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2009 H1N1 VIRUS

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BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

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2009 H1N1 VIRUS

THURSDAY, MAY 7, 2009

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES, COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Herb Kohl (chairman) presiding.

Present: Senators Kohl, Pryor, Brownback, and Bennett.

STATEMENT OF SENATOR HERB KOHL

Senator KOHL. Good morning and we thank you all for being here today. I would like to personally welcome Senator Brownback who is a new ranking member of the subcommittee. It is very good to have Senator Brownback and his knowledge and experience with us.

We also, of course, would like to welcome Secretary Vilsack and Dr. Sharfstein to this Committee Hearing.

In a normal year gentleman, your first appearance before this subcommittee would focus on the administration's budget request, which coincidentally, is being released today as you know. But we're going to ask you to come back for that once we have had a chance to study the budget and use this previously reserved time to hear from you on the steps the USDA and FDA are taking in response to the H1N1 outbreak, and we thank you both for being here in that regard.

The past 2 weeks Americans have witnessed lots of media coverage of the flu outbreak. In speaking with Secretary Napolitano yesterday, she indicated that it has not turned out to be as severe as we originally feared. The immediate sense of crisis, fortunately, seems to be passing.

We are no longer calling for schools to close, and the fear many people had in recent days should be subsiding at this time. But we still need to be vigilant as we all know, and if history is any guide, the second wave has historically been even more lethal.

But as of today there is good news, the number of new cases in Mexico is slowing. It seems to be a milder strain than previously thought. Hospitalization rates are comparable to the regular flu. Existing drugs have been effective. And finally, there has been good coordination among all levels of Government here in the United States and the messages given to the public have been consistent and timely.

But we all know there is more to be done. We need to work to spread accurate information about this flu and that it is not "swine

flu". Our food supply is safe and no one should be closing their borders to United States meat. Secretary Vilsack, that is one of your jobs.

We also need to make sure we have a vaccine for this, as well as the seasonal flu that will come around in the fall, and to make sure that it is safe, effective, and that there is enough for everyone. Dr. Sharfstein, that will be your job.

So, we look forward to hearing from you both after any statement from Senator Brownback that he wishes to make at this time, Senator Brownback.

STATEMENT OF SENATOR SAM BROWNBACK

Senator BROWNBACK. Thank you very much Mr. Chairman, it is a pleasure to join you here. I saw my colleague, and a former ranking member, Bob Bennett, in the elevator on the way up and he was handing me the reins as the ranking member and I'm delighted to be here. Being from the State of Kansas, this is an important topic for us. It is an important topic for all of the country, but certainly the Agriculture Subcommittee is one that a lot of people watch, and I'm looking forward to serving with you and getting your advice on any of the NBA playoffs. I'm sure you would know those as well as this topic.

This is a key topic in front of us on the H1N1. In early April doctors in California detected this new and unique influenza strain in two young children and immediately began working with officials at the Centers for Disease Control, and to determine the origin and makeup of this influenza strain. After identifying the strain as a novel H1N1 influenza and tracing it to a significant outbreak in Mexico it became clear that health officials were dealing with a serious situation of global importance. This outbreak is a true test of our Public Health Response System. And by all accounts it is working. The Department of Health and Human Services, working with State health departments has been able to quickly identify and respond to this virus, antiviral drugs that are effective in treating this type of influenza have been shipped to all 50 States and provided to Mexico to assist in the situation there. In addition, efforts are underway to develop a vaccine that would be ready for the Fall flu season if it is necessary. Each sector of our public health infrastructure is mobilized to combat H1N1 influenza.

While we have appropriately focused on the public health aspects of the situation we must not forget that the initial naming of this virus had erroneously caused concern that pork products pose a threat to public health, resulting in a decline in the pork market. I know the Secretary being from Iowa is critically aware of that. And I have to say, Mr. Chairman, my background in the trade field and working with the initial opening up of foreign meat markets to the United States to beef and pork exports, too often what we see taking place in a situation like this is another country using this as an excuse to block our products.

We have seen this happen in a dozen, a number of different health situations that are not a health concern to the population. So, we have seen to date 20 countries have placed trade restrictions on U.S. pork products that are healthy, that are safe, and I think

these are just being used as trade barriers to our products pure and simple.

Mr. Secretary, I am certain you share that view, and I am certain you are on top of this to push to reopen these markets, because this just happens all too often, and as a result our prices for pork in the United States have declined over 15 percent. So it has a real impact in already a difficult marketplace for our producers.

It is a huge public health concern. Dr. Sharfstein, we will look forward to your work and your comments on this. And it is one that we are going to be very supportive of your team and the efforts to make sure that we handle this in the best possible and effective way that we can.

Thank you, Mr. Chairman.

Senator KOHL. Thank you very much Senator Brownback. We have with us this morning Senator Mark Pryor, who is a member of the subcommittee now. Thank you for being here, and make any statement you wish.

Senator PRYOR. Thank you Mr. Chairman, I don't have any statement, but thank you both for your leadership on this issue and I look forward to hearing from the panel, thank you.

Senator KOHL. Thank you. Secretary Vilsack, we'll take your statement, please.

STATEMENT OF TOM VILSACK, SECRETARY, DEPARTMENT OF AGRICULTURE

Secretary VILSACK. Thank you very much Mr. Chairman and good morning to you and to Senator Brownback and Senator Pryor. I appreciate the opportunity to testify. I have with me today as well, Dr. John Clifford, Chief Veterinarian for the Animals and Plant Health Inspection Service of the Department of Agriculture, as well as Mr. Jim Miller, Under Secretary for Farm and Foreign Agriculture Services, and Dr. Kenneth Peterson, Assistant Administrator for the Food Safety and Inspection Service.

Before I begin I would like to express my sympathy and that of the USDA and our concern for all of those who have lost loved ones as a result of this flu, as well as those who have been sickened by it. I recognize that many Americans are worried about this virus and I want to assure them, and you, that Federal, State and local governments are working closely together to respond to the emergence of this virus.

2009 H1N1 OUTBREAK

The appearance of the 2009 H1N1 flu virus in humans and the associated concerns for animal health underscore the interdependent nature of human and animal health and the need for a one medicine approach to animal health surveillance. This emphasis is certainly true in USDA, and it is how we view our role in animal health safety, a role in which we are concerned with not only animal health, but with the optimal health of people, animals, and our environment.

Today I would like to emphasize several points relating to the flu outbreak. One, it is absolutely safe to consume pork products. Two, USDA is involved in surveillance and vaccine development for swine. Three, USDA is well prepared should we detect the 2009

H1N1 flu virus in U.S. swine. And finally, USDA is working hard to keep markets open for pork products.

I have been saying since day one and will continue to reiterate that pork and pork products are safe, and the American food supply is safe. Experts at the USDA and the Centers for Disease Control and Prevention have carefully examined this issue and found no evidence that this flu virus can be transmitted by food. It is important that consumers understand that you cannot contract this flu from eating pork or pork products. We are reiterating this message not only to the general public and industry, but to our trading partners and organizations such as the U.S. Commodity Futures Trading Commission and the Chicago Mercantile Exchange, in order to assure markets that U.S. pork is safe, and to protect producers, livelihoods.

Another point I want to reiterate is that there is no evidence that this virus is in U.S. swine. We continue to take steps to verify that there are no signs of this virus in our swine herd, including working with State animal health officials, private practitioners, and our own Federal veterinarians in the field. However, it is important to note that because of the inherent qualities of influenza, there could be transmission from humans to swine.

In fact, Canadian Food Inspection Agency officials have confirmed that swine from a herd in Alberta, Canada tested positive for the strain currently causing illness in humans. Canada has handled this situation appropriately and taken the necessary steps and precautions. No sick swine have left the farm, and animals and premises have been quarantined. We are working closely with our counterparts in Canada to keep abreast of the situation. This emphasizes the critical importance that pork producers be vigilant and understand and accept appropriate bio-security measures.

Vigilance is something we use at USDA, and we have an effective safeguarding system in place that utilizes surveillance, testing and monitoring to ensure diseases are kept out of the livestock industry. Just as our safeguarding system has been proven successful in the past, we are confident that our efforts, combined with those of our industry partners, will alert us to any possible disease in U.S. swine.

SURVEILLANCE

USDA is prepared. So while USDA's routine safeguarding efforts for animal disease are ongoing, we do recognize the need to be responsive to the heightened concerns surrounding this flu, and are undertaking additional measures around surveillance and research to reassure consumers, producers and the public.

To ensure early detection should the H1N1 flu be introduced into U.S. swine and because this particular strain has human health implications, we have accelerated implementation of a swine influenza surveillance program, which we began developing in July of 2008 in cooperation with the CDC and other stakeholders.

Dr. Clifford is here if you wish to talk more about this. If we were to detect an unusual case of swine influenza, USDA would take a series of swift and appropriate actions to contain the virus and protect animal and human health while the virus was being identified.

PRICE IMPACTS

Following the escalating media attention regarding the 2009 H1N1 influenza over the weekend of April 25 and 26, the pork industry has encountered as Senator Brownback indicated, an over 15 percent decline in the average cash based price for hogs. Prior to that weekend USDA reported a weighted average base price of $61.03 per hundredweight paid for barrows and gilts on a carcass basis. As of May 5 that price decreased to $50.95 per hundredweight, a decline of over $10 per head for pork producers. By comparison, the average base price was $75.07 a year ago, or a 32 percent decline in price.

Although the decline in pork prices has not been as large, the wholesale pork carcass cutout value decreased by 5.5 percent April 24 to May 5.

TRADE IMPACTS

Now let me turn your attention for just a minute to the international market for U.S. pork and other meat and poultry products. As you know, exports are vital to the success of U.S. meat and poultry industry. For example in 2008 total U.S. pork exports were $4.7 billion.

