instrumental in what we have constructed to address the possibility of pandemic in the future. We were focused on one thing. Tony, we made tremendous progress, and boy, now all of a sudden, we get a jog in the road and we are headed in a different direction. I think this is a challenging thing and something for all of us to remember. We may think we know where we are going but we do not always, and that is why we have got to have in place an architecture that allows us to address every possible scenario that can come up.

The good thing is that not only were we focused on a vaccine for pandemic. Now all of a sudden, we have H1N1 and we have the tools in the tool kit for Secretaries to make split-second decisions that I think will, when needed, affect the lives of the American people and communities in which they live.

Clearly, part of that whole process were folks at the CDC. It was Mike Leavitt at HHS at the time who was engaged—and we have staff there today that was set up under his leadership—that I am sure minute by minute, hour by hour is watching the risk that we are faced with.

The only thing I would like to add, Mr. Chairman, which I think I share with all members is that we are ready, willing, and able

to work with the Administration on any potential additional needs that we have.

I also want to urge my colleagues—we have never fully funded BARDA. We have relied on Dr. Fauci to surge moneys out of the NIH when needed when we saw promising research. That is not the way BARDA was designed. It was designed for us to be almost a venture capital partner with companies that had promising research, and we were going to fund them through that valley of death. We are not there yet.

I would just encourage my colleagues. Let us take what we are going through not as a definitive example of what could happen, but as a warning sign to us, to set up the things we knew we needed, fund them at the right level so that they can operate the way they were designed, and the basket of tools that we will have in the future will be even greater than what we have today.

I thank the chair.

[The prepared statement of Senator Burr follows:]

PREPARED STATEMENT OF SENATOR BURR

Senator Brown, thank you for holding today's hearing on this very important topic of the 2009 H1N1 flu outbreak, which has also been referred to as "swine flu", and our Nation's public health and medical response. I would like to thank our witnesses, Dr. Besser and Dr. Fauci, for taking the time to be with the committee today to bring us up to speed on the latest with this outbreak. Thank you for your leadership in protecting our Nation's health. I look forward to hearing your honest assessment of the current situation. We are deeply saddened and sobered by the news this morning of the first death in the United States, a young child. Americans, especially parents, are understandably concerned and are watching this situation very closely.

During the 109th Congress, I chaired the Subcommittee on Bioterrorism and Public Health Preparedness. Building on the lessons learned from Hurricane Katrina and September 11th, Congress took a hard look at how we could better prepare and respond to public health and medical emergencies. The subcommittee held multiple public hearings, roundtables, and meetings, and Congress received significant input from public health officials, medical experts, emergency managers, biotechnology companies, and stakeholders from across our Nation. These actions culminated with the passage of the Pandemic and All-Hazards Preparedness Act of 2006. I am very proud to have authored this important bipartisan law and to have worked with many of my colleagues on this committee, including Senators Kennedy and Enzi, on this bill and other important pieces of legislation.

Through the Pandemic and All-Hazards Preparedness Act, Congress empowered the Department of Health and Human Services with the tools it needs to protect the American people more effectively and efficiently in response to a public health emergency. Since 2006, the Department has made progress in implementing this law. I hope one good story that we will see come out of this situation is that the tools that Congress gave the Department are being put to good use in responding to H1N1. For example, this law established the Office of the Assistant Secretary for Preparedness

and Response, or ASPR, to unify the Department's preparedness and response programs. Since its inception, ASPR has carried out significant preparedness and response planning, and is now playing a critical role in the current public health emergency by helping to coordinate response efforts with Federal, State, and local public health partners. In addition, the National Biodefense Science Board, which was also created by this law, provides important advice and guidance to HHS on matters related to public health emergency preparedness and response. With the passage of this law in 2006, HHS now has additional authority to make sure we are prepared and can respond to an emergency like the one we are experiencing today.

In particular, in the Pandemic and All-Hazards Preparedness Act, Congress created the Biomedical Advanced Research and Development Authority, or BARDA, to speed up the development of countermeasures—such as vaccines or treatments—to protect Americans against a potential chemical, biological, radiological, or nuclear terrorist attack, or other public health emergency such as a pandemic flu. The Pandemic and All-Hazards Preparedness Act authorized over a billion dollars for BARDA. But, despite my best efforts, Congress has failed to provide this full funding.

Thankfully, even without full funding, BARDA has been able to identify promising countermeasures, fund the advanced research and development necessary for making these products available, and has supported their acquisition, stockpiling, and deployment. I believe firmly that, thanks to BARDA and the investment we have made over the last few years, our Nation is now much better positioned to quickly respond to the H1N1 flu outbreak and other potential pandemics.

I am ready to work with the Administration and my colleagues to do what we need to do to make sure that we fight the spread of the H1N1 flu as much as possible and protect the health of Americans, especially the most vulnerable of our society. While we have immediate needs at hand to address, we must also not lose sight of the ongoing work that must be done if our Nation is going to be fully prepared for future public health emergencies or a bioterrorist attack.

This outbreak should be a wake up call to all of us for why we cannot let our guard down. We must continue to invest in BARDA and other tools so that we can tackle not only today's public health emergency but also what we may have to confront in the future.

I thank the Chair.

Senator BROWN. Thank you, Senator Burr.

Senator Mikulski.

STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. I know we are all looking forward to hearing Drs. Besser and Fauci.

I wanted to reiterate what my colleague, Senator Burr, has said.

First of all, I just want to thank Dr. Fauci and Dr. Besser for what they do, not only in response to this now critical international situation, but we have turned to Dr. Fauci time and time and time again. When there was an outbreak of an unknown disease in the bath houses of California and then a new disease came on the

scene called AIDS, we turned to NIH, the institute on viruses. There was Dr. Fauci. When we were hit by anthrax in this capital, who did we turn to? We turned to Dr. Fauci.

Now once again, we are turning to Dr. Fauci, and I mean not only him as a talented public servant, but him as a metaphor for our public servants. If anything this shows us why we need to maintain the integrity of our public health infrastructure and honor the integrity of our public and civil servants. We are very good at funding emergencies. We love emergency hearings. We like getting all juiced up and funding things, but it is the faithful funding of our public health infrastructure and supporting them on days where there is not an emergency that prepares them to be ready for an emergency.

Now, as we respond to this, working with our President and our international partners, I would hope that when the appropriations comes up, we not only look at the emergency funding for swine flu, but you know you cannot respond to an emergency unless you have the right people in place and a public health infrastructure that works. I would hope we would look forward to funding it.

My colleague from North Carolina that we have worked with on these issues has talked about BARDA, but it is across the board.

We are glad to see you once again. I am relieved that the country can turn to you once again, and we are grateful that you have remained in civil service at NIH. You could have some cushy job in some university where you could be flying around to international conferences and on tons of boards and commissions. If only we could take your salary and put a bunch of zeroes behind it. We want to thank you for being you and we want to thank you for the metaphor for all those talented people who work every day so we can be ready to respond to the emergency.

Senator BROWN. Thank you, Senator Mikulski.

Our two witnesses are Dr. Richard Besser, Acting Director of the Centers for Disease Control and Prevention in Atlanta. He is with us by video from Atlanta. Also, Dr. Anthony Fauci is Director of the National Institute for Allergy and Infectious Diseases at the National Institutes of Health in Bethesda.

Thank you both for your public service. Thank you both for, as Senator Mikulski said, answering the call for public health. There are few higher callings in our country for the last many decades than devoting your life to public health and making such a difference in so many people's lives and so poorly paid and so underfunded, so often as public health overall, not just pay but in the services that it provides.

Dr. Besser, we will begin with you by video from Atlanta. Thank you for joining us. Thank you for your patience. Proceed please.

STATEMENT OF RICHARD E. BESSER, M.D., ACTING DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ATLANTA, GA

Dr. BESSER. Thank you very much. Good afternoon, Mr. Chairman and members of the committee. I am Dr. Richard Besser, Acting Director of the Centers for Disease Control and Prevention. I appreciate the opportunity to update you on the current steps we

are taking to respond to this unique and serious influenza outbreak.

First, I want to say our hearts go out to the people in the United States, in Mexico, and around the globe who have been directly impacted, in particular to the family of a child in Texas whose death was the focus of media reports this morning. People are concerned and we are 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. Our aggressive actions are possible, in many respects, because of the investments and support of this committee and the Congress and the hard work of State and local officials across the country.

Flu viruses are extremely unpredictable, making it hard to anticipate the course of this outbreak 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, make clear the uncertainties, clearly communicate what we are doing to protect the health of Americans and help Americans understand the steps that they can take to protect their own health and that of their communities.

Influenza arises from a variety of sources, and in this case we have determined that there was a novel 2009 H1N1 virus circulating in the United States and Mexico that contains genetic pieces from four different virus sources. Additional testing is being done on this virus, including a complete genetic sequencing.

CDC has determined that this virus is contagious and is spreading from human to human, similar to seasonal influenza, likely through coughing, sneezing, touching of hands that are infected, and so forth. Sometimes people may be 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 from eating pork or pork products.

I want to reiterate that as we look more intensely for cases, we are finding more cases. We fully expect to see not only more cases but also a greater spectrum of severity of disease. The specific numbers are less important in understanding the outbreak than the more general patterns that we will use to help guide our interventions.

Aggressive actions are being taken here, as well as abroad. We are working closely with State and local public health officials around the United States on this investigation and to implement appropriate control measures. We are providing both technical support on epidemiology and laboratory support for confirming cases. We are also working closely with the World Health Organization and the Pan American Health Organization, and the governments of Mexico and Canada on this outbreak investigation. There is a tri-national team on the ground right now in Mexico trying to better understand the outbreak and to enhance surveillance and laboratory capacity so that we can better address critical questions such as why cases in Mexico appear to be more severe than ini-

tially seen in the United States. We are working closely with HHS and other Federal partners to ensure that our efforts are coordinated and effective.

CDC has issued numerous health advisories for individuals, health care practitioners, schools, and communities, and these continue to evolve as our understanding of the situation changes. For example, on Monday, CDC issued a travel health warning for Mexico, recommending that travelers postpone nonessential travel to Mexico. CDC is also evaluating information from other countries and will update travel notices as necessary. As always, persons with flu or flu-like symptoms should stay at home and not attempt to travel.

In fact, a key message from CDC is that there is a role for everyone to play when an outbreak is occurring. It is a matter of shared responsibility. At the individual level, it is important for people to understand how they can prevent respiratory infections. Frequent hand-washing or use of alcohol hand gels is an effective way to reduce transmission of this virus. If you are sick, stay at home, and if your children are sick, have a fever, or flu-like illness, they should not go to school. If you are ill, you should not get on an airplane or other public means of transportation. 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. It is about planning, leaning forward that will help our communities be ready. Communities, businesses, schools, and local governments should plan now for what to do if cases appear in their communities. For example, parents should prepare for what they would have to 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 other regular updates, are posted on the CDC Web site, *www.cdc.gov*.

CDC maintains the Strategic National Stockpile of medications and other materials for the eventuality that they may be needed in a situation just as the one that we are facing. As part of our pandemic preparedness efforts, the U.S. Government has purchased extensive supplies of antiviral drugs and our preliminary testing indicates that this virus is susceptible to the drugs that we have been stockpiling.

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 the States in which we already have confirmed cases. The Department of Defense and individual States have also stockpiled these antiviral drugs.

Whenever we see a novel strain of influenza, we immediately begin to work toward the development of a vaccine in case one needs to be produced. Dr. Fauci will be talking more about this. The CDC is working to develop a vaccine seed strain specific to this novel virus, the first step in vaccine manufacturing. We have initi-

ated steps so that should we need to manufacture a vaccine, we can work toward that goal very quickly. Rapid progress will be possible through the combined forces of CDC, NIH, FDA, BARDA, and manufacturers.

