STOPPING AN AVIAN INFLUENZA THREAT TO ANIMAL AND PUBLIC HEALTH

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

JULY 8, 2015

Available via the World Wide Web: http://www.fdsys.gov/

Printed for the use of the Committee on Homeland Security and Governmental Affairs



U.S. GOVERNMENT PUBLISHING OFFICE ${\bf WASHINGTON} \ : 2016$

 $21\text{--}257\,\mathrm{PDF}$

For sale by the Superintendent of Documents, U.S. Government Publishing Office Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800

Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

RON JOHNSON, Wisconsin Chairman

JOHN McCAIN, Arizona ROB PORTMAN, Ohio RAND PAUL, Kentucky JAMES LANKFORD, Oklahoma MICHAEL B. ENZI, Wyoming KELLY AYOTTE, New Hampshire JONI ERNST, Iowa BEN SASSE, Nebraska

THOMAS R. CARPER, Delaware CLAIRE McCASKILL, Missouri JON TESTER, Montana TAMMY BALDWIN, Wisconsin HEIDI HEITKAMP, North Dakota CORY A. BOOKER, New Jersey GARY C. PETERS, Michigan

KEITH B. ASHDOWN, Staff Director
GABRIEL S. SUDDUTH, Senior Professional Staff Member
GABRIELLE A. BATKIN, Minority Staff Director
JOHN P. KILVINGTON, Minority Deputy Staff Director
ROBERT H. BRADLEY II, Minority Professional Staff Member
LAURA W. KILBRIDE, Chief Clerk
LAUREN M. CORCORAN, Hearing Clerk

CONTENTS

| Opening statements: Senator Johnson Senator Carper Senator Tester Senator Ernst Senator Peters Senator Baldwin Prepared statements: Senator Johnson Senator Carper | Page 1 2 17 20 22 25 41 43 | | | | | |
|--|--|--|--|--|--|--|
| WITNESSES | | | | | | |
| Wednesday, July 8, 2015 | | | | | | |
| John R. Clifford, D.V.M., Deputy Administrator, Animal and Planet Health Inspection Service, and Chief Veterinary Officer, U.S. Department of Agriculture Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, and Assistant Surgeon General, U.S. Public Health Service, U.S. Department of | 4 | | | | | |
| Health and Human Services | | | | | | |
| ural Resources and Environment, U.S. Government Accountability Office Jack Gelb, Jr., Ph.D., Director, Avian Biosciences Center, College of Agri- | | | | | | |
| culture and Natural Resources, University of Delaware | | | | | | |
| Scott Schneider, Owner, Nature Link Farm, Jefferson, Wisconsin, and President, Wisconsin Poultry and Egg Industries Association | | | | | | |
| Alphabetical List of Witnesses | | | | | | |
| Clifford, John R., D.V.M.: | | | | | | |
| Testimony | 4 | | | | | |
| Prepared statement | 45 | | | | | |
| Testimony | 8 | | | | | |
| Prepared statement | 58 | | | | | |
| Gelb, Jack Jr., Ph.D.: Testimony | 10 | | | | | |
| Prepared statement | 73 | | | | | |
| Schneider, Scott: | | | | | | |
| Testimony | 12 81 | | | | | |
| Schuchat, Anne M.D.: | 01 | | | | | |
| Testimony | $\begin{array}{c} 6 \\ 52 \end{array}$ | | | | | |
| APPENDIX | | | | | | |
| Chart referenced by Senator Johnson | 84 | | | | | |
| Statement submitted for the Record from Dave Rettig, Rembrandt Foods | | | | | | |

STOPPING AN AVIAN INFLUENZA THREAT TO ANIMAL AND PUBLIC HEALTH

WEDNESDAY, JULY 8, 2015

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

man of the Committee, presiding.

Present: Senators Johnson, Lankford, Ernst, Sasse, Carper, McCaskill, Tester, Baldwin, and Peters.

OPENING STATEMENT OF CHAIRMAN JOHNSON

Chairman Johnson. Good morning. This hearing is called to order.

I want to first thank the witnesses for taking the time to come here this morning and the time you have taken to provide some very thoughtful and, I think, important testimony.