When I first became aware of the 2009 H1N1 flu situation, one of the first steps I took was to instruct each of our Foreign Agricultural Service's representatives in other countries to reach out to all of our major trading partners to keep their markets open. Through this network of overseas posts, FAS worked quickly to remind the appropriate foreign ministries and key foreign officials that discovery of this virus in humans is not a basis for restricting imports of commercially produced U.S. meat and pork products. We wanted to make sure our trading partners knew that this is not a food safety issue and that we expected them to make decisions regarding the importation of U.S. pork based on sound science and internationally accepted rules. Because of our swift action, we have been able to significantly mitigate the impact on our international markets.

To reinforce our commitment, Ambassador Kirk and I put out a joint statement again urging our trading partners to make decisions based on scientific evidence and in accordance with their international obligations. We will continue to work with the U.S. Trade Representative's office to send a very strong and unified message in this regard.

One of our key markets we immediately contacted was Japan. Japan is the number one export market for U.S. pork, with trade worth over $1 billion a year. We are particularly pleased with the Japanese response, which was a very strong and unequivocal a confirmation that U.S. pork products are safe and there is no reason to restrict imports into their country.

Official and unofficial bans were quickly lifted in numerous countries, due largely to USDA's outreach efforts. For example, all Central American markets that initially closed are reported to have been reopened to U.S. pork products.

I'm disappointed that China and Russia have imposed restrictions in reaction to H1N1. These restrictions account for the bulk

of the impacts on exports. China had a record shipment of $273 million, roughly 6 percent of our exports in 2008. However, the pre H1N1 forecast expected 2009 shipments to be a bit lower.

Russia has banned all meats from some States, thus impacting not only pork, but also beef and poultry. Pork exports to Russia were valued at $414 million, accounting for 9 percent of our trade. Our USDA posts overseas have taken every opportunity to reach out at every level of both the Chinese and Russian governments. The message they are delivering is clear, U.S. pork and pork products are safe and these markets should be reopened consistent with international guidelines.

We will continue to focus our efforts on reopening these markets.

In closing I want to emphasize that USDA will continue to work with other government agencies, industry, and our counterparts around the world to monitor the situation and assure the public and our trading partners that U.S. pork is safe. I must reiterate that indeed our products and our pork are safe. We are moving swiftly to make sure that we understand the science behind this virus, have the tools in place to detect and identify it, and respond appropriately if needed. You also have my assurance that USDA will continue to press our trading partners to remove restrictions on U.S. products and that restoring the international market for U.S. meat and poultry is a top priority.

PREPARED STATEMENT

That concludes my statement Mr. Chairman, I look forward to working with members and staff of this committee and will be glad to answer questions you might have later.

[The statement follows:]

PREPARED STATEMENT OF TOM VILSACK

Mr. Chairman and distinguished Members of this Committee, I appreciate the opportunity to testify before you today on the 2009-H1N1 influenza. I have with me today Dr. John Clifford, Chief Veterinarian for the Department of Agriculture (USDA), Mr. Jim Miller, Under Secretary for Farm and Foreign Agricultural Services, and Dr. Kenneth Petersen, Assistant Administrator for the Food Safety and Inspection Service.

Before I begin, I would like to express my sympathy and concern for those who have lost loved ones to the 2009-H1N1 flu, as well as to those who have been sickened by the virus. I recognize that many Americans are worried about this virus, and want to assure you that Federal, State, and local governments are working closely together to respond to the emergence of this virus.

The appearance of the 2009-H1N1 flu virus in humans and the associated concerns for animal health underscore the interdependent nature of human and animal health and the need for a "one medicine" approach to animal health surveillance. This emphasizes how we at USDA view our role in animal health safeguarding—a role in which we are concerned not only with animal health, but with the optimal health of people, animals, and our environment.

Today I would like to emphasize several points related to the 2009-H1N1 flu outbreak. One—let me be absolutely clear: it is safe to consume pork products. Two—USDA is involved in surveillance and vaccine development for swine. Three—USDA is well prepared should we detect the 2009-H1N1 flu virus in U.S. swine. And finally—USDA is working to keep markets open for pork products.

Before I discuss these points, I would like to note that when I reference "2009-H1N1 flu," I am referring to the novel flu virus currently causing human illness, not flu viruses typically found in swine. There has been some confusion about why this virus is different from flu viruses we have seen before, so I'd like to provide a brief explanation.

Ecology of Influenza A Viruses

Influenza type A viruses are widely distributed in birds and mammals including humans. These viruses are sub-typed by surface proteins referred to as H and N. The primary types seen in humans are H1, H2 and H3, and in swine they are H1 and H3. The current virus of concern is an H1N1 subtype.

The genetic codes inside the virus further distinguish the subtypes. If viruses from 2 or 3 different species (for example bird, swine and human) infect the same person or animal, they can mix and create a new influenza A virus. Several of the gene segments in this 2009-H1N1 flu virus have previously been identified in swine influenza viruses, so it was initially called a swine influenza virus. However, this virus is different from other type A influenzas because of its unique combination of genes.

It is also important to understand that when genes are re-combined, as has happened with this 2009-H1N1 flu virus, the behavior of the virus changes. It may lose potential to infect or cause disease in its original host (in this case, swine) or it may become more transmissible to another host. This 2009-H1N1 flu virus has become fairly efficient in transmission among humans, as the spread of cases in this current outbreak has demonstrated. Now that we've discussed the science behind this virus, I'd like to talk about our approach to this situation.

U.S. Pork is Safe

I have been saying this since day one and will continue to reiterate that pork and pork products are safe—the American food supply is safe. Experts at USDA and the Centers for Disease Control and Prevention (CDC) have carefully examined this issue and found no evidence that this 2009-H1N1 flu virus can be transmitted by food. It is important that consumers understand that there is no evidence that you can contract this flu from eating pork and pork products. We are reiterating this message not only to the general public and industry, but to trading partners and organizations such as the U.S. Commodity Futures Trading Commission and the Chicago Mercantile Exchange, in order to assure markets that U.S. pork is safe and to protect producers' livelihoods.

Another point I want to reiterate is that there is no evidence of the 2009-H1N1 virus in U.S. swine. We continue to take steps to verify that there are no signs of this virus in our swine herd, including working with State animal health officials, private practitioners, and our own Federal veterinarians in the field. However, it's important to note that because of the inherent qualities of influenza, there could be transmission from humans to swine.

In fact, Canadian Food Inspection Agency (CFIA) officials have confirmed that swine from a herd in Alberta, Canada, tested positive for the 2009-H1N1 strain currently causing illness in humans. A Canadian carpenter who had been in Mexico, upon return, was exhibiting flu-like symptoms, did work on this Alberta farm, and subsequently swine on the farm became ill. Consequently, as a precaution, people with flu-like symptoms should not interact with swine, and swine showing influenza symptoms should be kept away from the public and brought to the attention of State animal health authorities or USDA. Canada has handled this situation appropriately and taken the necessary steps and precautions. No sick swine have left the farm, and the animals and premises have been quarantined. We are working closely with our CFIA counterparts to be kept abreast of the situation. This emphasizes the critical importance that pork producers be vigilant and understand and practice accepted biosecurity measures.

Vigilance is something we are used to at USDA, and we have an effective safeguarding system in place that utilizes surveillance, testing, and monitoring to ensure diseases are kept out of the livestock industry. What people outside of the livestock industry may not realize is that swine influenza, though not the 2009-H1N I strain, is actually endemic in the United States, and that USDA, as well as the swine industry, have a long history of successfully dealing with this virus. And just as our safeguarding system has proven successful in the past, we are confident that our efforts, combined with those of our industry partners, will alert us to any possible disease in U.S. swine.

USDA is Prepared

So, while USDA's routine safeguarding efforts for animal disease are ongoing, we do recognize the need to be responsive to the heightened concern surrounding the 2009-H1N1 flu virus, and are undertaking additional measures around surveillance and research to reassure consumers, producers and the public.

To ensure early detection should the 2009-H1N1 flu be introduced into the U.S. swine population, and because this particular strain has human health implications, we have accelerated implementation of a swine influenza virus surveillance pro-

gram, which we began developing in July 2008 in cooperation with CDC and other stakeholders. We have asked laboratories to send any swine influenza virus isolates that are difficult to subtype with current reagents or known to be associated with human illness to our National Veterinary Services Laboratories (NVSL). To provide additional capacity to further characterize these submissions, we will be working with National Animal Health Laboratory Network (NAHLN) laboratories to provide additional diagnostic assistance.

USDA's laboratories are ready, and are prepared to address potential findings of 2009-H1N1 flu in swine. We are growing virus to meet potential future diagnostic needs and determining if USDA can detect this strain with the screening test we currently use to detect avian influenza. NAHLN laboratories already use and are familiar with the avian influenza test and have been trained and proficiency tested, so they are prepared to use this test to screen for swine flu once this determination has been made.

To test swine for the virus, you need to swab their nasal passages when they are sick and shedding the virus. If the animals are not showing signs of sickness, the likelihood of detecting the virus is low. If the screening test shows that the animal does have a type A influenza virus, further tests, known as genetic sequencing, must be done to distinguish one influenza virus type and subtype from another. This genetic sequencing, which looks at the DNA-makeup of the virus, is conducted by NVSL in Ames, Iowa, as well as selected laboratories with this capability.

Laboratories with this sequencing capability conduct genetic sequencing on more than 500 swine influenza virus samples each year. USDA has contacted these laboratories and asked them to review their databases for their current and past sequencing analyses. The results of these reviews, including the most recent swine influenza season, revealed no detections of the 2009-H1N1 strain currently causing illness in humans.