Finally, it is important to recognize through the strong of the Congress, there have been enormous efforts in the United States to prepare for this kind of an outbreak and a 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 absolutely 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 that are undoubtedly going to come our way in the weeks ahead, we look forward to working closely with the committee to best address this evolving situation.

I want to thank you for holding this hearing, and I look forward to answering any questions you may have.

[The prepared statement of Dr. Besser follows:]

PREPARED STATEMENT OF RICHARD E. BESSER, M.D.

Good afternoon, Chairman Kennedy, Ranking Member Enzi and other distinguished members of the committee. I am Dr. Richard Besser, Acting Director of 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 United States 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 United States 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 27, 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 other 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 Website—*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 United States 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 committee to best address this evolving situation.

Senator BROWN. Thank you, Dr. Besser.

Dr. Fauci.

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE FOR ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, BETHESDA, MD

Dr. FAUCI. Mr. Chairman, members of the committee, thank you again—and I reiterate what Dr. Besser said—for calling this hearing. Thank you very much, all of you, for your kind words. I sincerely appreciate it. Thank you for the opportunity to discuss the public health threat that the Nation and the world are facing with regard to outbreak of the potentially pandemic 2009 H1N1 flu virus.

Thank you also for the extraordinary support that you and the committee have given to us at HHS in the development of the pandemic influenza preparative efforts. I can say quite sincerely and honestly that we would not be where we are right now in our high level of preparedness were it not for this committee.

As you have just heard, the number of influenza cases caused by this novel virus has continued to grow in the United States and internationally. Our colleagues at the CDC, the WHO, and international health authorities have done an outstanding job in tracking this potential pandemic virus and in implementing control measures. What I will do over the next couple of minutes is describe very briefly the research response at the NIH that is synergistic with and complementary to the efforts of our sister agencies, CDC, FDA, as well as other organizations.

As you know, over the last several years, we have launched a major research effort that builds on longstanding programs in seasonal influenza to improve our preparedness for the possibility of pandemic influenza. Although we have focused a good deal of attention recently on the H5N1 influenza, the so-called bird flu, it has always been clear that the next pandemic threat could come from another virus altogether. Indeed, such a threat is now upon us.

We have rapidly ramped up the research agenda that underpins the development of countermeasures for all influenza subtypes, including potentially pandemic strains.

Basic research has given us fundamental information about how influenza viruses re-assort. I know many of you have heard that word, "re-assort." What does that mean? This means that viruses exchange their genes within a cell to yield a new hybrid virus such as the one that we are now seeing.

We have also learned how viruses evolve and how different viruses cause disease. It is these kinds of studies that lead to the translation in clinical research that we need to develop new tools to diagnose, treat, and prevent diseases and prevent notably with vaccines.

Vaccines, of course, are essential tools for the control of any form of influenza. Basic research of advances have allowed for the rapid isolation and genetic sequencing of the currently circulating 2009 H1N1 virus and has given us important insights and technologies into the design of potential vaccines for this virus. The CDC should be congratulated in the extraordinary rapidity in which they did this.

Using our multifaceted research infrastructure, we are now working with our partners of HHS, CDC, FDA, and industry on the various stages in making a vaccine against this novel threatening virus. An immediate priority is the development and testing of a reference virus strain that will be made into seed viruses, as we call them, that will be used in the production of pilot lots by our partners in the private sector.

This process has already begun as part of our pre-arranged plan that Senator Burr referred to. Our clinical trials infrastructure, called the Vaccine and Treatment Evaluation Units, are at the ready right now to quickly evaluate the pilot lots when they become available to determine three things: the safety, the ability to adduce a response that you would predict would be protective, and the determination of the appropriate dose that we will ultimately use in a vaccine. All systems are go for this step-wise process.

Antiviral medications also are an important counterpart to vaccines as a means of controlling influenza outbreaks through both treatment and prophylaxis. Thankfully, the currently circulating 2009 H1N1 flu virus is sensitive to the two major antiviral drugs in our Strategic National Stockpile, Tamiflu and Relenza. However, experience tells us that drug resistance can occur, and NIH is working to develop with CDC and test the next generation of flu antivirals. CDC already has new and sensitive diagnostics available and other new diagnostics are being developed by NIH grantees and contractors.

In closing, I would like to emphasize that our longstanding collective efforts at HHS to prepare for an influenza pandemic with research, with a sufficient supply of effective vaccines and antiviral drugs, with public health measures, efficient infection control, and clear public communication has given us a head start in this serious situation that we are facing today. Again, we appreciate very much the support that you have given us to get to this level of preparedness. I would be happy to answer any questions that you may have. Thank you.

Senator BROWN. Thank you, Dr. Fauci.

Dr. Besser, thank you again. You had said that the CDC's Division of the Strategic National Stockpile has released one-quarter of the antiviral drugs and personal protective equipment and respiratory protection devices to those, I believe, 10 States that have had any kind of evidence of anyone who has contracted the virus.

Run through, if you would, what happens once these antivirals reach the State. Are they disseminated at hospitals, community health centers, public health departments? Where do they go? How is that determined? Run through that process, if you would.

Dr. BESSER. Thank you, Senator, for that question.

Actually we are distributing antivirals and other supplies to all 50 States, plus the other large cities that participate as independent recipients. We are targeting those areas that have been infected first.

The reason we are doing that is as a forward-leaning, aggressive move. At this point, it is too early to say whether this virus will cause severe disease in this country, how many people will be affected, and whether local supplies of drugs and other supplies will run low. We are in the process of moving 25 percent of each State's allocation to the State control.

Now, we exercise this all the time. States have plans and we report annually to the public on the status of planning and exercising around stockpile distribution. We turn over the Federal supplies to the State in their receipt staging and storage site. They are then responsible for the next stage of distribution down to where those drugs would be used.

Now, at this point with the number of cases we are seeing with the supply of oseltamivir and zanamivir that are around the country, we are not seeing shortages for use in treatment. Should that be the case, States have plans and we would be able to distribute that in the way that they have been planning. As you would expect, States will vary depending on whether they are a rural State or mainly a predominantly urban State. Those plans are in place and have been exercised.

Senator BROWN. President Obama sent a letter to Congress asking for an additional $1.8 billion to help fund a plan to build drug stockpiles and monitor future cases of the disease. Can you give me a general outline of how this money will be spent, and why it is so vitally important?

Dr. BESSER. Senator, I will need to get back to you for the record on that, but I can tell you that when we are in emergency response mode, when we are helping the State and locals and responding globally, it is very resource-intensive. At that time, resources are not to matter. It is the safety and health of people here and elsewhere. I know that a large portion of those funds are to support the ongoing emergency response capabilities and ensure we have flexibility and are not hampered in that regard. For additional components of that funding, I would like to get back to you for the record.

Senator BROWN. Thank you, Dr. Besser.

Dr. Fauci, why is the virus proving to be fatal in so many cases in Mexico but less so here in the United States and elsewhere in the world?

Dr. FAUCI. Well, I will tell you a bit about that, and then Dr. Besser may want to chime in.

It is still very unclear what people are interpreting as the differences between a virus in Mexico and what it is doing in Mexico and what it is doing in the United States. From a molecular virus-type standpoint, it appears to be essentially identical to the virus here. The numbers of cases in Mexico are larger than the numbers of cases in the United States, probably even much, much larger. We do not know what the true denominator is. Mainly we are hearing reports of cases that are reported of people who are very sick, a certain proportion, varying numbers, 100, 200, or more who have died, not all of them at all confirmed with that. In the United States, the numbers at this point are less, and as the CDC—and I will have Dr. Besser go into this. We should expect that we are going to see more serious disease over the next days to weeks or even beyond.

I think it is such a dynamic situation, Mr. Chairman, that we cannot say necessarily that there is an absolutely fundamental difference. It may be just that there are so many more cases in Mexico and we are still in the evolution of more cases in the United States. I will turn now to Dr. Besser and have him amplify that.

Senator BROWN. Dr. Besser, any thoughts on that?

Dr. BESSER. Yes, Senator. Thank you, Dr. Fauci.

This is a critically important question. Is there truly a difference between what is taking place in Mexico and what is taking place here in the United States? It is premature to say that there truly is a difference. It may be that we are earlier in the course of the introduction of this virus into our communities and that as it progresses, we will see more severe disease.

There may be differences in terms of treatment practices in Mexico. Our team that is part of the tri-national effort is looking at such factors as how long was the time between onset of symptoms and beginning of treatment. What were the treatment practices? What medications were used? Were there additional treatments that may have impacted adversely in that treatment? Are there other factors related to the population, related to the environment? There are many things that need to be looked at, and people are very aggressively trying to address those questions while, at the same time, we are working here to study transmission in our communities.

The best news would be if we were to find that this virus, as it goes from person to person to person, loses some of its strength, some of its virulence. We do not have evidence of that at this point, but that is one of the questions we need to look at.

But you asked, I think, the fundamentally most important question that we are trying to address.

Senator BROWN. Thank you. One real quick question. Then I will call on Senator Burr.

How many Americans typically die from the flu every year?

Dr. FAUCI. The number that you hear is about 36,000, at least tens of thousands. It is a number that changes a bit from year to year, and about 200,000 excess hospitalizations each year in a seasonal flu.

Senator BROWN. Tens of thousands. That number is annually? I mean, for the last many, many years, there have always been tens of thousands of Americans die from some influenza.

Dr. FAUCI. They are mostly in elderly people and people who have compromised, what we call, host defenses or compromised immune function.

Senator BROWN. Some 200,000 Americans have gone to the hospital, more or less, annually because of influenza?

Dr. FAUCI. Right.

Senator BROWN. Thank you.

Senator Burr is recognized for 5 minutes.

Senator BURR. Thank you, Mr. Chairman.

Dr. Besser, I think it is clear that our ability to diagnose this flu strain is absolutely essential. Let me ask two questions of you. What are our capabilities regarding point-of-care diagnostics, and have we begun to procure and deploy any type of rapid testing diagnostics?

Dr. BESSER. Thank you, Senator Burr.

First, I would like to say that the investments that we have made in our State and local laboratory capacity, through things such as the laboratory response network as part of overall preparedness and as part of pandemic preparedness have—it is an incredibly important network of laboratories, more than 160 labs across the country that use common diagnostic testing that assures that if a test result from North Carolina comes back positive, we will have confidence that it is the same as if we had done it here in Atlanta.

We are in the process now of distributing H1N1 diagnostic kits to all of the States. Right now, those kits are available in California and New York. We are rolling these out. We are making sure that they work well as we scale that up. By the end of the week, every affected State will have this test kit in their laboratory, and by early next week, we will have this in all of our State laboratories. This is part of our efforts to shorten the time between identification of a potential case of flu and being able to confirm that.

In terms of the issue of point-of-care tests, we do not have a point-of-care test for this strain. I need to say that the reason we were able to diagnose this case, the initial case of swine flu—and it was a case of swine flu—was because of the pandemic preparedness efforts. There was a study going on in San Diego at a Department of Defense site, a naval site, that was developing point-of-care tests, and it was a step as part of the investments Congress had made in preparedness. They were developing a test for point-of-care, and they identified through that a strain that looked different. They sent that strain to CDC and we were able to determine it was a novel strain of influenza that had components that were related to strains in affected swine. We shared this information with the international community, as we always do, and we were able to see that the strains that Mexico had sent to Canada were the same strain that we had identified in San Diego.

The work going on to develop point-of-care tests—and we agree that point-of-care testing is a very important piece. Those efforts

bore fruit here in the early detection of this novel outbreak of influenza.

Senator BURR. Thank you, Dr. Besser.

Dr. Fauci, do we expect this virus to go dormant at some point?

Dr. FAUCI. The one thing that we have learned about influenza, Senator Burr, is that it is quite unpredictable, in fact, extraordinarily unpredictable. Any possible scenario. It could take off more. It could go dormant. It could lay low over the summer and come back in the fall. That is the reason why we really are preparing for any of those options. We are preparing always for an unpredictable course, which is very characteristic of influenza, particularly a virus that you have actually never seen before or had experience with before.