This hearing is really about the recent outbreak of avian influenza (AI), bird flu, that has plagued, really, primarily the Upper Midwest, although it has—we have a map¹ here—unfortunately, we do not have a chart—but it has been sprinkled out west, a little bit further east. Fortunately for Senator Carper's State, it has not gone up and down the Eastern Seaboard yet.

But, this is a serious issue. We have a mission statement for this Committee: To enhance the economic and national security of this country. This is an economic issue, and it is a very serious one. I do ask for unanimous consent to offer my written opening statement for the record,² but I do want to just cover some quick statistics here because I think we may be interrupted by votes a little bit later on.

But, in terms of how this is going to effect our economy, there are 300 million egg-laying chickens. Over 40 million of them have been affected by this and have been destroyed. That is 13.3 percent of the total egg-laying population. There are 238 million turkeys raised every year. Eight million have had to be euthanized because of this outbreak. That is estimated to be about an \$8 billion impact in our economy. And fortunately, we have not seen a new outbreak since about mid-June, and the migration period is over, but it will startup again in the fall. And, so, we are extremely concerned

¹The map referenced by Senator Johnson appears in the Appendix on page 84.

about what is going to happen when we have the migratory bird

pattern once again.

The purpose of this hearing really is to examine what our initial reaction was to the outbreak this spring and also ask and really explore what our reaction is going to be, how we are going to further limit the damage for additional outbreaks that—I hate to say it—probable in the fall, including—we do not want to alarm anybody here, but we have all heard about bird flu potentially mutating from animals to human beings, and that is why we have a pretty good panel here to discuss that and try and minimize the concern, but also provide assurance that we are going to be monitoring that and do everything we can if something were to happen.

But, we have a real good panel, people from the U.S. Department of Agriculture (USDA), a representative from the Centers for Disease Control (CDC), from the Government Accountability Office (GAO), a professor from Senator Carper's home State, and Senator Carper will introduce Professor Gelb, and we have a victim, not a direct victim—you are a human—but somebody from the State of Wisconsin who lost his entire egg-laying flock of 200,000 chickens. Scott Schneider is here to just describe what he has gone through and his appreciation for what the USDA has done, but also just the frustrations in terms of getting compensated in a timely manner, as well, and that is part of the hearing.

But, again, this is, I think, a very important hearing and totally

appropriate for this Committee.

So, with that, I will turn it over to our Ranking Member, Senator Tom Carper, who, like I say, so far, Delaware has dodged the bullet, and let us hope that remains the case throughout the year.

OPENING STATEMENT OF SENATOR CARPER

Senator Carper. Thanks. We have not always dodged the bullet, as Jack Gelb knows. So far, we have been lucky. What is the saying, it is better to be smart—or lucky than smart. Lucky than smart. So far, pretty smart, and so far, we have been lucky. It does not mean we will always be.

I welcome you all today. I especially want to welcome Jack Gelb from Delaware. Mr. Chairman, I want to thank you and your staff, others who worked on this hearing, and we look forward to hearing

from each of you.

As some of you in the room know, the issue of avian influenza is important, I think to our country, to all of us. To the Delmarva Peninsula, which includes parts of Delaware, Maryland, and Virginia, it is hugely important. We raise more chickens in Sussex County, Delaware—we only have three counties. Sussex County is the third-largest county in America and we raise more chickens there than any county in America. We raise more soybean there than any county in America. And a big part of our agri-economy, about 80 percent of our agri-economy in Delaware is poultry. So, it is hugely important for us.

My hope is we come away from this hearing more confident than ever in the strength and the importance of America's poultry industry and be better prepared to respond to any further outbreaks,

should they occur.

I think some of you know this, but I am going to say it again. The poultry industry is an integral part of our national economy. It supports over one million jobs nationwide and about \$350 billion in total economic activity every year. Some of the industry is tied, as the Chairman has said, to egg production, which several of our colleagues know very well. Other parts of the industry, as in my home State of Delaware, focus on the kind of chickens we eat, and "Delmarvalous" is actually a word on the Delmarva Peninsula, and we call the chickens we eat, we call them "broilers." I do not know what you call them where you come from, but we call them broil-

As some of you know, the birthplace of the broiler industry actually comes from Sussex County, Delaware, that big county. We are very proud of that. And the industry brought to Delaware about \$3

billion in economic activity, I think, last year.