If we were to detect an unusual case of swine influenza, USDA would take a series of swift and appropriate actions to contain the virus and protect animal and human health while the virus was being identified. First, USDA and its State and industry partners would identify any infected or exposed animals and quarantine those animals. Second, USDA would take blood and tissue samples and would determine the virus type (i.e., H1N1) at a State diagnostic laboratory or the National Veterinary Services Laboratories in Ames, Iowa. Third, if we confirm that a sample is indeed positive for the 2009-H1N1 influenza, APHIS and State animal health officials will immediately begin an epidemiological investigation to determine any other herds that may have been exposed to the affected animals. This highlights the need to have significant producer participation in the National Animal Identification System (NAIS), which would make traceability much more effective if we do need to engage in a traceback effort related to this disease.

Enhancing our Understanding of the Virus and Increasing our Capabilities

To better understand and prepare to respond to a disease such as the 2009-H1N1 flu virus, it is important to understand its epidemiology. To that end, USDA has agreed, at the request of the United Nations Food and Agriculture Organization (FAO), to send a laboratory diagnostic expert to Mexico as part of an international team studying the epidemiology of the 2009-H1N1 flu outbreak. It is our hope that with a better understanding of the disease's incidence and distribution, we can tailor our preparations more appropriately to the specific virus.

Additionally, our National Animal Disease Center (NADC), which has conducted research on swine influenza since 1978, is studying the 2009-H1N1 flu virus with the end goal of developing a rapid and specific diagnostic test to target the unique genes in the 2009-H1N1 flu virus. This new test would be applied to samples that screen positive for any swine influenza virus. Even before the 2009-H1N1 case in swine was announced, scientists at NADC planned to inoculate pigs with the new virus to determine if it causes disease in pigs and how easily it is transmitted from pig to pig. We still plan to follow this course of action. The information obtained in these studies will be crucial for the U.S. swine industry to prepare for infection of swine herds with the new virus and their potential consequences, including spread of the virus to swine workers and others exposed to infected swine.

NADC scientists are also initiating critical new research to determine if current vaccines or previous exposure to current strains of swine influenza virus will provide protection against the 2009-H1N1 influenza virus. The results of these studies will provide important information on how vulnerable the U.S. swine population is to the new virus. We will also work with the swine industry to generate and produce new efficacious vaccines to provide protection to pigs against the disease. An outbreak of this virus in the U.S. swine production system could further exacerbate the potential for viral spread and replication in the human population, in addition to

costing the swine industry millions of dollars. All research will be conducted using appropriate biosecurity protocols.

Speaking of biosecurity, it is imperative that we take steps to prepare and protect U.S. swine from a potential 2009-H1N1 flu outbreak. We are reaching out to industry and encouraging them to intensify existing biosecurity practices. This includes not loaning/borrowing equipment or vehicles to/from other farms; permitting only essential workers and vehicles to enter the farm; disinfecting shoes, clothes, and hands of swine workers; thoroughly cleaning and disinfecting equipment and vehicles; and avoiding visiting other farms without proper cleaning and disinfection. In addition, we are working closely with our State and industry partners to ensure that officials take appropriate steps to protect themselves should they need to investigate suspect animals.

Impacts on the U.S. Swine Industry

Following the escalating media attention regarding the 2009-H1N1 influenza over the weekend of April 25–26, the pork industry has encountered a 16.5 percent decline in the average cash base price for hogs. Prior to that weekend, USDA reported a weighted average base price of $61.03 per hundredweight paid for barrows and gilts on a carcass basis. As of May 5, that price decreased to $50.95 per hundredweight, a decline of over $20 per head for pork producers. By comparison, the average base price was $75.07 a year ago, or 47.3 percent higher than the current price.

Although the decline in pork prices has not been as large, the wholesale pork carcass cutout value decreased by 5.5 percent from April 24 to May 5. While the USDA estimated pork carcass cutout stood at $59.28 per hundredweight prior to that weekend news cycle, the value declined to $56.01 by May 5. In comparison, the cutout was $76.63 a year ago, or 36.8 percent higher than now.

Softening demand and declining pork prices have resulted in reduced slaughter rates. Estimated hog slaughter for the week ending May 2, 2009, was 2,018,000 head, a drop of 4.2 percent from the previous week and 2.3 percent from the same period a year ago.

Reassuring Trading Partners

Now let me turn to the situation in regard to the international market for U.S. pork and other meat and poultry products. As you know, exports are vital to the success of U.S. meat and poultry. For example, in 2008, total U.S. pork exports were approximately $4.7 billion.

When I first became aware of the 2009-H1N1 flu situation, one of the first steps I took was to instruct the Foreign Agricultural Service (FAS) to reach out to all of our major trading partners to keep their markets open. Through its network of overseas posts, FAS worked quickly to remind the appropriate foreign ministries and key foreign officials that the discovery of this virus in humans is not a basis for restricting imports of commercially produced U.S. meat and pork products. We wanted to make sure our trading partners knew that this is not a food safety issue and that we expect them to make any decisions regarding the importation of U.S. pork based on sound science and internationally accepted rules. Because of our swift action, we have been able to significantly mitigate the impact on our international markets.

To reinforce our commitment, Ambassador Kirk and I put out a joint statement again urging our trading partners make decisions based on scientific evidence and in accordance with their international obligations. USDA will continue to work with the U.S. Trade Representative's office to send a very strong and unified message.

One of the key markets we immediately contacted was Japan. Japan is the number one export market for U.S. pork, with trade worth well over $1 billion a year. We were particularly pleased with the Japanese response, which was a very strong and unequivocal confirmation that U.S. pork products are safe and there is no reason to restrict imports into their country.

Official and unofficial bans were quickly lifted in numerous countries, due largely to USDA outreach efforts. For example, all Central American markets that initially closed are reported to have reopened to U.S. pork exports.

FAS works closely with the international organizations, FAO, World Animal Health Association (OIE), and the CODEX to ensure that all countries have a strong set of science-based guidelines for use in these types of situations.

Conclusion

In closing, I want to emphasize that USDA will continue to work with other government agencies, industry, and our counterparts around the world to monitor the situation and assure the public and our trading partners that U.S. pork is safe. I must reiterate that U.S. pork and pork products are safe. We are moving swiftly to make sure that we understand the science behind this virus, have the tools in place to detect and identify it, and respond appropriately if needed. You also have

my assurance that USDA will continue to press our trading partners to remove restrictions on U.S. products and that restoring the international market for U.S. meat and poultry is a top priority.

That concludes my statement. I look forward to working with Members and staff of the Committee and we will be glad to answer questions you may have.

Senator KOHL. Thank you very much, Secretary Vilsack. Dr. Sharfstein.

STATEMENT OF JOSHUA M. SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER AND ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SHARFSTEIN. Thank you Chairman Kohl, Senator Brownback, Senator Pryor for the opportunity to testify today. Let me also say Secretary Vilsack, it is terrific to meet you, the FDA supports completely your message on the safety of pork products and we share USDA's mission of assuring a safe food supply for Americans. I also should say we've had, in my 5 weeks on the job so far, just a terrific relationship with your staff at USDA collaborating on a whole range of food safety projects and I think there is just so much exciting and worthwhile to be done through that collaboration.

Among its other responsibilities, FDA protects public health by facilitating access to safe and effective human and animal drugs, human biological products and devices. This mission has been put to the test by the H1N1 situation in the last couple of weeks. Since the beginning of the outbreak when we became aware on Thursday, April 23, FDA has worked closely within HHS, with our sister HHS agencies, with USDA, other government agencies, the World Health Organization and foreign governments to address this serious challenge. I appreciate the opportunity to discuss FDA's response, including our approval of several emergency use authorizations and the efforts of internal FDA response teams.

I want to just start by explaining that the most public thing that FDA did, which was to issue several emergency use authorizations, this concept was part of the Bio-Shield Act of 2004. An emergency use authorization allows the use of an unapproved product or of an approved product for an unapproved use in a declared emergency. To authorize this emergency use FSA must find that the agent in this case, the flu virus, One, can cause a serious or life threatening disease or condition. Two, that based on the totality of the scientific evidence it is reasonable to believe that the product may be effective against the disease or condition. Three, that the known and potential benefits of the product's use outweigh the known and potential risks, and four, there is no adequate, approved and available alternative.

On Sunday, April 26 the Acting HHS Secretary issued a nationwide public health emergency declaration in response to human infections discovered from the 2009 H1N1 flu virus. In the days that followed the Acting Secretary issued justifications justifying emergency use of certain antivirals, in vitro diagnostics, and personal respiratory devices. And FDA followed very quickly with several emergency use authorizations. Two of these were for medications, for Tamiflu and Relenza, two antiviral drugs.

TAMIFLU

For Tamiflu, FDA approved, on an emergency basis, the use of this medication for children under age one and we had the first dosing for that age group. In addition, under emergency authorizations both medications may be distributed with information pertaining to emergency use to large segments of the population without complying with the label requirements otherwise applicable to dispensed drugs. For example both medications may also be distributed by a broad range of health care workers, including public health officials and volunteers, in accordance with applicable State and local laws or public health emergency responses.

It was this emergency declaration that allowed the stockpile to ship so quickly. FDA worked literally around the clock over the weekend and I signed those emergency authorizations at 3 a.m. in the morning on Monday morning, so that stockpile could begin to ship as they had scheduled.

FLU DIAGNOSTIC KIT

The third one was for diagnostic kit. It was the PCR flu panel diagnostic test that CDC put together to allow other labs, other than the CDC lab, to accurately diagnose this new infection. FSA approved this initially and then amended the authorization to allow the use of different sample types, such as throat swabs and different reagents for this test so that the supplies remain adequate. This was also approved that first night so that immediately CDC could begin distributing this test with all of the appropriate instructions to labs around the country.

The fourth one that we did right up front was around masks, and FDA received an emergency use authorization, permitting the use of N95 masks by the general public from the Strategic National Stockpile in accordance with CDC's guidance on how these masks should be appropriately used.

Taking together these authorizations helped CDC and State and local responders to take the actions needed to help meet the medical and public health threat, getting these products to patients and communities in need.