Senator BURR. One could say this has been very unpredictable, a late season eruption. It seems to be, if the accounts are correct, in the most severe cases this is an upper respiratory distress. Would that be accurate?

Dr. FAUCI. It starts off as a standard type of flu with fever, headache, muscle aches, some diarrhea and GI tract involvement. Then in the people who get seriously ill, it rapidly progresses to serious pulmonary involvement, which we call acute respiratory distress, which is the thing that people get at the point when they are dying. I am sure Dr. Besser can give you more details about the cases in Mexico. That is the general thing that happens. It starts off as an influenza type of an illness, which just progresses rapidly in people who get seriously ill. The cases in our country, as you know, at least the ones that are being reported now, relatively speaking have been the typical type of mild flu.

Senator BURR. I understand that the data set that we have right now is fairly limited from the standpoint of knowing how many cases, and therefore how many deaths.

Dr. FAUCI. Right.

Senator BURR. Can you find comparisons to at least the initial stages of this flu strain and its affects on humans and the 1918 strain? Some news accounts suggest that those who have died were in the lower age groups, which is counter to what we typically see in a flu patient. Again, the data set is much smaller right now.

Dr. FAUCI. Yes. I will defer the question to Dr. Besser.

But in general, we tend to be careful about making these kinds of comparisons because that immediately sets off alarm, even though we always assume the worst scenario.

The individual manifestations I will hand to Dr. Besser who has the experience of the numbers and what we are getting reported on a daily basis.

Rich.

Dr. BESSER. Thanks, Tony. I appreciate it.

We are gathering data still from Mexico to understand the various presentations. The presentations that Dr. Fauci was talking about of fulminant presentation of infection going on to a white-out of the lungs and respiratory failure—that is the picture of 1918 that we hear about. Getting a handle on how often that is being seen versus patients who have flu-like symptoms who progress, progress, progress and then go into failure or develop a secondary bacterial infection is going to be very important.

We have yet to see in this country any of that rapid progression. When we look at the cases here that have been hospitalized—and there are only five hospitalized cases so far—we are seeing the types of patients who typically have a problem with seasonal flu, and that is: people who have underlying medical conditions, may have immune problems or are taking drugs that could suppress the immune system or those who are at the extremes of age, that setting. That is a typical pattern for seasonal flu.

We are not seeing the evidence here yet of high attack rates and increased severity in the healthy adult population. That is an area we are really looking at, the 10 to 50 age. If we start to see fulminant disease in that area, if we start to see increased severity and high rates of hospitalization in that range, that would be very concerning.

Senator BURR. The last question. The Chairman has been very patient with me.

Is there any reason for us to believe that the annual influenza vaccine that millions of Americans took this year could play a role in moderating this current strain?

Dr. FAUCI. If you look at the laboratory, what we call, in vitro cross-reactivity, does the response of the seasonal influenza H1N1 that is part of the three virus vaccines that go into what we get on a seasonal basis, there does not appear to be any laboratory indication that you would predict would be protective. However, we have experience with vaccines that there are some things that might be unmeasurable and subtle, such as cell-mediated immunity that you do not measure or certain types of immunological responses. You would not expect or predict that that vaccine that we took would protect against this. But there are some subtle things that we need to pursue to see that there may be some things below the radar screen that might be beneficial.

Senator BURR. Thank you.

Senator BROWN. Thank you, Senator Burr.

Senator Dodd is recognized.

Senator DODD. Thank you very much, Mr. Chairman, and I thank both of you. Let us underscore the comments of the others about the tremendous value that both of you provide on these issues and so many others we have had to grapple with over the years.

I am not sure to whom I want to address this. I will start with Dr. Fauci. The first question I have is about public health lab personnel. I know the State budgets are such that it puts a lot of strain on them today. The number of people—I think something like 500 public health lab staff over the last year or so have lost their jobs because of budget pressures of the 6,500 that are out there. I know the States are cutting back. In my own State, the lab staff of 100 has been cut in recent years.

Could you give us any indication as to whether or not, in the coming days here, we are going to see some sort of an additional resource allocation so the States and the lab personnel will be in place so we have the workforce to help us at this point?

Dr. FAUCI. The CDC works very closely with the State and territorial officials. I am not sure there is an answer to your question. Dr. Besser would be more on the line of being able to answer that.

Senator DODD. Doctor.

Dr. BESSER. Thanks. Thanks, Dr. Fauci.

Clearly, a critical part of our preparedness and our response is those at the front lines, State and local public health. It has been very concerning to us as we have been hearing reports of more than 10,000 State public health employees who are at jeopardy of losing their jobs, in large part due to the economy.

One of the reasons we are as prepared as we currently are for a potential pandemic is the investments that have been made in State and local public health, in the infrastructure, in the laboratories, in the health communicators, in those people who are doing surveillance and investigating cases, those who are communicating to the public. This infrastructure allows us not only to respond to a potential pandemic, but to the everyday public health challenges that we face.

We have been pushing and emphasizing to our State colleagues the importance of planning and exercising. We do this at the Federal level and we have been holding their feet to the fire of State grantees. If they are getting money from the Federal Government, they need to be exercising and they need to be showing us how they are exercising and how they are using those exercises to improve their systems.

I can tell you that it is absolutely impossible to require States to do exercising at a time when they are laying off their personnel. They just do not have the capability to do their jobs and continue the preparedness efforts.

In terms of resources from the Federal Government to the States, I would need to get back to you on that. I do not have details on how the supplemental request is being directed. But I can tell you that what we hear from our State laboratory colleagues, from our State public health colleagues is that those systems are in jeopardy of being lost.

Senator DODD. Again, I appreciate that, and I would hope at least on a matter like this that it would not take this kind of a moment. It seems to me when you are dealing with potentially pandemic issues, they do not confine themselves geographically. In our States where we are relying on States to hire people to have in place, it seems to me in a matter like this, that this becomes more of a national policy rather than a State policy. Obviously, having the help of States means a lot. The fact that 10,000 people we do not have in place seems to me rather precarious. Just going out and doing that today—imagine if you had to do it today how hard that would be. I do not know where you would find 10,000 people necessarily to fill these jobs.

I would urge you to get back to us on that, and I presume you are communicating this to the Administration and others. Let us know if there is anything we need to do from this standpoint to support that effort. It seems to me this ought to be more a permanent place somehow, a combination, whether you do State, local, Federal, whatever, to keep having personnel on hand. I would appreciate that. If you could get back to us, I would appreciate that, as well, Doctor.

I will bring up a parochial issue for you, if I can. As I understand it right now, there is currently no vaccine available for H1N1. Is that correct?

Dr. FAUCI. Well, we have to be careful when we say H1N1. We have an H1N1 vaccine in our seasonal flu package of three vaccines that we vaccinate every year. There is not a vaccine for this particular 2009 H1N1 flu that we are in the process of trying to develop.

Senator DODD. So that is my question. Again, there is a company in Connecticut called Protein Sciences, which has been very involved with the CDC and has had a very responsive reaction. A vaccine company, a small company. They have had an application pending since 2007 with BARDA for the manufacture of a recombinant flu vaccine. The Mexican government have had them down there. They have been hired to come in and help deal with the situation. They just cannot get an answer to their application with BARDA here in the United States.

I just want to take the opportunity of this gathering here—from BARDA—I guess CDC or Dr. Besser might be the right one to raise this question with to see if we can get some answer for them. This is not a parochial issue for a company, but a company that has developed—they think with minor changes, they could have in 5 to 6 weeks 30,000 doses a week available of the product they have been producing.

Are you familiar with this, Dr. Besser, at all, what I am talking about?

Dr. BESSER. Senator, can you hear me?

Senator DODD. Yes, I can now.

Dr. BESSER. Very good. Senator, let me take this issue back to our colleagues at BARDA and ask them to give a direct response on that.

Senator DODD. I appreciate that. Again, I apologize. It is parochial but it is larger than that. It is a company that claims with minor variations they could produce a product in 5 or 6 weeks at 30,000 doses a week that would address this particular issue.

Dr. Fauci.

Dr. FAUCI. We will do what Dr. Besser said and bring it back to BARDA.

I am familiar with the company. They have been interacting and having scientific discussions with us at the NIH. I am familiar with the product, and we will bring it to the attention of BARDA.

Senator DODD. Is there any reason to be encouraged by what they are doing?

Dr. FAUCI. It is a very interesting approach. It is a recombinant process where instead of getting the whole virus itself and trying to make a vaccine from the whole virus, they take very specific components and in a recombinant DNA fashion make the two important components of a vaccine, the H and the N. So I am familiar with the work. It is very interesting work.

Senator DODD. Thank you very much. Thank you, both. Thank you, Mr. Chairman.

Senator BROWN. Thank you, Senator Dodd.

Senator McCain is recognized.

STATEMENT OF SENATOR MCCAIN

Senator MCCAIN. Thank you, Mr. Chairman.

Dr. Fauci and Dr. Besser, is there enough day-to-day data to show that H1N1 influenza is slowing or accelerating?

Dr. FAUCI. I will leave that to Dr. Besser since the CDC is tracking it. Rich?

Dr. BESSER. Thank you, Senator. At this point, it is very difficult to say. What we are looking at is an increased number of cases from day to day. Whenever you start an outbreak investigation, you are going to see additional cases from the process of doing surveillance and looking. The early cases that we were seeing were not very severe infection, and if we had not increased surveillance and asked people to be looking for these cases, these would not come to the attention frequently of their physicians or to public health.

It is too early to say where we are, whether this is ramping up greatly. It is our feeling that there is increased spread in this country and that there are increasing cases, but it is too soon to say what that really looks like. Each day we are reporting our cases and we are trying to do it at the same time to avoid some of the confusion around case numbers that frequently occurs.

Similarly, in Mexico, it is very difficult to get a handle on the rate of cases and whether they are increasing, staying the same, or starting to decline.

Senator MCCAIN. There is no doubt in either one of your minds that this originated in Mexico. Right?

Dr. BESSER. I could not hear that question.

Senator MCCAIN. That H1N1 originated in Mexico, and that the recorded cases—many of them in the United States—in fact, the first recorded death tragically was an infant that was from Mexico and came to Texas. Right?

Dr. BESSER. Yes, sir. The first case had traveled from Mexico.

Senator MCCAIN. Have we considered, if the influenza continues to increase in intensity, the option of closing our borders?

Dr. BESSER. As we have been doing our planning for pandemic preparedness—and there has been much planning going on over the past 5 years or more—the initial strategy, in particular, for bird flu, was to try and identify the first cases outside of our borders and to swoop in, as part of an international team, to try and quench this, to try and treat the initial cases and contacts and limit the spread so it would not leave where it was occurring.

If it started to spread from there, we had a strategy of trying to keep it or delay the entry from our borders. Modeling data showed us that if we were able to implement some pretty strict entry screening, we might be able to delay the entrance into our country for a few weeks to allow us to prepare so that we would be ready to take care of patients that we would see on our borders.

We have also learned from the modelers and from experts who have dealt with SARS during the large SARS outbreak——

Senator MCCAIN. Doctor, I do not mean to interrupt. I do not mean to interrupt, but I have a question.

Dr. BESSER [continuing]. Primary borders and is spreading from country to country. There is very little value in intensifying border

screening. It is a major use of resources that could be used in much more productive control efforts.

In my discussions with the Director-General of the World Health Organization, Dr. Margaret Chan, she led the response to SARS in Hong Kong, and there they put in place intensive efforts. Her recommendation to me and her recommendation to the global community from engaging with the experts in influenza is that that was not a productive effort during SARS, that cases were not identified in that way, and that control efforts could be directed in ways that would be much more likely to be productive.

Senator MCCAIN. Yet, countries like Singapore and others are screening people aggressively for people with fever and others. Is there a scenario that you can see where this influenza reached a point where we would be required to close the border with Mexico?