And, we export our chickens all over the world. The Trans-Pacific Trade Partnership which we are attempting to negotiate and will probably have a chance to vote up or down on later this year, one of the pushes there is to be able to sell chickens into Canada. They keep us out. They impose a 200 percent tariff on our poultry products going into Canada. Needless to say, we do not sell a lot of chickens there. And, Senator Chris Coons has worked very hard to get the markets opened up to Africa, and hopefully, we can be successful in the Trans-Pacific Trade Partnership and Africa and places like that, and instead of exporting 20 percent of our chickens around the world, we will take that to 25 or 30 or even higher.

Some parts of the poultry industry, particularly in the Midwest, continue to grapple with the devastating impacts of the recent outbreak of avian influenza. We have lost millions of chickens and turkeys to this disease and the economic losses are staggering. If that is not bad enough, some of our biggest trading partners have temporarily closed their doors to our poultry exports, and in some instances these bans affect not just one State, but every State that produces poultry products, not just those that have had a confirmed case of avian influenza.

Thankfully, there is also some good news. The frequency of new cases, as we know, has shown significant drops in recent weeks. Broiler chickens have yet to contract the virus. And, as of now,

there is no evidence that there is a threat to human health.

We have farmers all across America to thank for much of this fortunate news. Their efforts, their sacrifices really made a difference. I would also like to recognize our Federal and State agricultural and public health officials for all of their hard work. Our friends in academia and industry have also done a great job.

It is not a time to pat ourselves on the back, not a time to rest on our laurels. The possibility of new outbreaks, even here on the East Coast, is real, and all of us need to remain on high alert. This is especially true as we move into the migratory season in the com-

Today's hearing provides an important opportunity to better understand the threats posed by avian flu. It will also help us examine the steps so many people are taking to not only put an end to this outbreak, but to ensure that new cases do not spring up somewhere else. We should also use this hearing to identify lessons learned from our response as well as any best practices that can make a difference in stopping future outbreaks.

I am especially interested in hearing from Dr. Gelb about measures we have taken in Delaware and on the Delmarva Peninsula that could be applied nationwide to further contain the spread of this virus.

At the end of the day, we all need to work together to stop the spread of avian influenza. We all have a dog in this fight. That is mixing metaphors, I think, but a dog in this fight. We must all continue to act with a sense of urgency to reassure Americans, along with people all over the world, that our eggs as well as the meat from our chickens and our turkeys are safe to eat.

This current outbreak is a very serious matter, no doubt about it. We have experts around the country like those before us today who have dealt with these issues before and are laser focused on stopping the spread of this disease. With continued hard work and coordination and determination, we can and will solve this problem together.

Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator Carper.

It is the tradition of this Committee to swear in witnesses, so if you will all rise and raise your right hand.

Do you swear the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. CLIFFORD. I do.

Dr. Schuchat. I do.

Mr. Currie. I do.

Mr. Gelb. I do.

Mr. Schneider. I do.

Chairman JOHNSON. Thank you. Please be seated.

Our first witness is Dr. John Clifford. Dr. Clifford is the Deputy Administrator and Chief Veterinary Officer for the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). In that position, he provides leadership for safeguarding animal health nationwide. He has served at USDA since 1997 in a variety of positions across the country. Dr. Clifford.

TESTIMONY OF JOHN R. CLIFFORD, D.V.M., DEPUTY ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, AND CHIEF VETERINARY OFFICER, U.S. DEPARTMENT OF AGRICULTURE

Dr. CLIFFORD. Thank you, Mr. Chairman, Members of the Committee, and thank you for the opportunity to testify on behalf of the United States Department of Agriculture.

In recent weeks, the number of new detections of high path AI found in U.S. poultry farms has slowed considerably. In fact, it has been a little over 3 weeks now, I think, for Iowa and over 4 weeks for the State of Minnesota. A few farms impacted by this disease months ago have started the long process of repopulating with new poultry.

¹The prepared statement of Dr. Clifford appears in the Appendix on page 45.