I just want to give you a little bit of a background on how FSA was able to do this so quickly and so effectively, I think. And that is that we changed the management structure of the Agency in order to handle the H1N1 situation.

As soon as we became aware I asked Mr. Jesse Goodman, FDA's Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to lead FDA's efforts. Dr. Goodman is an international expert on biologics, he used to oversee the Biologics Center at FDA during the period where they significantly increased the number of flu vaccine manufacturers selling into the United States. He has tremendous experience in flu vaccine development and evaluation.

INCIDENT MANAGEMENT APPROACH

He's leading an incident management approach, which is a different type of leadership approach than the usual kind of organizational chart at FDA. This approach ultimately put together seven

substantive teams which are cross-cutting and include staff from the FDA as needed. All of the FDA Centers are engaged in the work on H1N1.

These teams work with the Office of the Assistant Secretary of HHS for Preparedness and Response, the CDC, other HHS agencies, and national and international partners. The teams are the vaccine team, the antiviral team, the in vitro diagnostics team, the personal protection team, the blood team, the shortage team, and the consumer protection team.

The incident command kind of approach is what is used by emergency agencies, it was originally developed to fight fires and is now widely adopted across the Federal Government. It also includes an operations section, a logistics section, a communications section that coordinates external relations, and has senior level health, international and legal advisers.

Very briefly I'm just going to tell you about what the teams are working on now. The vaccine team has a goal of facilitating the availability of the safe and effective vaccine to protect the public from the 2009 H1N1 flu virus as soon as possible in the event that it is needed. And this work goes all the way from the lab, where FDA grows the virus, tries to genetically reengineer a reference strain of the virus that could be used for vaccine production, to getting reagents to test the potency of the vaccine, which involves sheep, antibodies for that are apparently produced from sheep. All the way to helping you design the clinical trials or advise in the clinical trials that would be used to test the potency of the vaccine and the effectiveness of the vaccine. All the way through approving the final vaccine.

And that team is engaged with the NIH in BARDA, which does the purchasing of the vaccine for the Federal Government.

Then there is the antiviral team. This is the team that approved the emergency use authorizations that first weekend for the two antiviral drugs, and they have been working very hard on identifying other products that may be needed under an emergency use. For example, right now there are no intravenous flu medications that are approved for use. So that team is working with manufacturers of promising products to see whether it might make sense to do an emergency use authorization in case that would become necessary because there would be so many sick patients.

Like the vaccine team, this team is working closely with colleagues around the world. They got a lot of calls when this team put together the dosing for kids under age one based on their expertise in the science of drugs in the human body, and the rest of the world is very interested in following that and has been using their recommendations.

IN VITRO DIAGNOSTICS

The in vitro diagnostics team, is the one that led the development of the tests, and they are regularly communicating with other manufacturers about other tests that could get approved.

PERSONAL PROTECTIVE EQUIPMENT

The personal protective equipment team, oversaw the emergency use authorization on disposable N95 respirators and is working

with manufactures on the current demand for respirators, meaning the N95 masks, and they are working with CDC on public communications.

BLOOD TEAM

We have a blood team. The main focus of the blood team is to ensure that the blood supply remains robust during this period. That people, if they were to get too many people sick, maybe the blood levels would drop. But they are also looking at if there is any potential that the virus could have any safety concerns for the blood supply, and so far there has not been any significant problems identified.

We have a shortage team, which is solely devoted to identifying shortages, working with manufacturers of approved drugs to make sure that they can get their capacity up and going. Thinking a couple steps ahead about where there might be bottlenecks in the distribution process and how FDA can help.

And finally, we have a consumer protection team, which has the goal of protecting consumers from fraudulent and potentially dangerous FDA regulated products or other promotions for products that claim to diagnose, prevent, mitigate, treat or cure the flu virus. And, in fact, we have already found a number of these where people are promoting things that are potentially dangerous in the guise of treatment for H1N1 influenza. They have taken enforcement action and the promotions have been halted.

I just want to take one second to thank the subcommittee for the funding in 2006, which really was critical to FDA getting to this point. Where FDA's current efforts are built on a foundation that has been really built over the last 5 years. 2004 there was a major flu vaccine shortage, and Congress and the administration at the time really took that very seriously. FDA worked very hard to increase the number of manufacturers in the market from where we were down to one injectable flu vaccine manufacturer, they are now up at, I think, five, and that included a whole number of investments that were only made possible because of actual supplemental fiscal year 2006, $20 million to FDA. That paid for a special review team that went out and inspected the vaccine facilities quickly to get them online faster, including a second major facility, domestic facility, that's Sanofi Pasteur, just got the approval from FDA yesterday. And it is going to double their manufacturing capacity for injectable flu vaccine in the United States from 50 million to 100 million doses of seasonal flu vaccine a year. That facility approved yesterday is going to be available in case there is large scale production of H1N1 virus vaccine. And it is no exaggeration to say that that supplemental appropriation, the foresight that this subcommittee had in moving that forward, is directly related to the fact that we are starting from a pretty strong foundation.

PREPARED STATEMENT

So, to conclude I would just say that it has been a real pleasure for me as someone who is relatively new, very new to FDA, to see what the Agency is capable of, and its response to this challenge. The FDA is fully committed and engaged in protecting the public's health. Among us are laboratory scientists, medical reviewers, epi-

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

Thank you very much for the opportunity to testify. I look forward to your questions.

[The statement follows:]

PREPARED STATEMENT OF JOSHUA M. SHARFSTEIN

Introduction

Chairman Kohl and members of the subcommittee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner and Acting Commissioner at the U.S. Food and Drug Administration. Among its other responsibilities, FDA protects the public health by facilitating access to safe and effective human and animal drugs, human biological products, and devices. Recognizing the global nature of public health issues, we collaborate with foreign counterpart regulatory agencies and international organizations to carry out our mission.

FDA plays a vital role in the Nation's preparedness for, and response to, challenges such as the one presented today by the 2009 H1N1 Flu Virus. FDA is part of a team led by the Department of Health and Human Services. Since the beginning of the 2009 H1N1 Flu Virus outbreak on Thursday, April 23, FDA has worked closely with HHS, our sister HHS agencies, other U.S. government agencies, the World Health Organization (WHO), and foreign governments.

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

FDA 2009 H1N1 FLU VIRUS RESPONSE

Emergency Use Authorizations

Section 564 of the Federal Food, Drug, and Cosmetic Act, which was added by the Project BioShield Act of 2004 (Public Law 108–276), permits the FDA Commissioner to issue an Emergency Use Authorization following a determination and declaration of a public health emergency, provided certain statutory criteria are met. An Emergency Use Authorization allows the use of an unapproved product or of an approved product for an unapproved use in a declared emergency. To authorize the emergency use of a product, FDA must generally find that the agent (in this case, the 2009 H1N1 Flu Virus):

—can cause a serious or life-threatening disease or condition
—that based on the totality of the scientific evidence available it is reasonable to believe that the product may be effective against the disease or condition
—that the known and potential benefits of the product's use outweigh the known and potential risks, and
—that there is no adequate, approved, and available alternative.

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

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

On April 27, 2009, FDA issued four Emergency Use Authorizations in response to requests from the Centers for Disease Control and Prevention (CDC). Two of these Emergency Use Authorizations extend the circumstances in which two FDA-approved drugs, Relenza and Tamiflu, can be used to treat and prevent the 2009 H1N1 Flu Virus. A third Emergency Use Authorization makes available an rRT–PCR test for diagnosing infection with the virus. The fourth authorizes the emergency use of certain personal respiratory protection devices, specifically certain disposable respirators certified by CDC's National Institute for Occupational Safety and Health, known as N95 respirators. FDA later approved a fifth EUA for a diagnostic panel for laboratory screening.

By statute, these authorizations expire in one year unless previously revoked by FDA. However, the authorizations can be renewed if the conditions giving rise to the determination and declaration continue to exist.

Tamiflu has previously been FDA approved to treat uncomplicated illness due to influenza and prevent influenza in patients 1 year and older. Relenza had been approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than 2 days, and to prevent influenza in adults and children 5 years and older.

One of the emergency use authorizations now allows for Tamiflu also to be used to treat and prevent influenza in children under one year. In addition, under the emergency authorizations, both medications may be distributed with information pertaining to emergency use to large segments of the population without complying with the label requirements otherwise applicable to dispensed drugs. Both medications may also be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable State and local laws or public health emergency responses.

The primary Emergency Use Authorization for the rRT–PCR 2009 H1N1 Flu Panel diagnostic test allows the CDC to distribute the 2009 H1N1 Flu Panel test to public health and other qualified laboratories that have the needed equipment and the personnel who are trained to perform and interpret the results. FDA amended this authorization to allow the use of different sample types, such as throat swabs and different reagents for this test to help ensure that supplies of this test remain adequate.

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

The Emergency Use Authorization for certain disposable respirators permits HHS to deploy these products from the Strategic National Stockpile for use by the general public, including individuals performing work-related duties, to help reduce exposure to airborne germs during this emergency. These products, when used properly and in accordance with information that is provided, may help reduce the chances of getting sick. They do not eliminate the risk of illness or death. They should always be used in conjunction with other infection control measures, such as frequent hand washing, and other measures recommended by CDC and State and local public health authorities. Finally, this emergency use authorization only relates to requirements under the Food, Drug and Cosmetic Act, not other requirements such as the standards for safety in the workplace administered by the Department of Labor.

Taken together, these authorizations helped enable CDC and State and local responders to take actions needed to help meet the medical and public health threat, getting these products to patients and communities in need.

The FDA's Efforts on 2009 H1N1 Flu Virus

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

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

These teams work with the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, other HHS agencies, and national and international partners. The teams include: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team.

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

I would like to provide a brief summary of the focus of each team. This management approach is flexible and likely to change over time. It has already changes in response to evolving events.