Dr. BESSER. Senator, Singapore is, in a sense, how we would have been had this arisen in Singapore. We might be looking to see if we could screen and delay the entry of cases from Singapore into our shores. I would envision that Singapore does not expect that they are going to be able to keep this out of Singapore, but if they can delay, they can be more prepared and be able to manage the situation better.

There are times at which we would look at using border entry as a way of looking for containing infections and delaying entry into our shores. This would be the case if we had a novel strain or a novel type of infectious disease that was originating outside our borders to allow us time for that preparation.

At this point, we have this virus spreading across our country, and what it appears to be is spreading from person to person without a lot of difficulty, largely with an infection that is not very severe. The ability to control that by using a border strategy would not be effective.

Senator MCCAIN. I thank you. Thank you, Mr. Chairman. Thank you for your good work.

Senator BROWN. Thank you, Senator McCain.

Senator Casey is recognized.

STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you very much for chairing this hearing.

Dr. Besser and Dr. Fauci, we are grateful for your work, your presence here, your testimony, and for your work going back many years.

I wanted to focus on two or three areas, but certainly two. One is capacity and the other is with regard to children.

First, on the capacity question—and this is a tough question because I am sure you do not have time to do a full-blown survey of this, but just in terms of capacity state-by-state or looking at the States as a whole, do you see any shortfall or any deficiency with regard to what States can do in two areas? One is just in hospital capacity or bed capacity, and the other is in terms of any kind of antiviral drugs or any other medical capacity. Can either of you give us a sense of that? I know it may be redundant, but I think it is important to emphasize.

Dr. FAUCI. I think Dr. Besser in his interaction with the States and the territorials would be better to answer that.

Richard.

Dr. BESSER. Thank you, Dr. Fauci, and thank you for that question, Senator.

In terms of State capacity, there is variability. There is, I would say, dramatic variability. If you look at the investments that States put into public health, there is dramatic variability. There will be States that require more assistance than others. There are States that are really providing direction for other States. We have built an ability for States to provide direct state-to-state support for response.

In the area of hospital capacity, there has been study after study coming out of the Institute of Medicine that has been showing that we have very little in the way of excess capacity in our systems, whether we are looking at our emergency rooms or we are looking at bed capacity. There is a lot of working being done much by ASPR, the Office of the Assistant Secretary for Preparedness and Response, work done by the Agency for Health Care Research and Quality to provide guidance around how would you do medical surge capacity, looking at appropriate standards of care should your regular capacity be outstretched. That will be helpful. Should this turn into a strain that was much more severe and requiring more intensive hospital care, our hospital capacity is not very great.

In terms of antivirals, we see a similar situation. We report out each year or every other year on States' capacity to receive and distribute and dispense antiviral medication, and you will see, if you look at that report, a variation in terms of the score. Some of that represents differentials again by investment within those States so that some States are relying almost exclusively on Federal dollars, but some of it is that not all States put the same attention to the issues of preparedness and response. We have seen issues of complacency. It has been 3½ years since our country suffered the devastating impact of Hurricane Katrina, and in many areas we see complacency. So there is a difference.

There are differences in States' abilities to purchase antivirals, and so you will see that there was differential utilization of the Federal contract to have purchased Tamiflu. We are nowhere near taxing our reserves of Tamiflu, but we will find that some States will be exclusively relying on the Federal stockpile and other States will have their own stockpiles as well.

Senator CASEY. Well, thank goodness we are not being fully tested yet in terms of capacity, but I know it is something we are concerned about for the near-term and the long-term.

Second, with regard to children, we hope what we will see in the next couple of days and weeks is that children are not disproportionately adversely impacted. We know now that the first fatality was, I guess, a 23-month-old.

What can you tell us about the approach we have to take with regard to children, understanding that they are not just smaller versions of adults? We hear that a lot in our health care debates. Is there a particular strategy we need to be focused on with regard

to children in terms of the threat posed by this flu, or is there not? Is there no difference in how we approach it? Doctor?

Dr. FAUCI. Dr. Besser is a pediatrician. So we will ask him that question.

Dr. BESSER. Thank you, Senator. Thank you, Dr. Fauci.

As a pediatrician and as a parent of two young children, this is something I think about all the time. Your words about children not being small adults resonate. Frequently when it comes to drug development, they are treated like small adults, and so we do not see licensed products for children in the same way that we see them for adults. There are many gaps in that regard. We are forced, in a time of emergency, to use emergency authorization to utilize drugs that are only licensed for adults—to use those in children. So that is a gap in our preparedness.

There is a major gap in terms of our capacity should we see increased impact on the health of children and an increased need for hospitalization.

This is an important area. The American Academy of Pediatrics has a disaster preparedness committee that is focusing on these issues and trying to draw more attention to them. I think that this is an area that definitely requires additional attention.

Senator CASEY. Thank you very much to both of you. Thank you for your work.

Senator BROWN. Thank you, Senator Casey.

Senator Roberts is recognized.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Thank you very much, Mr. Chairman. Thanks to Dr. Fauci and to Dr. Besser.

We are holding a hearing today to discuss the current H1N1 flu situation. I want to emphasize the H1N1 designation as opposed to what some call the swine flu. I was instructed not even to say that, let alone point it out.

I would like to say that this committee has done much to help better prepare us for a response to an outbreak of this or any other virus. One of the efforts I am most proud of is the legislation that I introduced with Secretary of State Clinton when she was a Senator from the State of New York. We introduced the Influenza Vaccine Security Act, portions of which were included in the overall Pandemic and All-Hazards Preparedness Act. That is a mouthful, but it was signed into law in December 2006. Those provisions that were signed into law should really help us prepare for any vaccine development distribution and tracking that may well occur due to this virus.

We have also taken important actions on this committee through the Bioterrorism Preparedness Act reauthorization and through general oversight to ensure that these agencies involved are better prepared.

I do have to say, I am just not pleased with the 24-hour news cycle on this issue. We should not unnecessarily be creating fear among the American public and some of our trading partners. If you watch the newscasts on this issue, you would think in some cases a pandemic was already occurring. That simply is not the case. Bottom line: The American people need to be aware and able

to protect themselves from the H1N1 virus, but I do not think we need to scare or terrify the public.

Since we are talking about the media, I also want to point out what I said earlier, that I represent a State that is a major agriculture producer. Every time some reporter or some politician calls this the swine flu, they are doing a disservice to the agriculture producers in Kansas and also throughout the Nation. Let us call it what it is, H1N1 virus, and quit trying to blame it on farmers and ranchers and current production practices. These claims just do not hold water.

A very clear example, Mr. Chairman, of this is Egypt's decision to cull their entire swine herd despite any indication of this virus in their swine or human population. There is no evidence of the existence of this virus in the U.S. swine herd—zero—backed up by the World Organization for Animal Health. Our swine herd and pork products are safe, and I encourage everyone here, including both doctors, to enjoy two strips of bacon tomorrow with your breakfast.

Finally, Mr. Chairman, the emergence of this new virus further demonstrates our need. I know Dr. Besser talked about complacency. We also need to be prepared to react to disease outbreaks and undertake the necessary research that allows us to stay one step ahead of them.

On this front, the Department of Homeland Security announced in January that it intends to build a new National Bio and Agro-Defense Facility—the acronym for that, by the way, is NBAF—in Manhattan, KS. This facility will do research on existing and emerging diseases. It is the kind of research that we need to protect the American people, and our DHS Secretary has said it is a top priority. And it is. I will be urging our colleagues to support funding—let me repeat that—to support funding—for the construction of this facility so that we can move forward on this important research.

I thank the chair.

Dr. FAUCI. Thank you, Senator Roberts, for those comments. They are very well taken. And the name that is now being used, as you pointed out, is 2009 H1N1 flu. It is important to say 2009 because we do not want people to get confused with the H1N1 that is a seasonal flu. Your point about calling it swine flu is very, very well taken, and as Dr. Besser pointed out in his opening statement, there is no danger in eating pork to get this particular virus. It would not be appropriate to call it swine flu.

Senator ROBERTS. Well, just have a pork chop as well.

[Laughter.]

I would point out that we have the regular flu every season. Everybody gets a flu shot. Unfortunately, people get sick and some meet very untimely deaths. This is a different thing, but we are approaching it in a different way and it should be labeled correctly. And I appreciate your comments, sir.

Senator BROWN. Thank you, Senator Roberts.

CNN just reported that the World Health Organization just raised the alert level from 4 to 5. What might that mean, Dr. Fauci?

Dr. FAUCI. I will give you my quick comment, and then turn it over to Dr. Besser.

It is very likely related to the fact of the increased evidence of spread in different places. If you look at the categorization of the levels, that is the level you go to when you get a more enhanced spread.

I will have Dr. Besser comment more on that.

Senator BROWN. Anything briefly you want to add, Dr. Besser?

Dr. BESSER. Yes, thank you. Two comments. That indicates a recognition of community outbreaks. That is the difference between phase 4 and phase 5. The important thing for us to recognize here as Americans is that the label does not matter. It is what we do, and our actions are driven by what is taking place here in this country, in our communities. The recognition of 4 to 5 is of more relevance to countries around the world, especially less-developed countries that have not been able to prepare in the way that the wealthier countries have been able to get ready. I do see that as major should this virus spread to countries with less resources.

Senator BROWN. Thank you.

Senator Reed is recognized.

STATEMENT OF SENATOR REED

Senator REED. Thank you very much, Mr. Chairman.

Dr. Fauci and Dr. Besser, thank you for your excellent work.

Let me raise an issue which may already have been addressed. I will either make a point or reaffirm a point, and that is that at the local level the capacity with personnel, with resources to do what we all know has to be done, even if they receive adequate Tamiflu or other clinical support, is not going to be there. I spoke to Dr. David Gifford, our health director in Rhode Island, today and his major concern is that even with additional Federal spending, there will not be the resources at the local level to hire the personnel, the nurses, the 24-hour hotlines, etc. If I am repeating some of my colleagues, I apologize, but your comments would be appreciated.

Dr. FAUCI. We will ask Dr. Besser to answer that. We did discuss it just a bit ago, but I am sure he will be able to quickly summarize it for you.

Senator REED. Thank you.

Dr. BESSER. There is excellent data from the Trust for America's Health looking at the impact currently of the economic downturn on State and local public health capacity. It is very concerning. We discussed that without strong State and local public health, it is impossible to respond to emerging threats such as the one we are currently facing.

Senator REED. Thank you very much. Again, I think your comments suggest to us that we have to target resources not only to vaccine research and to other clinical approaches, but to some of the more mundane operational approaches of people and hotline operators, etc.

Dr. Fauci, let me ask a question. We are in the process, I believe, of preparing a vaccine. I have heard estimates of taking up to 16-plus weeks to get it online. Would that vaccine be simply dedicated to the H1N1 flu, or would it try to anticipate the seasonal flu? If

that is the case, do you have strategy of one that is better than the other, or how will you proceed?

Dr. FAUCI. Right now, we are in very active discussions of how we are going to in parallel—if we could possibly not interrupt what we do with the seasonal flu, as well as on a parallel track, get what we call a monovalent, or a single individual vaccine for this 2009 H1N1 strain.

Senator Reed, I want to make sure that there is not a misunderstanding because you used the words "16 weeks." Let me clarify that, because there is a process that is staged in how you develop a vaccine. The first thing that is going on right now is that the CDC has isolated the virus and made it available for a reference strain, of which you then get what we call a seed virus to grow up to get a pilot lot to begin to test the vaccine for the right dose, the safety, whether it induces an immune response. The couple-of-month process that that generally takes is not having a lot of vaccine at your disposal to distribute. The process of vaccine development really started right from the point that the CDC isolated that virus.

Senator REED. Well, I think that is an important point to make, Dr. Fauci. I do not want either of us to leave here with the suggestion that in X number of weeks we will have a vaccine for everyone who needs it.

Dr. FAUCI. Exactly. That is a very good point.

Senator REED. Thank you, Dr. Fauci.