These are bright spots in the largest animal health emergency in our country's history. While encouraging developments, the impact of this unprecedented disease outbreak is still being felt throughout our industries. Trading partners have restricted U.S. poultry exports, and the risk of disease reemerging in the fall is significant.

Our hearts go out to the affected producers, their employees, and the communities they live in and support. I assure you that this disease has the USDA's fullest attention and we are committed to standing with our producers and industry to get them back on their feet.

The Secretary is leading efforts to respond to this virus, to assist producers and maintain trade markets. As we look to the fall, we

will be ready for the challenge.

More than 400 USDA staff and over 2,000 USDA contracted personnel have been working around the clock in every affected State on the response. We delivered over \$180 million in indemnification payments to producers to control the spread of the disease and to help them recover. All told, USDA has committed over \$500 million, an amount more than half of the APHIS yearly budget, in responding aggressively to this outbreak. We can and will request additional funds should we need to.

We have carefully studied and assessed the epidemiology of this virus as well as our response efforts in conjunction with our State and industry partners. We know that wild birds brought this disease to the Western United States in late 2014. As the birds and the virus moved into the Midwest, we saw point source introductions as well as farm-to-farm spread of the virus. Although we cannot pinpoint a single specific practice that caused this, our epidemiological report suggests that lapses in biosecurity were a contributing factor. We have talked at length with our State and industry partners about our findings and the need for all of us to think more comprehensively about on-farm biosecurity.

We all agree that we are in this fight together. We have a shared interest in eradicating this disease and getting the poultry industry

back on its feet.

Last week, we met with industry and State officials to ensure that we have a high level of preparedness to deal with the reemergence and possible spread of this virus come fall. We encouraged our partners to review the existing avian influenza response plans so that they will understand what we expect and what actions we will need them to take should the disease strike.

We are also urging States and industry to develop site and county-level specific depopulation plans for landfilling or composting of birds. Our experience in the Midwest showed that the biggest road-block to efficient depopulation is the lack of ready sites to receive

and process dead birds.

For our part, we are taking proactive steps to be ready for the fall. We are identifying staffing needs and hiring more than 450 additional temporary employees, including 210 animal health technicians and 90 veterinary medical officers. We are also developing a potential vaccine strategy. Should we decide to use vaccine to address the outbreak, we will have the systems in place to do so.

As part of our planning, we are also working with our partners to increase surveillance of wild bird populations. We need to be able to identify the virus' presence as quickly as possible to be able to stamp it out.

Later this month, we will be meeting directly with State veterinarians and industry to discuss the need for more biosecurity. The meeting in Des Moines, Iowa, will help ensure that our collective biosecurity is more stringent and that we are as prepared as we can be for the fall.

I want to thank all of our partners in the industry and the States for their cooperation in this process. Their efforts and their willingness to work with us are appreciated and will help us as we plan for the fall.

Mr. Chairman, this concludes my testimony. Thank you.

Chairman JOHNSON. Thank you, Dr. Clifford.

Our next witness is Dr. Anne Schuchat. Dr. Schuchat is currently the Director of the National Center for Immunization and Respiratory Diseases with the Centers for Disease Control and Prevention, a position she has held since 2005. She is Assistant Surgeon General within the U.S. Public Health Service. She joined the Centers for Disease Control and Prevention in 1988 as an Epidemic Intelligence Services Officer. Dr. Schuchat.

TESTIMONY OF ANNE SCHUCHAT, M.D.,¹ DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND ASSISTANT SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. Schuchat. Thank you, Mr. Chairman and Members of the Committee. I am here to discuss the potential public health impact from the highly pathogenic avian influenza (HPAI) outbreaks in U.S. birds and CDC's actions to prepare for human infections with these viruses.

Influenza virus is a formidable adversary. The virus's propensity to change presents unique challenges, and each human case of infection with an animal influenza virus represents the potential for a pandemic. Strong collaboration between animal and human health sectors and robust domestic and international partnerships are critical to identify, monitor, and respond to viruses of concern, like the highly pathogenic avian influenza viruses currently circulating in birds in the United States.