Vaccine Team

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

Members of the team are working collaboratively with CDC and other partners in efforts to grow and genetically engineer the 2009 H1N1 Flu Virus in the laboratory for possible use in a vaccine. FDA is also beginning to prepare reagents that will be essential to help manufacturers produce and test the vaccine. The Vaccine Team also is working with CDC, NIH and other WHO centers on laboratory studies that may help us better understand this new virus, including whether seasonal flu vaccines may provide some protection against the 2009 H1N1 Flu Virus.

At the policy level, the Vaccine Team is fully engaged in discussions with the Biomedical Advanced Research and Development Authority (BARDA), a component of ASPR in HHS. These discussions also include the National Institutes of Health (NIH) and manufacturers on the issue of designing and initiating clinical trials to evaluate the immune response to vaccines derived from the 2009 H1N1 Flu Virus and on options for vaccine production and dosage regimens. FDA is a WHO/Pan American Health Organization collaborating center and is working closely with WHO on vaccine issues, including testing and development of seed strains in preparation for vaccine development. FDA is also fully engaged with its sister regulatory agencies throughout the world. In collaboration with CDC, FDA is also preparing to monitor the safety of the vaccine, were it to be utilized.

Antiviral Team

The goal of the Antiviral Team is to identify and evaluate antiviral drugs that can be used to prevent and treat illness caused by the 2009 H1N1 Flu Virus and to facilitate access to these medications. This team led FDA's efforts to issue the April 27, 2009, Emergency Use Authorizations for Relenza and Tamiflu. In addition, the team is in communication with manufacturers to explore potential investigational options for treatment of the 2009 H1N1 Flu Virus. Like the Vaccine team, the Antiviral Team is working closely with our colleagues in other HHS agencies and with our sister regulatory agencies throughout the world, including, Mexico, Canada, the European Union, Australia, and Singapore.

In Vitro Diagnostics Team

The goal of the In Vitro Diagnostics Team is to identify and evaluate in vitro diagnostics that can help test for the 2009 H1N1 Flu Virus. This team led FDA's efforts to issue the April 27, 2009, Emergency Use Authorization for the rRT–PCR test developed by CDC. This team regularly communicates with ASPR, BARDA and manufacturers regarding potential shortages with the FDA-approved rapid influenza A test.

Personal Protective Equipment Team

This team works to facilitate the availability of personal protective equipment that may help reduce the risks from exposure to the 2009 H1N1 Flu Virus. This team led the efforts to issue the April 27, 2009, Emergency Use Authorization for disposable N95 respirators. The team regularly communicates with manufacturers regarding current demand and ability to increase production if needed to meet expected demands. The team is working with CDC on public communications about appropriate use of various forms of respiratory protection.

Blood Team

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

Shortage Team

The Shortage Team works to facilitate the availability of antiviral drugs to the American public. The team participates in daily calls with the ASPR's Biomedical Advanced Research and Development Authority and manufacturers to assess current needs and availability of these products. FDA has alerted consumers to the possibility of spot shortages in the consumer market and to encourage appropriate purchasing practices, and will be referring private individuals, including health care

providers, to their State and local health departments to obtain information about product availability in their locale.

Consumer Protection Team

This team has the goal of protecting consumers from fraudulent and potentially dangerous FDA-regulated products or other promotions for products that claim to diagnose, prevent, mitigate, treat, or cure the 2009 H1N1 Flu Virus.

FDA considers the promotion and sale of products that have not been approved, cleared or otherwise authorized by FDA to diagnose, mitigate, prevent, treat or cure H1N1 Flu virus to be a potentially significant threat to the public health. Many of these deceptive products are being sold over the Internet through illegitimate web sites. The operators of these web sites take advantage of the public's concerns about H1N1 influenza and their desire to protect themselves and their families. The fraudulent products come in all varieties and could include dietary supplements or other food products, or products purporting to be drugs, devices or vaccines.

FDA has an aggressive strategy to identify, investigate, and take action against individuals or businesses that wrongfully promote products in an attempt to take advantage of this current public health emergency. In addition, on April 30, FDA asked the public to voluntarily report suspected criminal activity, Websites and other promotions for products that claim to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 influenza virus. As a further effort, on May 1, FDA issued a joint announcement with the Federal Trade Commission alerting the public to be wary of deceptive products that may be offered for sale over the Internet via illegitimate web sites. On May 4, FDA began posting a list of any firm issued a warning letter for such practices.

Fiscal Year 2006 Influenza Pandemic Funding

During fiscal year 2006, this subcommittee had the foresight to appropriate $20 million to FDA for pandemic influenza preparedness in an emergency supplemental appropriation. The fiscal year 2006 appropriation allowed FDA to invest in priorities that are critical to America's preparedness for an influenza pandemic. This $20 million supplemental became part of FDA's base resources in the Vaccine Program and allowed FDA to achieve a higher state of preparedness for events like 2009 H1N1 flu virus outbreak. I would like to report to you on what FDA achieved with the fiscal year 2006 funding and how the work begun in 2006 makes us better prepared for today's response to the 2009 H1N1 flu virus.

FDA invested pandemic influenza supplemental funding in three key areas: strengthening our capacity to expedite the development of flu vaccines, conducting essential monitoring and inspection of flu vaccine manufacturers, and conducting FDA-wide pandemic planning and preparedness activities.

Strengthening FDA Capacity to Expedite Flu Vaccine Development:

Within FDA's Center for Biologics Evaluation and Research (CBER), FDA expanded its capacity to expedite development, evaluation and licensing of additional flu vaccines and manufacturing facilities to meet pandemic preparedness needs. The expanded science capacity funded through the supplemental allowed CBER to work, in collaboration with ASPR/BARDA, on science, product review, and product guidance to facilitate the development and evaluation of new technologies, including recombinant and cell-based technologies. Increased funding also allowed CBER to develop better tools and systems for monitoring the safety and effectiveness of vaccines. With these resources, CBER provided highly interactive advice to manufacturers on product development and worked closely with ORA on inspection issues for vaccine manufacturing facilities.

CBER constructed high containment facilities to safely grow and genetically engineer pandemic influenza viruses and support vaccine development. CBER also expanded its testing program to speed the release and distribution of influenza vaccines and expanded its capacity to produce and distribute reagents to manufacturers. Reagents are used to determine the potency of influenza vaccines.

CBER scientists developed new methods and techniques to characterize influenza vaccines and to measure protective immune responses, which help assess the effectiveness of pandemic influenza vaccines. CBER also defined an accelerated approval pathway for both annual and pandemic influenza vaccines based on the immune response, and we worked expeditiously to evaluate new vaccines and enhance manufacturing quality.

In April 2007, FDA licensed the first vaccine to immunize individuals against H5N1 avian influenza, and this accomplishment was in part due to the investments in the 2006 pandemic supplemental. For the 2008–2009 influenza season, a record 146 million doses of seasonal influenza vaccine produced by six licensed manufacturers were available for distribution in the United States. CBER staff is working with

public health partners and manufacturers to develop globally coordinated and expedited approaches to vaccine production, to develop new molecular tools to evaluate these vaccines, and to conduct collaborative research projects.

Monitoring and Inspection of Flu Vaccine Manufacturers

The fiscal year 2006 Pandemic Flu Supplemental allowed Team Biologics, a joint effort of Office of Regulatory Affairs field operations and CBER, to conduct annual inspections of influenza virus vaccine manufacturing facilities. These annual inspections have helped to carefully monitor production practices and quality, with the goal of detecting potential problems early and, wherever possible, intervening to address them to better prevent future disruptions in supply or effects on final product quality.

FDA-Wide Pandemic Planning and Preparedness

To strengthen our preparedness for an influenza pandemic, FDA's Office of Crisis Management led the effort to create FDA preparedness plans and conduct a functional exercise to text our preparedness. The exercise occurred in October 2008 and involved more than 600 FDA staff from FDA offices across the Nation. In this exercise, we confirmed FDA's ability to conduct essential functions with reduced staff. We also tested FDA's IT system with a large number of employees accessing the FDA network simultaneously from home or another remote location. The October 2008 exercise provided invaluable lessons, and we are benefiting from those lessons during the 2009 H1N1 Flu Virus outbreak.

Finally, the 2006 Pandemic Influenza funding also allowed FDA to put plans in place intended to ensure continuity of operations during a pandemic. FDA, including CBER, installed dedicated servers, applications, laptops and other software and hardware to support critical personnel that must respond to an outbreak. The goal was to make certain that crucial data and applications for pandemic response are available on a 24/7 basis. FDA also strengthened the system on which we rely on for pandemic flu tracking, status, and reporting. We also enhanced systems and infrastructure that help integrate and expedite work flow for vaccine development, laboratory screening and testing, and adverse reporting.

Conclusion

FDA is fully committed and engaged in protecting the public's health during this difficult time. Among us are laboratory scientists, medical reviewers, epidemiologists, product experts and field inspectors. We will bring every skill and resource we have to this critical mission.

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

VACCINE DEVELOPMENT

Senator KOHL. Thank you Dr. Sharfstein, if it takes 4 to 6 months as we understand it to develop an effective vaccine, we will be into fall before we know it. Do you anticipate that you will be in a position to have a flu vaccine available by that time, if necessary?

Dr. SHARFSTEIN. The way I've been thinking about that question is to separate out into two separate issues. One is the manufacturing capacity and what the system can do, and the other is the virus and the unknowns about the virus.

Because of the investments that have been made the manufacturing capacity is very robust. The question is how the virus is going to behave, and it is impossible to make predictions at this point. The first stage is to get a very good reference screen of the virus, it is growing well and can be used to turn into seed lots for vaccine. And that is the stage we are in now. That has to be completed to get to the next stage.

When you get to seed lots and those pilot amounts of vaccine that can be made by the manufacturers, then it has to be tested for potency, chemically, and then tested in humans.

Those tests could show, boom it works right away. You know, the humans do well. They have a good immune response to it and now it is ready for wholesale manufacturing if that is what we want to do.