Let me go back also to the issue that Senator Casey raised about children and with respect to immunization and vaccine. Are you going to target—or is part of your strategy to target certain groups to receive this H1N1 vaccine, or is it going to be available, have you thought about, across the board?

Dr. FAUCI. I will answer part of it and then give the rest to Dr. Besser.

Again, with your permission, Senator Reed, I want to emphasize the difference between the process of developing a vaccine and administering a vaccine. It is very, very important. There is no talk about administering. We are in the process of trying to get it online.

With regard to the various categories of who you give it to, I will yield that to Dr. Besser.

Dr. BESSER. Thanks, Dr. Fauci.

That is a very important question, who should get a vaccine? As we have been doing pandemic planning for avian flu, we have had discussions around who should get an avian flu vaccine when that is available.

In the scenario that Dr. Fauci is talking about in terms of the process for manufacturing a vaccine, there is a period of time there that allows for real community engagement so that the public can be involved in the discussions around that. In 1976, we all remember the issues around swine flu vaccine, and we do not want to repeat that. We want to make sure that there is engagement with the broader public in this decision. There are issues around who is at most risk of dying or having adverse events from this flu that we do not have the answers to. That information will be very useful in defining the risk groups for this particular infection. Apart

from the science, which can say who is at risk, there is a societal decision that would need to be made. There is a policy decision, and clearly, we would want to engage broadly in that process.

Senator REED. Thank you all, gentlemen. Thank you, Dr. Fauci. Dr. Besser, thank you.

Senator BROWN. Thank you, Senator Reed.

Senator Merkley is recognized.

STATEMENT OF SENATOR MERKLEY

Senator MERKLEY. Thank you much, Mr. Chair.

I wanted to step back a moment because I keep seeing in the testimony and other places that each year in America on average 10,000 to 30,000 individuals die of influenza. What is it about this particular strain, as it appeared and developed, that creates so much attention? I mean each year we have many different strains appear. Many deaths result. It is, obviously, a concern for all of us that we work on steadfast. This particular strain has leapt into the public mind in a spectacular way. We are all very concerned, but I want to understand how it differentiates from the many mutations that occur annually and appear in our population.

Dr. FAUCI. When we think in terms of seasonal flu, what it generally does from year to year is it drifts a little. That is the word we use. There are mutations that it changes a bit from year to year, which generally necessitates what you see each year of a modification of the vaccine that we annually administer on a seasonal basis.

When a virus changes a bit, it is fundamentally the same virus with a little bit of differences. Generally what we see are H3N2's, H1N1's or B. This virus is an entirely new virus that we have never seen before. There has been what we call re-assortment of the genes. It has viral genes from a swine, viral genes from human viruses, and viral genes from a bird. It has the potential of a pandemic. We have never seen it before. There is no background immunity in society against that, and it has the potential to cause widespread disease. That is the difference between this virus and a virus that might change just a little bit from season to season.

Senator MERKLEY. Does the makeup of the genetic code of the virus give us some clues as to how it may have come to be?

Dr. FAUCI. At this point, no. What we do know is that when you have these re-assortants—they are called re-assortants because the genes sort of rearrange themselves and join together. This is very unusual because, one, it is a re-assortant, but it is also what is called a triple re-assortment. The molecular analysis has not yet given us a clue of how or why that happened.

Having said that, I will have Dr. Besser comment because the CDC was absolutely wonderful in how quickly they got on top of this virus. So I will leave the other comments.

Dr. BESSER. Thank you, Dr. Fauci.

I do not have much to add on that, but I do want to comment on why people are so much more worried about this virus and this situation. A number of things.

First, the comment about 36,000 flu deaths a year. I think that is tragic, and I think that a large proportion of those are preventable. And if people had the same concern looking at seasonal flu

as we have today about the emergence of this new strain with pandemic potential, tens of thousands of lives could be saved.

Right now, we are faced with a period of uncertainty, and people have fear. Many people in their minds think back to what they have read and seen about 1918, and that is driving some of that fear. Some of the comments around fear being paralyzing, we do not want this to be driven by fear. We want to inform people. We want people to be concerned, and we want to change that concern into preparedness and action.

The virus that has been isolated contains four parts, and as Dr. Fauci said, it has components from many different viruses that have been seen elsewhere, including a fourth component that came from Eurasian swine flu.

We are going to continue to share the strains of virus. The network that NIH has, the research community, is the place where we will continue to learn more about this and learn more about how do these viruses arise. Is there any way in which we can prevent that from occurring in the first place? Is there any potential for a vaccine that would take care of the entire flu problem? That is where our biomedical research is so critically important.

Senator MERKLEY. Dr. Besser, you mentioned that if we had a high level of attention to influenza in general, we could have a huge impact on the tragic loss of 36,000 lives a year. Do you have some specific thoughts about additional work we should do to take on that influenza challenge?

Dr. BESSER. Thank you for that question.

Some of it has to do with behavioral change, and the measures that we are promoting right now, the measures of hand-washing, the measures of personal responsibility when you are sick of doing what you can to not make other people ill. I know many schools give an award to children who do not miss a day the entire year. I think of that as the Typhoid Mary Award because what it encourages is children to go to school when they are sick, and they get a certificate for it.

I think we need to encourage the exact opposite behavior and make it possible for people to go to work if their child is sick and know that their child will be well cared for. For many people, they do not have that choice. If they keep their child home, that means they are not going to work and they are not getting paid. There are things we need to do as a society to promote and support responsible behavior. There are things individuals need to do as well, and we need to learn how do you get people to view the issue of transmission of a respiratory infection in the workplace in the same way we currently view exposure to passive smoke.

Senator MERKLEY. I thank you both for your expertise and for your attention to helping us address this issue. Thank you.

Senator BROWN. Thank you, Senator Merkley.

Senator Burr has a last couple of questions, but I want to follow up on Senator Merkley's question, the Typhoid Mary Award from the Centers for Disease Control notwithstanding, because I thought that was exactly the right question to ask. You made the statement that if we showed the same vigilance and attention annually for the seasonal flu as we are showing for the 2009 H1N1, we would save tens of thousands of lives. I totally support and agree on

hand-washing and some of the other things you said, personal responsibility.

Are there structural things that the public health system should be doing differently, more thoroughly to pre-empt, to prevent some of these more regular, if you will, seasonal flu deaths?

Dr. BESSER. There have been efforts taken in terms of looking at vaccine recommendations. There has been in many circles a demonization of immunizations, and in order to address annual flu, it requires annual immunization. Our infrastructure for administering an annual shot is not as good as it is for, say, school immunization where there is an entry point that you can ensure that every child has been immunized before they start school. We do not really have that mechanism for annual flu vaccination.

I think we need to think creatively about that, how seriously do we feel this problem should be addressed, and what should be done in terms of requiring people to take measures to prevent influenza each year.

Senator BROWN. Could I ask you and Dr. Besser—I assume you have done some of this, but would you put together for this committee and share it with me personally and anybody on the committee. We will start with the committee—your thoughts for future years on how to—just thinking, focused on putting aside this potential public health problem right now, but for future years about how, in terms of both infrastructure—and infrastructure meaning CDC, local public health departments, all that—and in terms of personal responsibility what we should do in the future to better deal with these 36,000—30,000-some deaths every year, if we can reduce those numbers and how we would do it, and put together a document for us that this committee might be able to use in a preventive way in the future?

Dr. BESSER. We would be glad to, Senator.

Senator BROWN. Good. Thank you.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

I do not want to speak for Dr. Besser. I think it starts with making sure that the vaccination program for the seasonal flu is much more productive from the standpoint of the American people's willingness to participate at all ages. I think that when you look at the level of participation and then the infrastructure that it requires to be in vaccine production in this country, you understand why several years ago we started in a big hole with Dr. Fauci's efforts to try to regenerate a vaccine research business, much less the vaccine production side of this. I look forward at another time, Dr. Fauci, to talking with you in depth about some of the multipurpose manufacturing facilities that we can construct that give us the ability in short order to produce the type of vaccines from the standpoint of quantity that we are going to need for a true pandemic or other potential threats.

Any concern, Tony, that you have that the cultivation through egg-based production might not work? Is that our focus as to how we would cultivate?

Dr. FAUCI. Yes. Right now, a part of the planning process, you know, a substantial amount, will be through the classic, tried, true, and used egg cultivations. There are companies, as you know,

through the efforts that you and others and your colleagues put in to get these programs going, that are trying to push the envelope and convert ultimately to a cell-based. There will be a substantial amount of egg-based involved.

I always have concern. The field of vaccinology, although it does great things, is somewhat fragile in the sense of things can go wrong and there are land mines. When you do try to grow up vaccines, most of the time you are very successful and it is very reliable, but there could be some glitches. I do not anticipate that there will be. I think the critical issue that we will be facing with the development of a vaccine is how well and quickly it grows. If it grows well when we make those seeds and grow them up, then I think we will be in relatively good shape.

Senator BURR. Can I assume that the course of treatment will be designed for one vaccination shot?

Dr. FAUCI. Well, no. We do not know that. That is a very important point, Senator. The question is, is it going to be one or two shots, and that is why we are doing those trials of what the right dosage and the dose regimen is. When you get a vaccine for a virus to which you have had no prior exposure, not infrequently you need to do more than one dose, two doses as a possibility. We see that sometimes with children because they have never had the kind of exposure or experience that we as adults have had with influenza. There is certainly possibility, if not likelihood, that there will be more than one dose.

Senator BURR. It makes it quite challenging——

Dr. FAUCI. It does. Indeed, it does.

Senator BURR [continuing]. From the standpoint of the number of eggs.

Dr. FAUCI. Right.

Senator BURR. The last thing, and I would ask this to both you and Dr. Besser. Let us assume for a minute that the strain does go dormant this summer at some point. How do we plan for next fall, and given that the flu strains are so unpredictable, are there any additional needs that NIH has from Congress or CDC has from Congress as it relates to next fall's preparation that we need to begin to talk about now?

Dr. FAUCI. We will definitely be coming back to you. The leadership at HHS has been fully now briefed on all of these issues that will come up, and we are in very active discussions about those things. Regarding next fall, I will kick it over to Dr. Besser.

One of the things that is going to be interesting is what happens in the southern hemisphere over the summer because that often—you know, if you make the assumption that it is going to go low for a while, what is going to happen on the other side of the globe in predicting what might ultimately happen.

I will have Dr. Besser comment about that.

Senator BURR. Before we go to Dr. Besser, just for the purposes of all of us, it is possible that you could have a mutation over our summer and potentially have a different strain in the fall and we plan for the original vaccine strain?

Dr. FAUCI. There is always that possibility. What impact it would have on the vaccine versus things like virulence and ability to spread is not predictable. Any of those combinations could occur.

Obviously, with influenza, which is a very mutable type virus, there is always the potential of that happening. That could happen in a way that does not necessarily impact the vaccine but impacts spread and virulence.

Also, I would like Dr. Besser to have the opportunity to comment on that.

Senator BURR. Dr. Besser.

Dr. BESSER. Thank you, Dr. Fauci. [audio interference] and your comment about the southern hemisphere is very important. [audio interference] relationships with many things with many [audio interference] in the southern hemisphere [audio interference] surveillance [audio interference] are there changes that are being seen. During the summer, there would need to be very important discussions and policy decisions around, do we move forward. In discussions so far, the issues of could the virus just go away, fizzle out, that is possible. Could it go away and come back stronger, as was seen in 1918? That is also possible. We will most likely be in a situation [audio interference] dealing with infectious diseases and emerging infectious diseases in particular.

Senator BURR. Mr. Chairman, let me take this opportunity to thank both doctors for not only their willingness to be here today, but the expertise that they bring to the country and to our public health infrastructure. It is absolutely essential that we do everything we can to provide them with the tools to do what they do and for us not to substitute ourselves for them. I think Senator Mikulski made probably the most important statement at the beginning. Let us put ourselves in a position where we are rewarded because of how well we planned, not our ability to respond to an emergency. I think this is one time we will get our money's worth if in fact, we do that planning.