CDC continues to assess the risk for these viruses for the general public as low. However, people with close or prolonged unprotected contact with infected birds or contaminated environments are likely at greater risk of infection. This includes poultry workers and workers responding to the current outbreaks in U.S. birds.

Although there have been no reported human cases of H5 influenza among Americans to date, CDC is taking action to prepare and ensure that we have the systems and tools in place to protect the public's health. We have issued public health guidance for testing, treatment, and prophylaxis and worker protection.

In January, we posted guidance for clinicians and public health professionals on testing, specimen collection, and processing for people who may be infected with novel influenza A viruses. We

¹The prepared statement of Dr. Schuchat appears in the Appendix on page 52.

posted guidance on the followup and antiviral chemoprophylaxis for people exposed to these viruses. And the Department of Health and Human Service (HHS) amended its guidance on use of antiviral drugs stockpiled for a flu pandemic to be available for use in response to the current domestic outbreaks.

In June, we posted recommendations for worker protection and the use of personal protective equipment. We recommend personal protective equipment (PPE), for those in direct contact or going into buildings with sick or dead birds and carcasses, feces, or litter from potentially infected poultry. Recommended personal protective equipment includes properly fitted safety goggles, disposable gloves, boots, and an appropriate respirator, as well as disposable fluid-resistant coveralls.

We have protocols in place for field investigations and contact tracing in the event of a suspected novel flu case. State health departments are asked to investigate potential human cases of H5 virus infection and notify us within 24 hours of identifying a person under investigation. The States are monitoring the health of workers who have had contact with infected poultry for signs and symptoms of illness that could occur within 10 days of their last exposure. We have also equipped and trained public health labs to detect novel flu strains, including the recent H5 strains, using test kits that we developed and distributed.

We have received samples of these viruses and carry out genetic analyses, which do not show any markers previously associated with increased severity or transmissibility in people. We have also got ongoing studies in animals, including mice and ferrets, to evaluate the transmissibility and disease severity of these viruses. Seasonal flu vaccines do not protect against avian influenza, so we are preparing candidate vaccine viruses for humans, should a vaccine become necessary.

The collaboration between CDC and the USDA is critical to our efforts to protect Americans from avian and other novel influenza viruses with pandemic potential. During the current outbreak, we have coordinated messaging and communications, collaborated on the analyses of the viruses and the development of candidate vaccine viruses, and we have embedded a CDC influenza expert with the USDA Incident Command Unit for this response.

I want to emphasize the importance of our collaboration with USDA and our strong partner networks for successful response to flu and other infectious disease threats. There must be strong public health capacity at the Federal, State, and local levels. Our investments in domestic public health capacity, surveillance, communication, and public health preparedness will help protect the public in this and future outbreaks. Effective preparedness and response requires strong collaboration between public health and clinicians and the health system.

Our global partnerships continue to protect Americans from infectious disease threats like this. We work with ministries of health, public health labs, and the World Health Organization (WHO) to strengthen global capacity to conduct flu surveillance, perform lab testing, and prepare to respond to influenza pandemics. More rapid detection and characterization of novel flu viruses bolsters our Nation's preparedness.

The current H5 avian influenza situation has caused enormous impact on farmers and agricultural communities in several States, but fortunately, it has not yet led to human infections. This is only one of the challenges that influenza viruses pose to our economy and health. We must continue the efforts to detect, respond, and prevent the consequences that these viruses pose here and around the world.

Thank you.

Chairman JOHNSON. Thank you, Dr. Schuchat.

Our next witness is Mr. Chris Currie. Mr. Currie is a Director at the Government Accountability Office, where he leads the agency's work in evaluating emergency management, national preparedness, and critical infrastructure protection issues. He is accompanied by Steve Morris, a Director at GAO's Natural Resources and Environment Team, which leads food safety and agriculture issues. Mr. Currie.

TESTIMONY OF CHRISTOPHER P. CURRIE,¹ DIRECTOR, HOME-LAND SECURITY AND JUSTICE, U.S. GOVERNMENT AC-COUNTABILITY OFFICE; ACCOMPANIED BY STEVE D. MOR-RIS, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Currie. Thank you, Chairman Johnson and Ranking Member Carper and other Members of the Committee that are here today. We appreciate the opportunity to testify before you. Thank you for the introduction. As you mentioned, I handle our work on emergency management and national preparedness issues. Steve, sitting behind me, is responsible for our work on food safety and agriculture and he can answer any questions that I cannot that may come up in that area.