But it could also say, wait a second, there is a problem with the immune response, you know, we've got to go back and figure out what we need to do to boost the immune response so that it actually works. And we don't know exactly how that is going to go.

So, I know that there is a lot of interest in saying it is going to be 4 to 6 months, it is going to be 4 months, what is the exact production. The truth is, each of these steps has its own uncertainties, and when you are dealing with a completely new virus you are not sure. It could be that every step moves very quickly. It could be that there is a particular step which causes a big challenge and we have to figure out a way around it.

So, I think the good news is we have the capacity. Once the technical things are solved the capacity to produce the vaccine is there, but there are a lot of unknowns. There is also the unknown of whether we would recommend the vaccine. You know in 1976 there was a decision, very quickly after a new flu virus was identified, to make and also give the vaccine right away. The President announced that he wanted everyone to get a vaccine, it was February 1976 that the new virus was identified at the time and the President announced, I think in March, that he wanted everyone to be inoculated in the fall.

That is not the approach that we're taking now. We want to be prepared with the vaccine, but there may be a separate decision based on the way the epidemic is, the other factors, what we know about the vaccine at the time. We are going to wait to make a decision whether to recommend it.

So, I'm sorry that was not as, you know as clear an answer as I would like to give. I think we are confident that the manufacturing base is there. We believe we are putting all of the expertise we can into it, but there are going to be number of uncertainties as we go through in order to be able to answer when the vaccine will be available and whether we will even recommend it.

Senator KOHL. Are you saying that we first have to determine what particular kind of a vaccination we need, and that will be determined once an outbreak starts occurring? We can then figure out, but then in a sense it is too late; isn't it?

Dr. SHARFSTEIN. No, I think we're at full scale, right now our efforts are full steam ahead to make a vaccine. But we don't know exactly what type of vaccine to make until we test it in people to find out whether it works.

So, for example how much of the flu virus antigen goes into each vial? We don't know that. If you have a certain amount of, like the material for flu vaccine and you don't know exactly how much, you wouldn't know how much goes in each vial until we do the testing to see how people respond to it.

So there are a whole bunch of technical questions before you figure out what kind of—we're going to be working on that before the fall. So that is going on full steam ahead. But how that resolves itself will determine whether a vaccine is available in September,

or October, or November, or how much is available, you know, and when.

There are just these outstanding technical questions. It is really true in any flu season, but it is particularly true now because it is a brand new virus, people don't know exactly how it will behave in all these tests until we actually do the tests.

MAINTAINING FOREIGN MARKETS

Senator KOHL. Secretary Vilsack, what more do you anticipate doing to be sure, beyond statements and urgings that our foreign markets don't get closed to us?

Secretary VILSACK. Senator, we are working in a combination of steps. First and foremost I think it is important for us to continue reiterating at all levels that our pork products are safe and that there should not be any restrictions.

So, we are consistently, on a daily basis, particularly in China and Russia, conveying that message. We are updating them on the science. We are updating them on what we know about this virus to reassure them that there is no scientific basis for bans.

Second, we are working with international organizations to ensure that statements from those international organizations are supportive of what we are saying, that our pork products are safe. Whether it is the WHO, or the OIE, or the FAO, we are working with a variety of international organizations to make sure that those statements are consistent and that they are repeated on almost a daily basis.

We are working with Ambassador Kirk to determine whether or not, as Senator Brownback suggested, there are other issues this is tied to, or tied in with, and if so, whether or not those can be rectified as well.

So, there is an ongoing process. We are working with our Canadian partners to also send a very strong and consistent message. That message is resonating and we are beginning to break through. Central American countries are a good example. We have continued to emphasize Japan's attitude about this, because I think it is instructive to other Asian nations. So, it is a combination of factors.

And the more we know about this situation, the more we continue to talk about it and educate and inform. At this point in time that is the strategy that we are utilizing.

Senator KOHL. Thank you. Senator Brownback.

PREDICTIONS FOR FALL

Senator BROWNBACK. Thanks Mr. Chairman. A couple of questions that seem to really bounce around a lot on the flu situation Dr. Sharfstein is the idea that this is going to, the potential for this to get worse in the fall. It's like you get a bump of flu and then it takes off once it gets to incubate or mutates. When will we get some sense or, do you get a sense about that, at an earlier stage? Does that just come on you? Can you develop any thought as to whether that will indeed happen?

Dr. SHARFSTEIN. That is an excellent question. I think that there are several ways to try to get a sense of it. One is sort of the biological way to study the virus and see whether it is mutating. And so the CDC has been sequencing different viruses that people are

getting from around the country. And they have not found dangerous mutations at this point.

Now, everybody knows that can change. In addition there is surveillance of a number of hospital emergency departments, so the CDC was able to say, you know, when this all started in these States, these emergency departments are seeing more respiratory illness, it is probably the flu. But they also were able to see that it was not that severe, very quickly.

I think the CDC will be right on top of any changes in the severity, given the nature of the surveillance that they have. And some of their surveillance systems they are getting literally information on every patient in certain emergency departments. Confidentially, without identifying information, but they are getting information that allows them to kind of draw a picture of how severe the situation is.

I think that this is a situation where we have to hope for the best, but prepare for the worst. And given the experience of the flu virus in previous seasons, the fact that it does get worse and like Chairman Kohl said, it could come back with a voracity in the fall, that's why all the agencies are really working full steam ahead on preparing a vaccine.

Senator BROWNBACK. Does it come back with a voracity because it mutates?

Dr. SHARFSTEIN. It is a couple factors. It is going to probably pass around the world, so you'll see it. One scenario is it doesn't exactly go away, it may go to the Southern hemisphere during their flu season. That will actually be a key sign to see what it is like there, before it comes back here.

Part of it is that it can mutate. The other thing is that for some, I think not entirely known reason, the flu really does transmit better during flu season. And I'm not sure there is an exact answer as to why. Some people think it is because people are indoors more in the cold. That could be another factor. But if more people get it, more vulnerable people get it. And there will be, you know, many more people dying. Rather than a time when there is just less transmission overall.

So, I think the third thing is, you know I've been testifying and meeting with Dr. Fauci from NIH, who you know, is a world expert on these things. He is, I think, really making the point of being very humble when it comes to a new virus and what can happen. We know the fact that it is new means we're not sure what could happen and we better just be prepared and watch it very carefully.

ZOONOTIC DISEASES

Senator BROWNBACK. For both of you gentlemen, this is another zoonotic disease, I remember the last head of CDC telling me that 10 of the last 12 major health concerns we have had have been zoonotic, where it is animal to humans that it jumps and can go back and forth. Are we sufficiently invested in research on how to handle these zoonotic diseases that seem to be the most ferocious on us?

Secretary VILSACK. Senator, let me first of all say that in the summer of 2008 we began an extensive research project involving swine flu and various strains that we were aware of in an effort

to try to learn more about the impact of this particular influenza. As a result of that work we are in a position to integrate this recent strain and we're going to accelerate our efforts to try to learn more about it.

So, in a sense we began that research in July 2008. We continue this 2-year project, which is a combination of work between us and CDC to understand more about the mechanics, if you will, of the flu.

I will say that it is fairly obvious that the amount of resources that have been dedicated to USDA and to animal research generally has been relatively flat in terms of investment over the last several years.

And so that has required us to prioritize and to make decisions about what gets researched and how. And, of course, we get a great deal of instruction from members of Congress about concerns that they have that are particular to their region, and very important to agricultural production and livestock production.

We will hopefully have an opportunity with a new administration to take a look at the structure of our research program.

Senator BROWNBACK. But you're going to have to do them back and forth. This is going to be both animal and human that the research needs to take place and you're going to have to work with CDC and other places to make sure these are, they go back and forth.

Secretary VILSACK. And the flu project is, in fact, a joint project between CDC and USDA. So we are working in concert with CDC on that particular project and there are a number of interagency hearings and memoranda that we have entered into. So that work has started and will continue. And we are going to make sure that we prioritize the research as best we can with the resources that are provided to us.

Dr. SHARFSTEIN. If I can just say before I took this job I was the Health Commissioner in Baltimore city for 3 years, and the public health world is very clear that there needs to be a lot of attention to the issue that you're raising. The West Nile Virus, as you may know, was really evident in birds and it took quite a while for people to realize that there was something new going on in birds, and that was actually transmitted over into humans.

I would say in addition to the basic research, to understand that the surveillance systems and bridging the surveillance systems between animal diseases and human diseases, is something that at a public health level is extremely important. And you know, it is something that I think the CDC probably at the Federal level has a big interest in. Especially given the very kind of cautionary tale of what happened with West Nile.

BORDER SURVEILLANCE

Senator BROWNBACK. Mr. Chairman, just one final thought to Secretary Vilsack: I have had other members raise to me that we have a number of agricultural workers coming into the United States from around the world, but particularly from Latin America, and concern about the flu virus, and I presume that is something you're going to be looking at, or ICE will be looking at and con-

cerned and watching taking place, right? I appreciate your thoughts on it.

Secretary VILSACK. Senator, first I think it is fair to say that significant aspects of agriculture are dependent on seasonal workers. And it will be important for us to continue to be vigilant at the borders as Homeland Security currently is, to ensure that the people coming into this country, from wherever they are coming in, as Dr. Sharfstein suggested this is a global issue, so it really doesn't make any difference where they are coming from they can be carriers. So, we need to continue to be vigilant at the borders at all points of entry for all people coming into this country. And I have been working with Secretary Napolitano to ensure that there is adequate training and adequate understanding of what to look for. And she has indicated to me that they are working very, very hard to make sure that the people who are suspected of this are, in fact, stopped and potentially questioned and possibly quarantined for a period of time.

Senator BROWNBACK. It is a tough issue because we need a lot of support and help within the agricultural industry, but it also has to be, you know safe, that is safety first.