Thank you both.

Senator BROWN. Thank you, Senator Burr.

One last question probably for Dr. Besser. Would you just tell us what are the signs and symptoms of the 2009 H1N1 virus, what people should look for, and what they should do if they see any symptoms?

Dr. BESSER. Thank you, Senator.

The symptoms of the 2009 H1N1 virus are no different than seasonal flu. We wish that there was a telltale sign that we could say to people. Individuals would look for fever. They would look for malaise, fatigue, body aches, respiratory symptoms such as cough. They may have some intestinal symptoms, some nausea, some diarrhea. Individuals who have those symptoms who have traveled to Mexico are in a much higher likelihood group for having this new strain of flu. Individuals who have flu-like symptoms and have underlying medical conditions should see their doctors or contact their doctors and see whether they should come in to be seen. Other individuals who have mild infection who have been in contact with diagnosed cases should as well contact their doctors in terms of management. There is no telltale symptom. It is the symptoms that we look for each year during the flu season.

Senator BROWN. Thank you, Dr. Besser. Thank you for joining us. Thank you for your public service.

Dr. Fauci, thank you again for joining us and for your public service.

This hearing certainly again underscores the importance of a good public health infrastructure, which we are all working toward. I thank you all for your involvement and your good work on public health. This committee stands ready to work with the Administration in dealing with this.

The committee is adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

RESPONSE BY RICHARD E. BESSER, M.D. AND ANTHONY FAUCI, M.D. TO QUESTIONS OF SENATOR KENNEDY, SENATOR ENZI, AND SENATOR MURRAY

QUESTION OF SENATOR KENNEDY

Current CDC guidelines recommend that healthcare workers use fit-tested N95 respirators when treating patients infected (or potentially infected) with the H1N1 influenza in order to protect against respirable exposure. We understand that some in the infection control community have been urging CDC to change its recommendation to provide for droplet precautions, instead of airborne transmission precautions, and to recommend the use of surgical masks instead of N95 respirators by healthcare workers who come into close contact with patients. Both NIOSH and OSHA, the two agencies primarily responsible for workplace safety, have strongly supported at least the need for N95 respirator use by health care workers.

Question 1. Is CDC actively considering changing its recommendations for the protection of health care workers involved in the care of patients who are suspected or confirmed to have the H1N1 virus? Can you assure the committee that CDC will consult closely with OSHA, NIOSH and representatives of workers before any changes are made to the recommendations for protecting health care workers from the H1N1 virus?

Answer 1. When the novel influenza A (H1N1) outbreak began, CDC issued "Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting," which recommended that "All health care personnel who enter the rooms of patients in isolation with confirmed, suspected, or probable novel H1N1 influenza should wear a fit-tested disposable N95 respirator or higher. Respiratory protection should be donned when entering a patient's room." The interim guidance noted that "this recommendation differs from current infection control guidance for seasonal influenza, which recommends that healthcare personnel wear surgical masks for patient care. The rationale for the use of respiratory protection is that a more conservative approach is needed until more is known about the specific transmission characteristics of this new virus."

CDC is continually evaluating our guidance as we learn more about this virus, and we will provide updates to our guidance as appropriate based on the best available science. Staff from across CDC—including NIOSH staff—were involved in drafting the interim guidance relating to protecting health care workers, which was issued early in this outbreak, and they have been involved in evaluating this guidance as we have learned more about the virus. CDC has and will continue to communicate with OSHA and labor unions regarding this guidance.

QUESTIONS OF SENATOR ENZI

Question 1. Dr. Fauci, there are concerns regarding our capabilities to produce enough vaccines if this flu outbreak becomes a pandemic. Has the NIH prioritized funding for vaccine research that explores new cell-based technologies rather than egg-based technologies that would allow us to "scale up production" or more quickly manufacture a greater volume of vaccine?

Answer 1. The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), supports and conducts research on the development of new and improved influenza vaccines (including the use of cell-based technologies), and basic immunology research that underpins all vaccine research and development.

Although egg-based manufacturing methods have been used successfully for more than 40 years, they are logistically complex and can lead to delays if the vaccine strain of influenza virus will not grow efficiently. Furthermore, egg-based production cannot be rapidly expanded to meet the expected demand that a pandemic event will generate. To address these concerns, NIAID continues to conduct research that will help to increase U.S.-based pandemic influenza vaccine production capacity, and lead to the further development of new vaccines and manufacturing methods that are faster and more flexible for influenza vaccine production. While NIAID supports basic and applied research toward cell-based influenza vaccine production, the Department of Health and Human Services, through the Biomedical Advanced Research and Development Authority (BARDA), now leads efforts to advance cell-based influenza vaccine production as a viable alternative to egg-based techniques.

NIAID also supports innovative research on new methods that could allow for "scale up" production, or "stretch" the existing supply of influenza vaccines. These methods include recombinant DNA technologies that yield subunit vaccines, in

which influenza virus proteins are produced in cultured cells and used in a vaccine; DNA vaccines, in which harmless influenza genetic sequences are injected into an individual to stimulate an immune response against influenza proteins; and approaches that use harmless transport viruses to deliver influenza virus proteins via an injection and stimulate an immune response. While these candidate vaccines and approaches have not yet reached the licensing stage, they hold promise as novel methods for controlling influenza in the future.

In addition, NIAID supports basic and translational research to develop new and improved adjuvants. An adjuvant is a substance that augments or boosts a vaccine's effectiveness so that less vaccine is needed to produce an immune response. Results from NIAID-supported clinical trials of avian influenza vaccine candidates indicate that one promising adjuvant increased the immune response and could significantly decrease the amount of antigen required for each dose and expand the total supply of this vaccine. NIAID is considering clinical evaluations of this adjuvant in a 2009–H1N1 vaccine candidate. Several other promising adjuvants also are currently under development. These novel adjuvants are still in the testing phase and are not currently licensed in the United States.

While studies to develop prototype 2009–H1N1 influenza vaccines that rely on experimental strategies hold promise, such "next-generation" vaccines will require additional safety and efficacy testing before they can be deployed. Since the candidate vaccines and adjuvants described above are not yet at the licensing stage, they are unlikely to reach the public before more traditional types of vaccines become available for the 2009–H1N1 influenza virus. Because of the urgency of addressing influenza outbreaks and preparing for possible pandemics, it is crucial to advance traditional vaccinology as well as to support basic and applied research on innovative vaccine strategies. NIH and NIAID are committed to this two-pronged approach to be as well-prepared as possible to respond to urgent public health needs.

Question 2. Dr. Fauci, has the NIH invested in new technologies that will result in therapies for flu that are not susceptible to drug resistance?

Answer 2. Antiviral medications are an important counterpart to vaccines as a means of controlling influenza, treating infection after it occurs and, under certain circumstances, preventing infection prior to or immediately after exposure. Although the 2009–H1N1 virus is currently sensitive to oseltamivir (Tamiflu®) and zanamivir (Relenza®), it is important to recognize that resistance to influenza antiviral medications frequently emerges. In fact, over the past 2 years, the circulating seasonal H1N1 influenza viruses have become oseltamivir-resistant, even while other influenza viruses have remained sensitive to the drug.

NIH has been working to develop and test the next generation of influenza antivirals. Three new drugs are now in clinical testing: a long-acting neuraminidase inhibitor; an inhibitor of the enzyme that replicates viral genes; and a drug that prevents the virus from entering human lung cells. NIH soon will evaluate how well these candidate antiviral drugs block the 2009–H1N1 strain. If they are determined by FDA to be safe and effective, these antiviral drugs will increase the arsenal of approved therapeutics available to physicians, expanding our options against influenza strains that are resistant to currently available drugs. NIH also is screening numerous additional compounds for activity against influenza, including the current H1N1 strain.

NIH also supports an extensive research portfolio on human immunology. This research focus represents an important strategy for tackling drug resistance, as the ability to prevent or reduce infection by enhancing the body's immune response has the potential to improve outcomes and reduce disease burden even if a pathogen is drug resistant.

Question 3. The National Strategy for Pandemic Influenza designates the U.S. Department of Health and Human Services as the leading agency for pandemic preparedness. Is it also the leading agency for response? There have been multiple reports from several agencies. If this becomes a pandemic, will we have a central command? Who is in charge?

Answer 3. As stated in the National Response Framework, HSPD–5, and other guiding documents, the Secretary of Homeland Security would serve as the leader of the Federal response. The Department of Homeland Security (DHS) through the Federal Emergency Management Agency (FEMA) is responsible for the coordination of the overall Federal response during an influenza pandemic, including development of a common operating picture for all Federal Departments and Agencies, and ensuring the integrity of the Nation's infrastructure, domestic preparedness and response capabilities, domestic security and entry and exit screening for influenza at the borders. DHS will work closely with all Federal partners, including the Depart-

ment of Health and Human Services (HHS), that have responsibilities in preparing for and responding to a pandemic.

Each Federal Department is responsible for coordination of pandemic influenza response efforts within its authorized mission under the National Response Framework and its own agency authorities. Lead departments have been identified for the public health and medical response (HHS), international activities (Department of State) and the overall domestic incident management and Federal coordination (DHS/FEMA).

The Secretary of Health and Human Services will fulfill the major responsibility of overseeing the public health and medical response during a pandemic under section 2801 of the Public Health Service Act and under Emergency Support Function (ESF)–8, including coordination of domestic disease containment and control activities. Among other responsibilities, HHS will lead the procurement, stockpiling, deployment and distribution of vaccines, antiviral drugs and other life-saving medical countermeasures from the Strategic National Stockpile and coordinate the use of Federal public health and medical personnel.

There is close cooperation between the DHS Principal Federal Officials for Pandemic Influenza and the HHS Senior Health Officials for Pandemic Influenza in this lead role. In support of domestic incident management during a pandemic, DHS has organized the Nation into five pandemic influenza regions (Regions A through E) and the DHS Secretary has pre-designated one National Pandemic Influenza Principal Federal Official (PI PFO) and five Regional PI PFOs for each of the five pandemic regions. In support of this DHS structure, the HHS Secretary has pre-identified one National and five Regional Pandemic Influenza (PI) Senior Health Officials (SHO) to lead and guide HHS support to States during an influenza pandemic and to support the DHS PI PFO Team with public health and medical expertise in preparation for and during an influenza pandemic. These are senior departmental officials including Public Health Service (PHS) Flag Officers who are dedicated to the response. During a pandemic, HHS PI Senior Health Officials will deploy to the five Pandemic Regions to support the DHS PFOs with public health and medical expertise, to coordinate HHS strategic decisionmaking and provide liaison between the PFO and HHS activities and assets deployed in the region. We convene a monthly teleconference meeting and a quarterly in-person meeting in Washington, DC, and also conduct joint training and exercises to coordinate activities in this leadership role.

On a regional level, the HHS Regional Health Administrators, often with their DHS colleagues, lead regular regional meetings and exercises with the State health directors and State, local and tribal emergency preparedness personnel as well as continuing engagement with the National Governor's Association pandemic influenza exercises.

Question 4. Is the Public Health and Social Services Emergency Fund adequately funded to respond to the threat of a flu pandemic?

Answer 4. On April 30, 2009, the Administration submitted a proposal requesting $1.5 billion in supplemental appropriations for H1N1 response and preparedness activities. On June 2, 2009, the Administration submitted an additional and contingent request for additional resources to prepare the Nation in the event of a potential H1N1 influenza pandemic. On June 25, 2009, Congress appropriated $7.65 billion to HHS for pandemic influenza preparedness and response in an fiscal year 2009 supplemental to respond to the novel H1N1 influenza pandemic. In addition to the immediate H1N1 response, this funding allows HHS to prepare for the potential future outbreaks or emergence of a new flu strain and provides additional funding in the event of an escalation of the H1N1 virus or other influenza strain. The funding includes $200 million for the Centers for Disease Control and Prevention (CDC) and $350 million to support State and local activities.