Today, I would like to discuss some key themes and recommendations across GAO's biodefense work, particularly as it pertains to the outbreak of highly pathogenic avian influenza in the Midwest. While we have not evaluated the response to the current outbreak yet, we plan to do so very soon, later this year. We have reported on efforts to prepare and respond to such outbreaks, though. We have also reported at the highest levels on broad national biosurveillance and defense efforts and coordination, all the way down to more specific efforts within sectors like food and agriculture.

It is important to note that biodefense in the United States is a huge and complex effort that requires coordination and cooperation among different Federal agencies, various levels of government, and the private sector. Our work has shown that preparing for emergencies, whether they be natural disasters, accidents, or intentional attacks, requires careful planning to better know who is responsible for doing what, how we will coordinate, and what resources we are going to need.

One key area we have evaluated is biosurveillance at the Federal, State, and local level, and that is a big word, but biosurveillance is the collection, analysis, and interpretation of data to better monitor pathogens in either humans, animals, plants, or in the

¹The prepared statement of Mr. Currie appears in the Appendix on page 58.

food and agriculture sector. Coordinating biosurveillance efforts is a challenge because it requires working across traditional agency boundaries and missions, such as CDC and USDA. For example, Departments of Health and Human Services, Agriculture, and Homeland Security all have separate missions and authorities but have common goals under the Federal framework for preparing for and responding to disease outbreaks.

Planning and coordination are so important because they dictate the actions that will be taken in the event of a real emergency. For example, in 2010, we found that there was no national strategy or designated focal point lead for developing national biosurveillance capabilities. We recommended the Homeland Security Council (HSC), which is within the White House, develop a strategy and

designate a focal point for coordination.

They did issue a strategy in 2012 and designated a focal point. However, that strategy has not yet identified certain resource and investment needs and priorities, which was an element we thought was critical to help prioritize resources across such a complex en-

terprise, such as biosurveillance.

Now, drilling down a little deeper into the area of animal and plant disease surveillance, our findings are very similar. In 2004, the President issued Homeland Security Presidential Directive 9 (HSPD-9), to better coordinate various Federal agencies' responsibilities and efforts in animal and food surveillance. For example, under HSPD-9, the Homeland Security Department is responsible for coordinating efforts across all Federal agencies, like HHS and USDA. However, while DHS has made some efforts, it really has not yet fulfilled that role fully.

In addition, we found that USDA had not developed a Department-wide strategy for implementing all of its HSPD-9 requirements. We recommended that they do so and they told us that they intended to do so, but that resource challenges and certain com-

peting priorities have sort of stalled those efforts so far.

So, back in 2007, we reported on various Federal efforts to prepare for and respond to an avian flu outbreak similar to the one we are facing now and made several recommendations. For example, we recommended that USDA, one, identify the capabilities it would need among Federal, State, local, and private entities to respond to an outbreak; two, develop a response plan that identified various responsibilities and resource needs; three, help States develop their own response plans for high path avian influenza; and four, conduct exercises to actually test these response plans.

Now, USDA implemented all of these recommendations and now these response plans and actions are being tested during a real life outbreak and with some new challenges, as Dr. Clifford mentioned,

such as the disposal issue.

So, we will continue to monitor these efforts and will begin work looking at the specific response later this year.

This completes my prepared remarks and Steve and I would be happy to answer any questions you have.

Chairman JOHNSON. Thank you, Mr. Currie.

I think we will have Senator Carper introduce our next witness. Senator Carper. Thanks, Mr. Chairman.

I am pleased to introduce Mr. Jack Gelb, Jr., the Director of the University of Delaware's Avian Biosciences Center. As the Director, Dr. Gelb coordinates teaching and research activities at the center and participates in national and international outreach. He also receives the center's poultry disease surveillance efforts and worked closely with Delaware's agricultural sector on matters of poultry health. Dr. Gelb is a poultry industry-wide recognized expert.