Secretary VILSACK. It is a balance absolutely. It doesn't do much good for the market if we have situations like this.

Senator KOHL. Thank you, Senator Brownback. Senator Pryor.

PORK CONSUMPTION

Senator PRYOR. Thank you Mr. Chairman. I'd like to start with you Dr. Sharfstein, on the World Health Organization. They recently said that pork products from infected meat should not be consumed by people. Their comments, as far as I understand it, seem more cautious and maybe even at odds with what USDA, or the food agricultural organization, the world organization for animal health and others have said.

Can you talk about the science of that for a minute?

Dr. SHARFSTEIN. Sure. My understanding is that the WHO has been pretty clear, so I want to hear from you more what the specific concern is, but I understand that they have said that influenza viruses are not known to be transmissible to people through the eating process of pork or other food products derived from pigs. That this virus has not been shown to be transmissible to people through eating pig meat or other products derived from pigs. And that heat treatments commonly used in cooking meat will readily inactivate any viruses potentially present in raw meat products. And that pork and pork products handled in accordance with good hygienic practices will not be a source of infection.

So, from what I have heard from the team inside FDA is that WHO has been pretty good on this.

Senator PRYOR. You guys are pretty much on the same page then?

Dr. SHARFSTEIN. Yes, yes. I think there has been—I don't know if you know anything about that?

Secretary VILSACK. Senator, if I might clarify. I think yesterday there was a question that was hypothetically answered and responded to by someone from WHO that suggested as your question indicated. Today there has been a clarification made by WHO that

is very consistent with what the Doctor just indicated, which is that pork products are safe and safe for consumption. And that there really is no scientific reason for banning pork or pork products. And we are working very, very hard, Senator, very hard, to make sure that all of the international organizations are very consistent with their language. We appreciate their renaming this after the media basically took the name swine flu. We appreciate their assistance. But it was clarified today, and it was an unfortunate circumstance which led to that.

TRADE STATUS

Senator PRYOR. That is great. That is helpful. I must be working on yesterday's news, but thank you very much. And let me ask you, Secretary Vilsack, if I may as a follow-up, right now as it currently stands how many countries are either banning our pork from North America, or seriously contemplating that, do you know?

Secretary VILSACK. Senator, I want to make sure I get the number right. Twenty-two countries have banned pork products or pork, either from our country totally, or from various individualized States within the country. That number was larger, as I indicated earlier, Central American countries have indicated a desire to ban and they have reversed that.

We are continually working, as I indicated earlier in response to the chairman's question, we are continually working with the U.S. Trade Representative, and with international organizations, with our own field offices, with our Foreign Agriculture Service to convey a very consistent and clear message. And we are going to continue to do that.

I think we are beginning to have some success. And I think the fact that there are several countries that have reversed bans, or several countries that were considering them that didn't go through, or perhaps modified what they were doing is an indication that we have had some success, but we have got more work to do.

IMPORTS OF POULTRY PRODUCTS

Senator PRYOR. Do you have any indication that that number 22 will go down in the next week so or? Or do you know that yet?

Secretary VILSACK. I don't know that. Our hope is it does go down and as I said earlier, we have been focusing specifically on China and Russia because those are the two large importers of our pork and pork products. We have been working daily with ministries in those two countries to provide them up-to-date information and respond to questions that they have.

We know that our Canadian counterparts are doing the same and we hope that in the short term those situations which are, and decisions which are not based on science, and not based on international rules are reversed.

Senator PRYOR. Thank you. I have just one more question, Mr. Chairman, and that is, it is a follow-up to Secretary Vilsack, and that is that I know in the omnibus appropriation there was a section 727 added on the House side, that basically prohibits funding from being used to establish or implement a rule that would allow for importing poultry products from China.

And I know you have been in discussions with China about pork and imports, exports from the United States into China about pork, and there is this section 727, do you have any indication that China is, you know, part of their contemplation on this is just retaliation for 727?

Secretary VILSACK. Senator, I have no specific knowledge of that, but to amplify, we are working very, very hard with Members of Congress who have concerns about food safety, to reassure them that we can take steps and will take steps to make sure the products that are imported from China into our country are, in fact, safe.

We're in the process now of preparing and providing some information to Members of Congress at their request, to begin that process of reassuring them. I will be meeting with the Chinese minister I think next week, and I'm sure this will be a topic of conversation as will the pork ban, if it is still in place when the minister arrives.

Senator PRYOR. Thank you both.

Secretary VILSACK. Thank you, sir.

Senator KOHL. Thank you, Senator Pryor. Senator Bennett.

OUTREACH

Senator BENNETT. Thank you very much, Mr. Chairman. Mr. Secretary and Dr. Sharfstein, let me thank you for following up on what Senator Pryor talked about. Let me thank you for your effort to make sure that the people understand that this does not come from eating of pork products.

We have a significant industry, the pork industry in Utah, and they have been affected by the publicity here. People think back of Avian flu when people wouldn't eat chicken, indeed I traveled in parts of the world during that period of time and you could not buy scrambled eggs for breakfast at some of the supposedly best hotels in the world, because everybody was afraid of the connection to the birds and they were slaughtering huge populations of birds, chickens, whatever it might be throughout Asia.

Can we keep that publicity up, that we don't need to slaughter pigs, that we don't need to avoid bacon wrapped burgers at Wendy's, or wherever it is you can buy that. All of these things are not an enormous danger.

Secretary VILSACK. Senator, I can assure you that every day we are reinforcing that message, and we're doing it in the context of reminding the people of this country, when other countries ban or place unfair restrictions on trade that it not only impacts the pork producers in that respect, but it also potentially dampens consumer activity here in America.

And I want to take this opportunity by virtue of your question, to remind all of America that there are hardworking farm families that are playing by the rules, working hard every day to put food on our tables, and through no fault of theirs, absolutely no fault of theirs, and because of a mis-messaging from, and a convenience on the part of those reporting all of this, they are now suffering a significant financial hardship and stress.

We will reiterate every day, pork products are safe, safe to consume, and safe to import. We will continue to do that until this crisis has passed.

ANTIVIRAL MEDICATION

Senator BENNETT. Thank you. I appreciate that statement and the passion behind it, as I share that.

Now, I understand the chairman raised with you the question of how long it takes to develop an antiviral vaccine before I came in.

As part of your incident management approach you have a shortage team that attempts to spot shortages in the consumer market of antivirals. Can you give us an overall view of where you think some of the shortages are, in addition to your answer to the chairman's question about timing, there is always the question about distribution. Again, going back to the experience with avian flu, we had the concern that, well there's enough here, but there's not enough there. And could you just reassure us all, or inform us all if reassurance is too strong a word, of what the various problems would be and how quickly you think you can get them revolved.

Dr. SHARFSTEIN. Sir, I'm happy to answer that. Let's talk about the medicines to treat flu and then the vaccine second.

Senator BENNETT. Right.

Dr. SHARFSTEIN. The medicines to treat flu, there is, the government invested and I'm sure through your committee, or through the Senate, a significant amount of money in building up stockpiles of antiviral drugs.

Senator BENNETT. Right.

Dr. SHARFSTEIN. 50 million or so courses for the United States. And so far we're not even touching the top of that in terms of use. A quarter of the State's supplies have already been in the process, or have already been distributed to the States. And so in the public side there are a tremendous amount of resources that have already been mobilized. And if the problem were to become worse, people who needed the treatment would be able to get it. Up to quite, it would have to be an extremely severe problem to really be pressing that.

It doesn't look like it's going to be that any time soon.

At the same time the manufacturers are actually ramping up production in concert with FDA where, you know, if they need to use a new distributor, or something like that, we are going out and making sure that they are all set so that they can keep doing that. And we actually had a whole bunch of product that just needs to be put into packs, so they have been doing that.

So, they are actually meeting, increasing production for the longer term, and we have the stockpile.

In the private side, which is what the pharmacies have, there have been spot shortages, so in a particular area a pharmacy may sell out of Tamiflu as people might go and try to get prepared and have some at home, or something like that.

There are some attempts to reduce that on the private side. The companies are working with suppliers and our team helps them spot those shortages, but what people should know is, even if they can't get it at their pharmacy right now, their public health department has a lot of it. And there is not an overall shortage of these antivirals right now at all.

ANTIVIRAL VACCINE

On the vaccine side, it relates to, as I was saying before, the complexity of the vaccine. We have the infrastructure to make a lot of vaccine, and actually one of the smartest investments that was made by the Federal Government was actually the chickens. There are flocks that were purchased to make eggs just in case of a pandemic might happen, and if there was no pandemic those eggs go into cakes and the Government gets part of the money back.

And those eggs are basically sitting around making, I'm sorry, those chickens are sitting around making eggs, making eggs and now it is like their moment. And those eggs are going to be able to be used. It was 5 years ago when there was a flu vaccine shortage. People were very concerned about the egg supply. And people thought, depending on the time of year, if the pandemic hits, it will take months to be able to get eggs, even to begin to make the flu vaccine. But now we've got a ready supply of eggs. And because it is an egg based vaccine for the most part still, those eggs can go right into the process, the plant that FDA licensed yesterday can be used for that. And really the manufacturing capacity is there. The question is going to be more about the virus, how it behaves in clinical studies, how it behaves in the grower tanks. And that's going to determine whether, you know, how many months it takes, or how much vaccine is available how quickly. There are some just unanswered scientific questions because it is a new vaccine. But the good news is the manufacturing capacity, the eggs, all that is there. And we are working with NIH and CDC to think a couple steps ahead. We are helping things along. Even though we don't have the pilot lots for clinical studies, what would a clinical study look like? Let's get it all set up in advance, and then as soon as we have the pilot lots we can do it.

So, we're going to try to facilitate everything we have and have the only, you know, delays, or not really delays, the only steps be the scientific steps, and not, you know, we've got the eggs, we have got the facilities. We are going to have all of the designs of the studies, all that will be ready to go.