The FY 2010 Budget builds on the supplemental request with another $584 million for HHS, including $276 million in no-year funds and $308 million in annual appropriations. The no-year funds requested for fiscal year 2010 will go toward the Department's continuing efforts to prepare for future outbreaks by supporting ongoing contracts to develop vaccine technology and production capacity and to develop the next generation of antivirals, diagnostics, and ventilators. The annual funds in fiscal year 2010 will be used to expand domestic and international surveillance and detection capabilities, accelerate research and development of rapid diagnostic tests, improve pandemic preparedness and response capabilities, and support international efforts to strengthen public health and vaccine infrastructure.

Question 5a. Dr. Besser, do we have the necessary tools to test people quickly and accurately crossing our borders to monitor the migration of pandemic flu?

Answer 5a. CDC's Quarantine System has the capability to assess reported symptoms of illness in travelers. However, we are not able to determine immediately whether the cause of a person's illness is the novel H1N1 virus or some other common virus such as the seasonal H3N2 influenza virus or adenovirus, for example. Definitive diagnosis of novel influenza H1N1 virus infection requires special laboratory tests that are not available at the border crossings. It is also important to remember that people infected with any influenza virus don't show symptoms during the first 24 to 48 hours after infection, and may not develop an elevated temperature during their entire illness.

Question 5b. How quickly are you able to determine the health status of that person?

Answer 5b. The laboratory tests that are authorized for use to confirm if a person has the novel H1N1 virus can only be performed at CDC and a few laboratories in each State. It can take several hours or even days to get results, depending in part on how far the specimen needs to be transported for testing and the urgency of the situation.

Question 5c. Can you test for the flu virus on the spot?

Answer 5c. We do not have the capacity to identify the novel influenza H1N1 virus or any other specific influenza virus on the spot. Rapid tests that identify influenza A and B are available and can be performed by trained staff anywhere. However, in addition to being unable to identify specific virus subtypes (i.e., they can't differentiate between normal seasonal influenza viruses versus the novel H1N1 virus), these rapid tests can miss as many as one-third of influenza infections. Said in another way, among people that are infected with influenza, the rapid tests may not detect influenza in many of those people. Subtyping of influenza A viruses (i.e. testing to see if an influenza A virus is the novel influenza H1N1 or a seasonal influenza strain) requires specialized testing at laboratories with highly sophisticated technology and specially trained staff.

Question 6a. Dr. Besser, in the Senate version of American Recovery and Reinvestment Act, $870 million was included for pandemic flu, but was stripped and replaced with general funding for prevention and wellness that totaled $1 billion.

Do you have the flexibility and authority to direct funding from the stimulus towards the Swine Flu response?

Answer 6a. The spending plan for Section 317 Immunization under the Recovery Act has been approved by HHS and OMB. The 317 ARRA plan overarching goal is to reach more unvaccinated persons across the lifespan, including influenza vaccines. Section 317 grantees are in the process of finalizing spending plans for the operations dollars and some of these funds could be used for the novel H1N1 preparedness if determined a priority by the State. In addition, there is still a small portion of Recovery Act 317 funds that have not yet been designated that could be used for H1N1. CDC continues to work with HHS to develop plans for the remaining $650 million under the Prevention and Wellness Fund.

Question 6b. Is there adequate and consistent funding for pandemic flu?

Answer 6b. We thank Congress for its strong support of pandemic influenza preparedness. The level of readiness and public health response to the current novel H1N1 epidemic would not have been possible without the help Congress has provided. However, now that the United States is in a response mode, higher, sustained levels of funding are needed.

Effective, well-tested preparedness and response programs can protect public health and minimize illness, death, and the social and economic disruption. These programs depend on dependable public health resources available at international, Federal, State, and community levels. CDC bases continued successful preparedness and response on the following indicators:

- Early recognition and reporting of a human outbreak through the use of laboratory and epidemiologic disease surveillance resources, including H1N1 rapid test kits to laboratories throughout the United States and in other nations.
- Rapid assistance with the necessary resources and actions to contain outbreaks and reduce and delay further spread of disease.
- When available, adequate and successful provision of vaccine to provide prophylaxis to at-risk populations.
- Adequate and successful provision of antiviral medications to treat affected populations.

Question 7. In fiscal year 2008 the Public Health and Social Services Emergency Fund received $804 million in appropriations and $570 million for fiscal year 2009,

with a total amount of $1.3 billion for the fund. Is the Public Health and Social Services Emergency Fund adequately funded to respond to a flu pandemic?

Answer 7. On April 30, 2009, the Administration submitted a proposal requesting $1.5 billion in supplemental appropriations for H1N1 response and preparedness activities. On June 2, 2009, the Administration submitted an additional and contingent request for additional resources to prepare the Nation in the event of a potential H1N1 influenza pandemic. On June 25, 2009, Congress appropriated $7.65 billion to HHS for pandemic influenza preparedness and response in an fiscal year 2009 supplemental to respond to the novel H1N1 influenza pandemic. In addition to the immediate H1N1 response, this funding allows HHS to prepare for the potential future outbreaks or emergence of a new flu strain and provides additional funding in the event of an escalation of the H1N1 virus or other influenza strain. The funding includes $200 million for the Centers for Disease Control and Prevention (CDC) and $350 million to support State and local activities.

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QUESTIONS OF SENATOR MURRAY

Question 1. Dr. Besser, as you know, the earlier detailed potential pandemic warnings are issued the better the response and the greater the potential degree of containment. Does the CDC utilize or rely upon systems that provide the earliest possible detection of infectious disease threats?

Answer 1. The GDD Operations Center, a component of the CDC's Global Disease Detection Program and physically located within the Emergency Operations Center at CDC Headquarters in Atlanta, serves as CDC's central analytical clearinghouse and coordination point for international outbreak information gathering and response. Information about outbreaks worldwide is collected from many sources, including GDD Regional Centers in Thailand, Kenya, Guatemala, China, Kazakhstan, and Egypt; CDC programs; and a wide range of public and private sources, including the World Health Organization, the U.S. Department of State, USAID, DOD, DHS' National Biosurveillance Integration System, Georgetown University's Project Argus, the Global Public Health Information Network, and other governmental and non-governmental organizations. Information is analyzed using the expertise of scientists from across CDC to assess all of the information received, determine the public health threat posed by a given event, and guide the appropriate level of response.

It is important to understand the process of how reports of individual infectious cases eventually progress into determinations of disease epidemics. CDC uses several reporting systems and every month receives hundreds of reports of unexplained respiratory illness throughout the world. For example, media scanning systems reported more than 800 and 600 such outbreaks in March and April 2009, respectively. The media reporting systems used by CDC are very useful for alerting us to potential events of international importance; however, the information in the reports must be further investigated. CDC follows up on significant reports and consults with country officials, specifically looking for trends and patterns, particularly of severe illness, among such reports before classifying them as unusual or epidemic. Given the numbers of news reports received and the limited information available in those reports, it is not possible to predict which events will become significant until there is a definitive pattern in the disease or the country's government mounts a response. Highly fatal conditions such as viral hemorrhagic fevers are much easier to using these alerting systems.

Further complicating the analysis of novel respiratory illnesses is the ongoing disease burden caused by seasonal influenza, a wide number of common respiratory pathogens, viral pneumonias, environmental contaminants, and other diseases that may seem to be notable or "novel" in countries with less-than-optimal disease surveillance capacity.

It is always possible that individual cases of a disease may circulate before established disease patterns appear. We can reasonably compare the current situation to the SARS outbreak of 2003. During SARS, individual cases existed for months be-

fore public health authorities could see the pattern. Looking retrospectively, one media scanning system had reported the occurrence of undiagnosed pneumonia during the early phase of the outbreak, but its significance was not appreciated at the time until there were more cases and international spread.

Since CDC went into full activation on this outbreak, we have seen extraordinary leadership from the World Health Organization and our global partners. In addition, Mexican and Canadian health authorities have been extremely transparent in their actions and collaboration with CDC.

Question 2a. Health officials have expressed particular concern about this flu strain because reports from Mexico indicate that it can cause severe disease in young adults. That's different from what happens with the seasonal flu, which tends to be most severe in older adults and young children.

Do you know why young healthy adults are being hit so hard by this virus?

Answer 2a. As of May 22, infections with this novel H1N1 virus have been reported mainly in younger people. However, we do not know whether this is because older people may have some pre-existing protective antibody to this virus, or whether it is merely that the virus has not yet spread significantly to this segment of the population. A recent antibody study was conducted by CDC involved analyzing stored serum samples from over 350 people in various age groups ranging from 6 months to over 60 years of age. Results from this study showed that about one-third of adults older than 60 years of age had cross-reactive antibody against the novel H1N1 flu virus. However, we do not know if such antibodies provide any protection against the novel influenza A (H1N1). A possible explanation for the pre-existing antibodies in adults is that they may have had previous exposure, either through infection or vaccination to an influenza A (H1N1) virus that was more closely related to the novel H1N1 flu virus than are contemporary seasonal H1N1 strains. The findings described above were reported in the MMWR May 22, 2009/58(19); 521–524.

Question 2b. What are you doing to investigate why the virus hits this group so hard?

Answer 2b. As part of CDC's H1N1 response, we are continuing to monitor trends in the reporting of influenza-like illness and are conducting multiple studies to identify risk factors for developing severe illness following infection with the novel H1N1 influenza virus. An article was published in the MMWR on May 22d (58(19);521–524) showing the results of a recent antibody study conducted by CDC, as mentioned in the response to the previous question. Other studies are under way that will examine how long people shed the virus, how long people can be infectious, how easily the virus is spread, and how transmission of the virus takes place.

Question 3. How long it will take to develop and test a new vaccine for this H1N1 strain and the next generation of antivirals Dr. Fauci mentioned? Are they tracking the virus to monitor whether it is changing over time?

Answer 3. A key goal of the *HHS Pandemic Influenza Plan* (Nov. 2005) is to provide pandemic influenza vaccine to every American within 6 months of the onset of an influenza pandemic. To achieve this goal, HHS through the Biomedical Advanced Research and Development Authority (BARDA) invested in the expansion of domestic vaccine manufacturing infrastructure to increase surge capacity, the advanced development of new cell-based influenza vaccines, antigen-sparing adjuvant technologies, the establishment and maintenance of a national pre-pandemic influenza vaccine stockpile, as well as in next-generation recombinant approaches that may shorten the time necessary to manufacture a pandemic vaccine.

From the results of these initial investments, HHS is able to forecast that the earliest that H1N1 vaccine would be available is autumn 2009, if epidemiological and viral reasons warrant the implementation of an H1N1 immunization program. The forecast is based on the current timelines we developed with HHS agencies, vaccine manufacturing partners, and the availability of clinical study results that may inform vaccine formulation. HHS already has multiple active contracts to obtain pandemic vaccine.

There are no new influenza antiviral drugs that have completed phase 3 development. However, a neuraminidase inhibitor that can be given intravenously is under study and consideration for Emergency Use Authorization (EUA) in severely ill patients with influenza. In addition, some studies are under discussion to look at combinations of the licensed antivirals for influenza to explore whether combination therapy might be a more effective way to combat the virus and decrease emergence of drug resistance.

There is an international surveillance network that continues to isolate and characterize influenza viruses that are causing disease in the general population. These

efforts are headed up by the CDC here in the United States and by the WHO internationally. It was this surveillance network here in the United States that initially discovered the 2009–H1N1 virus in San Diego. The monitoring and characterization of 2009–H1N1 virus isolates continues, and the network is watching for changes in the virus over time.

Question 4. What steps is CDC or other U.S. agencies taking to work with other countries to monitor the global spread of disease and monitor changes in the virus and severity of the outbreak?