He is joined today by his wife of 39 years, Becky, joined by their 11 children and their 37 grandchildren in the audience. [Laughter.]

Well, part of that is true. [Laughter.]

His wife of 39 years, Becky, is here. We rode down here on the train together. It was nice to see them. They left all their children and grandchildren at home. They do not have 11 children and 37, but when asked why they have such a healthy family, Jack and Becky also said, "We eat a lot of chicken." [Laughter.]

Jack, welcome.

Chairman JOHNSON. Good thing we do not swear you in. [Laughter.]

Dr. Gelb. Thank you, Senator Carper. Senator Carper. There is an old saying that says, never let the truth get in the way of a good story. [Laughter.]

TESTIMONY OF JACK GELB, JR., PH.D., DIRECTOR, AVIAN BIO-SCIENCES CENTER, COLLEGE OF AGRICULTURE AND NAT-URAL RESOURCES, UNIVERSITY OF DELAWARE

Dr. Gelb. That is very true. Thank you very much, and it is a

great pleasure and, in fact, an honor to be with you today.

Delmarva and the Delmarva region, which includes the Eastern Shore counties of the States of Maryland and Virginia, experienced a low pathogenicity avian influenza outbreak firsthand in 2004. We were very fortunate to have a successful outcome because of advance planning and rapid implementation of the regional response plan by our incident command system.

We are very fortunate in Delaware to have many outstanding experts in the poultry health field. These are, again, within academia, but I also want to emphasize within our poultry companies. We are very blessed to have those individuals working hand-inhand with us. And, obviously, members of the States and the Fed-

eral Government.

Only three farms were positive in our Delmarva incident, which is remarkable given the very high densities of poultry and farms

in the Delmarva region.

AI outcomes, like those of cancer and other potentially fatal diseases, are time dependent. Recognition at the earliest stage of the disease is critical. But, unlike cancer, the situation with AI is arguably a bit more complex because the AI virus, the cause of the disease, is highly contagious and it will multiply to enormous concentrations in poultry and spread via the air and by off-farm movement of infected poultry, human carriers, and contaminated farm equipment.

All normal farm activities must cease immediately when AI strikes, and the farm must be prepared to implement an emergency

¹The prepared statement of Dr. Gelb appears in the Appendixn on page 73.

biosecurity plan. Part of the emergency plan is that infected flocks must be depopulated, ideally within 24 hours, at the earliest time following the identification of the virus on the farm. This is important to end animal suffering and, importantly, to stop the spread of the virus into the environment, which represents a very significant threat in transmission.

There are several areas that I went into more detail as far as things that we might look at in the future. I will just briefly refer to them here.

No. 1, develop and implement educational outreach biosecurity programs designed to help farmers to respond to avian influenza on their facilities. Biosecurity is a term that describes everyday and emergency disease processes a farmer uses to prevent and control diseases. It is probably the single greatest weapon that we have against avian influenza. But, unfortunately, biosecurity is not consistently applied by all farmers and by all poultry companies.

We also need to look at, as far as No. 2 is concerned, a few aspects of our current emergency response plan so we can respond more quickly, more rapidly, to an incident, and we can get into that

a little bit later.

No. 3, provide an insurance program for poultry farmers who contract with poultry companies to raise their flocks. Dr. Clifford mentioned indemnifications that have been paid, and this is very important. But for farmers who are contract farmers with poultry companies, they may or may not receive those indemnifications. So, there is really a need for a new program, and there are discussions underway on this particular topic and I think we should look into this area seriously.

Vaccination for controlling avian influenza in poultry requires very careful consideration. Again, there was mention earlier about developing vaccines and utilizing them in poultry, and I am talking more specifically not for humans, but for poultry. But there are some limitations to vaccines. Vaccines have limited efficacy, even under somewhat the best conditions. We certainly need more research on poultry vaccines to make them more effective than they currently are. But, vaccination is a slippery slope and we need to very carefully determine whether or not we are going to go down this road, the effect on trade, the fact that these vaccines are not particularly effective, can push the virus and drive it to further mutations.