We just have to, you know, get the best minds and the best science working on the vaccine itself.

Senator BENNETT. Thank you for that. I think that is a very helpful review for the public to understand. So, let me summarize and then you tell me whether or not I'm right or wrong.

I like the word you used earlier when you say we're very humble with respect to this, which means we're not predicting, oh, everything is going to be under control, and we're smart enough to have everything figured out. We are very humble. But at the same time it sounds as if we are really quite well prepared. So that if it does, in fact, turn into a pandemic, as there are some indications that it might, that we are taking all the steps we need to take to deal with it.

Is that a fair summary of what you are trying to tell us this morning?

Dr. SHARFSTEIN. I think that is an excellent summary. Much better than I said.

Senator BENNETT. Thank you, Mr. Chairman.

Senator KOHL. Thank you. I am trying to follow that to another point. Are you suggesting that we will be prepared for an outbreak this fall if it occurs?

Dr. SHARFSTEIN. I think that we are, I anticipate that there will be everything done to prepare for an outbreak this fall. But because of the humble issue, because we don't know exactly what an outbreak could look like, we don't know about what could happen in vaccine production process, whether this virus is going to behave differently, I don't want to give any guarantees.

I do think that we have the infrastructure and the capacity so that if things play out like we think they will, we will be able to have a good protection for almost any circumstance. But, you know, I think we have to recognize that this is a new situation. And you know, just think about how much this has changed over the past couple weeks when it first started, you know, it looked like one thing and now people are thinking it looks like another thing, and it probably will take a couple more, people will look at it differently over the next few weeks. We are just going to have to, you know, live with a little bit of uncertainty in this.

But I do think that the foundation for preparation is extremely strong. The resources we have, the manufacturing capacity, the partnerships with private industry, the expertise in the Federal Government, all of these things are working very hard to, you know, do everything possible to be prepared. And that personally makes me have some degree of confidence about it. But I do think we have to balance that with the fact that this is a new virus.

AMERICAN MARKET FOR PORK PRODUCTS

Senator KOHL. Secretary Vilsack, has there been a precipitous decline in the American market for pork products?

Secretary VILSACK. Senator, we have not seen a significant decline, and I appreciate the fact that American consumers have taken our message to heart. But any time you have the kind of publicity that this particular influenza has received, and the concern that has been spread globally about it, you always are concerned and worried that it might. Clearly, pork producers have suffered, and will continue to do so until we get this turned around.

And so we are very, very conscious of the stress that this industry currently has. We are in the process of obviously looking at ways in which we can be of assistance and help.

Senator KOHL. How did it happen that this thing has been so mischaracterized to the American public?

Secretary VILSACK. I think part of the problem was, and Dr. Clifford could probably do a better job of explaining this, the make-up of this particular flu is multifaceted, and unfortunately in the early, early days of reporting, the media latched onto one, but not the only component of this flu as a way of describing it. And once it got described in that way, it became a bit difficult to redescribe it.

We have seen consistency within Federal Government. We've seen consistency with our State partners. We have been in contact with State agricultural commissioners and secretaries and they have re-enforced the message.

We have seen consistency from our Nation's Governors, we've also seen consistency now with the message on international partners as well. And we are going to continue to reinforce the message. But I think part of it had to do with sort of the makeup of the flu. But Doctor, if you could, if I might.

Senator KOHL. Dr. Clifford.

VIRUS COMPONENTS

Dr. CLIFFORD. Thank you Chairman Kohl. Actually, this particular virus as Secretary Vilsack has indicated has different components. Many of these components have been found in swine, but this particular virus is made up of avian, human and swine components. And when these things get into a particular species, then they get kind of tagged, when they are first found they are tagged with that species as being swine flu, or avian flu or human flu.

So, this particular virus has both Euro-Asian lineage that has been found in avian species that was transferred to pigs. And then the United States, the North American part of this, has been found has reassorted from humans, chickens and swine and has been in the swine population. So, it has reassorted itself. And where that occurred we don't know. We don't know if it occurred in swine initially, or not. But all indications are that there has been no findings of this particular virus in the U.S. swine population to date. There has been no reported cases of this in Mexico.

And we have just had the first case identified in Canada, where it was associated with humans passing it to pigs. So, this appropriately should be tagged really more of a human flu because it is passing from human to human.

Senator KOHL. Senator Brownback.

VACCINE PLANNING

Senator BROWNBACK. Dr. Sharfstein, I was looking at the notes here that there is a good possibility this fall we may ask people to get vaccinated for two different types of flu?

Dr. SHARFSTEIN. I think it is premature to be thinking about what could happen this fall. I think that I was talking a little bit before about 1976 when right after the new virus came on the scene all of the health agencies, even the President were saying, we know exactly what is going to happen 6 months from now. I think everybody looks back on that as a mistake that was made by everyone who was involved, in that they didn't adopt their thinking to the nature of the vaccine and the nature of the epidemic at the time.

And I think that we're going to have to walk through a bunch of decisionmaking points. How much vaccine gets made. It will be a decision that is made a little bit later, once we know what the right vaccine to make is.

Senator BROWNBACK. True, but you have got to make that within a timeframe that you can produce a new vaccine.

Dr. SHARFSTEIN. Absolutely.

Senator BROWNBACK. And you're already producing, are you already producing a fall vaccine for a normal influenza?

Dr. SHARFSTEIN. Yes, that is already being produced.

Senator BROWNBACK. That is already being produced now.

Dr. SHARFSTEIN. That is in full scale production right now. Probably more vaccine than we have ever had before.

Senator BROWNBACK. So, you will have to make the cut point, or the call on this for H1N1 by when?

Dr. SHARFSTEIN. Well, I think right now they are producing the reference strain, which is the strain that grows into the actual vaccine. The way you make the vaccine is you take the key elements of this new virus that are new, that need to be stimulating the immune system for the response. You are going to take those out and you plug it into another flu virus that grows really fast and is a good strain for a vaccine.

So, it is actually like you create this new virus to make, then it gets treated and killed for the injectable, or dealt with differently for the live attenuating.

So, that process is going on now to develop a reference strain that could be used. Then you've got to make the pilot lots. Then you've got to develop your strategy, and then there is a moment that comes when, and you'll have to take a look when you are at that moment, when you are done with the seasonal flu vaccine supply, are in the middle, is there still some seasonal to be done? Do we want to interrupt that or not?

Senator BROWNBACK. When is that decision point?

Dr. SHARFSTEIN. The decision point——

Senator BROWNBACK. What time?

Dr. SHARFSTEIN. Probably within the next 1 to 2 months, I think.

Senator BROWNBACK. That you've got to make the call whether or not to vaccinate for H1N1?

Dr. SHARFSTEIN. No, that call is not getting made till the fall. But the call about whether to immediately switch over production is probably going to have to be made within the next 1 to 2 months.

Senator BROWNBACK. What if the call is made we should do both? We should do it, because we lose what 35,000 people a year to flu?

Dr. SHARFSTEIN. Right. We're going to have——

Senator BROWNBACK. If you don't vaccinate for that you could have more people die of the normal flu.

Dr. SHARFSTEIN. That's why it is going to be in part a tough decision. But you should know that the seasonal flu vaccine for this fall is well into production. Those doses will be there, tens of millions of doses. So, we're really only talking about the tail end there.

Whether we cut off the tail end of that production. We are going to have a lot of seasonal flu vaccine no matter what this fall. It is a question of whether you have to cut off the tail end to switch over. That will be a call that will have to be made, probably in the next 1 to 2 months.

Then the decision to vaccinate is going to be made probably in the fall. Let's say the decision is made to make a whole lot of H1N1 vaccine. That is still different from the decision to recommend that people get it.

Senator BROWNBACK. I understand. I am just trying to get, what I hear you saying then is that you will get your production for the normal flu season, you are going to try to do everything early so you've got it. And then the switch over, that will be done in a month or two, that you switch over the H1N1 turning the production machinery toward that?

Dr. SHARFSTEIN. Right. I would say that the regular flu vaccine is already in production. And it is nothing different than what was already happening. This is the season for that. And then only when you're ready to go to production for the H1N1 does it become a decision that you make and that will depend on when we're actually ready. As that decision approaches we'll be able to look at the seasonal flu vaccine supply and say, are we 80 percent done, are we 90 percent done; are we 100 percent done? And then it is not even an issue. But that decision will come when that decision needs to be made, based on whether we're at that point with the production process.

Senator KOHL. Gentlemen, does the USDA or FDA have a role to play in the Southern hemisphere with respect to manpower and supplies and the flu?

Dr. SHARFSTEIN. I can answer for FDA, definitely. There are a couple different levels. One is that we're in contact with regulatory agencies around the world about the appropriate way to treat this, and all the different products and tests, and the things that have been licensed or authorized I should say, by FDA.

And in addition through CDC we're going to been keenly interested in what is happening there, in terms of what it means for how severe it could be in the United States in the fall. That will affect a lot of issues that relate to the vaccine production.

Senator KOHL. Secretary Vilsack.

INTERNATIONAL ASSISTANCE

Secretary VILSACK. Senator, we have specifically offered help to Mexico through the Food and Agricultural Organization of the United Nations and we will continue to offer that help. We also have APHIS contacts and communication and attachés in countries throughout the world. They are prepared to serve as local contacts to animal health service organizations and operations in foreign countries. If we receive any requests for assistance and help as it relates to this, we will do everything we can to the extent we can to provide help and assistance and technical assistance.

I'm sure that as we learn more about this from the research that is now taking place, we will be in a position to share what we know with scientists and researchers in other countries.

CONCLUSION OF HEARING

Senator KOHL. Well, we thank you for being here today, it has been informative and instructive. And I think we have a sense of comfort that you are really on top of it and doing everything you can and that you have a sense of confidence that we are going to be successful. Thank you for being here.

[Whereupon, at 11:12 a.m., Thursday, May 7, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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