Answer 4. CDC is working very closely with public health officials around the world to respond to novel H1N1 influenza. As of May 19, 2009, CDC has deployed a total of 34 staff to Mexico (including 16 currently deployed) including experts in influenza epidemiology, laboratory, health communications, emergency operations including distribution of supplies and medications, information technology and veterinary sciences. These teams are working under the auspices of the Pan-American Health Organization/World Health Organization (PAHO/WHO) Global Outbreak Alert and Response Network and a tri-lateral team of Mexican, Canadian and American experts. The teams are working to better understand the outbreak, including clinical illness severity and transmission patterns, and answer critical questions such as why cases in Mexico initially appeared to be more severe than those that were first seen in the United States. In addition, CDC's Emergency Operations Center is hosting liaisons from PAHO, the European Centre for Disease Prevention and Control (ECDC) and the China CDC to facilitate coordination and collaboration. Staff deployments to Guatemala and Costa Rica have also been supported by CDC.

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

Additionally, CDC's Global Disease Detection Program, commonly known as GDD, has not only been vital in dealing with the current situation but has also laid a foundation for the United States to respond to infectious disease outbreaks globally. Established by Congress in 2004, GDD develops and integrates epidemiologic, laboratory, surveillance, veterinary, medical, and public health programs and resources. GDD's Regional Center in Guatemala is providing evidence that this new virus is expanding south of Mexico. It is also serving as a regional laboratory for influenza A testing and is processing samples from suspected cases and identifying those that need further investigation, including additional testing at CDC laboratories. Other GDD Centers in Kenya, Thailand, Kazakhstan, Egypt, and China have increased their surveillance and laboratory testing activities for respiratory diseases and influenza-like illnesses and are sharing valuable surveillance information for those illnesses. These GDD Centers are also providing regional leadership.

As a WHO Collaborating Center for Influenza, CDC is providing its real-time RT–PCR protocol and kit for detection and characterization of H1N1 influenza free of charge to domestic and international public health institutions, and is providing laboratory testing of specimens which are not able to be characterized in their country of origin. As of May 18, 2009, 250 labs in 142 countries have requested these kits; 119 have been provided (either delivered to the recipient or are in customs awaiting pick-up or additional documentation), and CDC is working to provide the other shipments as quickly as possible.

In addition to our close collaboration with WHO and affected country governments, CDC is working closely with other U.S. Government agencies such as the Department of Defense, Department of State and USAID. CDC has had staff assigned as a liaison to USAID working first specifically on influenza planning and now on response, and staff within CDC's Emergency Operations Center are in daily contact with USAID experts in Washington. Finally, CDC overseas field staff are sharing information and working closely with our embassies and USAID missions overseas in terms of preparedness and response in their host countries.

RESPONSE TO QUESTIONS OF SENATOR BURR BY RICHARD E. BESSER, M.D.

Question 1. The Pandemic and All-Hazards Preparedness Act (P.L. 109–417) unified HHS' preparedness and response programs under a re-named Assistant Secretary for Preparedness and Response (ASPR); however, this office was not represented at the April 29 hearing.

How is CDC collaborating with ASPR to respond to the current influenza outbreak?

Answer 1. The Office of the Assistant Secretary for Preparedness and Response (ASPR) has provided ongoing strategic guidance and support throughout long-term

planning for influenza pandemics. As the Federal response to the current novel H1N1 epidemic continues, ASPR and CDC are working together to meet both immediate and longer term challenges. Examples of how ASPR and CDC are collaborating include the following:

- Planning for development, production, and use of a pandemic vaccine.
- Communication with partners, stakeholders, and policymakers on pandemic planning and emergency response.
- Engagement with other Departments and Agencies on technical and policy issues.
- Participation in HHS and ESF–8 strategic planning.
- Collaboration with BARDA on medical countermeasure acquisition.
- Interaction through CDC and HHS LNOs at respective Emergency Operation Centers.
- Development of guidance for Faith-Based and Community-Based Organizations.
- Review of PREP Act application to 2009 H1N1.
- Collaboration with BARDA on joint management of contracts for development of point-of-care and hospital-based influenza diagnostic devices; this investigational point-of-care device detected the first case of novel H1N1 in April 2009.
- Collaboration with BARDA on achieving FDA approval of a PCR diagnostic test for detecting seasonal and non-seasonal influenza, now being used to detect the novel H1N1 under an EUA.

Question 2a. How will CDC work with ASPR in the coming months to ensure our Nation is prepared for the upcoming influenza season?

Answer 2a. CDC and ASPR will continue to work together with vaccine manufacturers, distributors, other Federal agencies, and public health stakeholders to ensure adequate supplies of seasonal vaccine for the 2009–2010 season.

Each year, CDC and ASPR work closely with other organizations to plan the Vaccination Education Campaign for the influenza season, which will begin in September 2009. National Influenza Vaccine Week (NIVW), scheduled for the last week in November 2009, has become an increasingly important part of the campaign, emphasizing the importance of continued influenza vaccination through the latter part of the season. Over the years, the Education Campaign has been a cost-effective initiative that has reached ever-increasing numbers of people, including those within vulnerable groups. CDC will continue its efforts to make those populations most vulnerable for complications from seasonal influenza aware of the annual vaccination recommendations.

CDC will continue to partner with its Immunization Grantees to make seasonal influenza vaccine available to those populations through existing programs (Section 317 Immunization Program; *Stimulus Funds, and the* Vaccines for Children Program).

- Because of the novel H1N1 epidemic this summer, CDC and ASPR are working with partners to ensure that educational messages are flexible to meet potential changes in the influenza virus as the season progresses, such as changes in populations recommended for vaccination.
- CDC and ASPR will work to distribute new point-of-care devices in strategic locations in the United States and around the globe to assist in early detection of first cases of the novel H1N1 infections.
- CDC and ASPR will utilize the Influenza Reagent Resource (IRR), a CDC-supported reagent stockpile and virus library, to provide viruses and testing reagents to vaccine, antiviral, and test developers. In addition, the IRR will distribute testing kits to U.S. and international laboratories to allow for characterization of influenza viruses. As of May 18, the IRR has distributed to 95 sentinel U.S. laboratories and 253 international laboratories.

Question 2b. More specifically, what steps will CDC take to ensure that our Nation is prepared in the event that a more virulent form of the 2009 H1N1 virus resurfaces during the 2009–2010 flu season?

Answer 2b. As of May 20, 2009, evidence-based information CDC is receiving indicates that the current novel H1N1 epidemic (1) continues to spread among populations in the United States and globally, and (2) is causing influenza illness similar in severity to seasonal influenza viruses, except in some people who have underlying illnesses. It is difficult to predict whether the 2009 H1N1 virus will resurface in a more virulent form during the 2009–2010 influenza season. However, CDC is taking critical preparedness steps in case this happens—or in case another novel influenza virus emerges as a pandemic influenza candidate. These steps include the following:

• While the H1N1 epidemic continues, CDC is analyzing initial lessons learned and ways the agency might apply these lessons to a more severe epidemic or a pandemic.

• CDC has developed candidate seed vaccines to use in testing and development of a monovalent H1N1 vaccine.

• CDC is working closely with State and local partners (both public and private) to address concerns or gaps that may occur in the 2009–2010 influenza season.

• CDC is working with the World Health Organization, ministries of health in many countries, and other global partners to identify and address potential challenges before they occur.

• HHS and CDC are working with influenza vaccine manufacturers to monitor the status of the production of seasonal influenza vaccine and consider implications of the development of an H1N1 vaccine on seasonal flu vaccine supply.

• CDC is working with HHS, States and vaccine manufacturers to plan for the distribution of vaccine during the 2009–2010 influenza season, including the seasonal trivalent influenza vaccine and a possible H1N1 vaccine.

• CDC is working with its Advisory Committee on Immunization Practices (ACIP) to review its seasonal influenza vaccination recommendations and identify any necessary policy reviews/recommendations that will be needed, such as revised vaccination recommendations based on seasonal flu vaccine supply, or recommendations related to the implementation of a simultaneous H1N1 vaccination program. A special session devoted to influenza and, in particular, novel influenza A (H1N1), has been added to the June 2009 ACIP meeting to allow discussion by ACIP members and CDC subject matter experts of issues related to epidemiology, virology, possible development of a new vaccine, program implementation, possible use of pneumococcal vaccines during a pandemic, and use of antiviral drugs. The ACIP meeting agenda is posted and updated regularly at *http://www.cdc.gov/vaccines/recs/acip/meetings.htm#agendas*.

• CDC is in the process of developing its annual influenza vaccination communication campaign and is consulting with its partners to plan for the inclusion of H1N1 in the annual campaign as appropriate. CDC will be conducting communication research during the upcoming months that will inform the development of messages and educational materials for the public.

• CDC will continue to monitor H1N1 and other influenza virus strains, and will perform influenza disease and antiviral resistance surveillance during the summer and annual influenza season both in the northern and southern hemispheres to determine the severity and spread of the influenza viruses circulating in the United States and inform disease control measures.

• CDC will be closely monitoring events in the southern hemisphere this summer to inform disease control measures in the northern hemisphere during the fall and winter months.

• CDC will be providing reagents to U.S. and international laboratories through the Influenza Reagent Resource. This will provide a stockpile of diagnostic reagents to assure that adequate testing is performed to monitor changes in the virus that might indicate a vaccine mismatch or might indicate rising antiviral resistance.

RESPONSE TO QUESTIONS OF SENATOR BURR BY ANTHONY FAUCI, M.D.

Questions 1a and 1b. On April 29, CDC and NIH testified that the Department was working to develop a vaccine seed strain specific to the 2009 H1N1 influenza, which is the first step in manufacturing a vaccine. Has the decision been made to proceed with manufacturing a vaccine specific to the 2009 H1N1 influenza strain?

(a) If so, does the Department plan to pursue a monovalent vaccine or fold this new vaccine into the seasonal flu vaccine?

(b) If a decision has not yet been made, when will HHS make that decision and will there be sufficient time to manufacture a vaccine for the upcoming flu season if that is the approach the Department pursues?

Answer 1a and 1b. A key goal of the HHS Pandemic Influenza Plan (Nov. 2005) is to provide pandemic influenza vaccine to every American within 6 months of the onset of an influenza pandemic. To achieve this goal, HHS through the Biomedical Advanced Research and Development Authority (BARDA) invested in the expansion of domestic vaccine manufacturing infrastructure to increase surge capacity, the advanced development of new cell-based influenza vaccines and antigen-sparing adjuvant technologies, the establishment and maintenance of a national pre-pandemic influenza vaccine stockpile, as well as, in next-generation recombinant approaches that may shorten the time necessary to manufacture a pandemic vaccine.

Question 2. If HHS has decided not to proceed with manufacturing a vaccine, what are the implications for the upcoming flu season?

Answer 2. From the results of these initial investments, HHS is able to forecast that the earliest that H1N1 vaccine would be available is autumn 2009, if virus transmissibility and disease severity warrant the implementation of an H1N1 immunization program. The forecast is based on the current timelines BARDA developed with other HHS agencies, vaccine manufacturing partners, and the availability of clinical study results that may inform vaccine formulation. HHS has multiple active contracts to obtain pandemic vaccine including H1N1 vaccine and adjuvants. On May 22 HHS Secretary Sebelius announced $1.1 B in support of vaccine development by HHS agencies and the acquisition of vaccine components—H1N1 bulk antigen and adjuvants—to establish an initial stockpile of H1N1 vaccine using all remaining HHS pandemic influenza funds. More H1N1 vaccine may be acquired during the summer months provided new funding becomes available. In September 2009 decisions on whether to acquire additional H1N1 vaccine from vaccine manufacturers may be made based on the results of clinical studies that will inform vaccine formulation, H1N1 virus spread that will inform whether an immunization program is needed, and the availability of funds. If a vaccination program is initiated, then vaccine may be available in late October 2009 for immunization in the United States. Vaccination in States will follow the availability of vaccine for several months thereafter.

[Whereupon, at 4:38 p.m., the hearing was adjourned.]

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