Last, there is a growing body of evidence that terrestrial wild birds may be playing a role in the transmission of avian influenza. We have known for years that ducks and geese, so-called wild waterfowl, are the main reservoirs where avian influenza resides on a long-term basis, and we have heard earlier from Dr. Clifford they are the primary source for the point introductions at various parts of the United States. We have known this for years.

So, these terrestrial birds, why might they be important? Well, there is some research that suggests that they do support virus replication and they could be so-called bridge vectors, carrying viruses not only to poultry—many times you see finches and sparrows in poultry houses—but maybe also to humans.

I would like to thank Senator Carper and Senator Johnson for their kind invitation to be here today, and I also want to thank

Robert Bradley of Senator Carper's office for reaching out to me about this opportunity. Thank you. Chairman JOHNSON. Thank you, Professor Gelb.

Well, because Senator Carper got a witness from Delaware, I got one from Wisconsin. And, it is unfortunate that we have Scott Schneider here because you lost your flock and you are losing a lot

of money in this process.

Our next witness is Mr. Scott Schneider and he is the owner of Nature Link Farm, located in Jefferson County, Wisconsin. Unfortunately, his 200,000 chicken farm was the first egg-laying operation to be hit by the H5N2 strain that then ravaged other chicken farms across the Midwest. He is also the President of the Wisconsin Poultry and Egg Industries Association.

Mr. Schneider, we are very glad you could come here and provide

your testimony.

TESTIMONY OF SCOTT SCHNEIDER,1 OWNER, NATURE LINK FARM, JEFFERSON, WISCONSIN, AND PRESIDENT. CONSIN POULTRY AND EGG INDUSTRIES ASSOCIATION

Mr. Schneider. Thank you, Mr. Chairman, Ranking Member Carper, and Members of the Committee, thank you for inviting me to discuss the impact of highly pathogenic avian influenza on poultry and egg producers. I appreciate the opportunity to be a part of developing a comprehensive solution to recover from the current outbreak and prevent the future spread of the disease.

My farm is my livelihood. My flock of 200,000 cage-free egg-laying hens did more than produce a product. It helped me meet American consumer demand. My flock and my farm fed my family, they paid my bills, and it enabled me to help my ten-plus employ-

ees feed their families and pay their bills, too.

I have always played by the rules and tried to ensure pristine conditions for my employees and for my birds. I have done my part to keep the American egg industry competitive. But as producers from around the world know all too well, hard work and strictly fol-

lowing regulations does nothing to protect against AI.

My flock of 200,000 egg-laying hens has been reduced to zero in the face of the AI outbreak. My short-term prospects have been grim, and the middle-and long-term prospects are challenging, especially in the face of future AI threats. Although containment and biosecurity efforts have been admirable, survival of my family farm and the American egg industry at large depends on meaningful

protection against future outbreaks.

AI will cost my farm a minimum of \$500,000 in revenues before this year is over. That is a sizable blow for any operation, but almost an unimaginable financial hit for a smaller producer such as myself. My farm will be completely out of production for at least 4 months and generate no new revenue. My current plans call for gradual repopulation over the 4-months to follow, building my flock back toward its pre-AI size. When all is said and done, under a best case scenario, I am facing a minimum of 8 months with either zero or heavily reduced revenues and surviving by using my life's savings.

¹The prepared statement of Mr. Schneider appears in the Appendix on page 81.

In addition to the direct loss of revenue, I am also fronting payments for some of the costs of remediation and containment efforts until the USDA is able to reimburse me.

Of course, my farm is just one of the many operations devastated by AI. To date, more than 48 million birds have been infected by the disease and 220 operations in 20 different States. AI has killed

more birds in the egg sector than in any other to this point.

The reported loss from the current outbreak has set egg-layer inventories back by more than a decade. Prior to the current outbreak of AI, there were just over 300 million egg-laying hens in the United States. Over the past 6 months, about 35 million of those have been lost. That loss is hurting American egg supplies and driving up prices, as indicated by the USDA's 4.1 percent reduction of forecasted egg production for 2015. It has even led to the importation of shell eggs from Europe. This is an extreme situation that very seldom is seen in our industry.

Consumers are also hurt. We have seen significant increases in the prices of eggs and products made with dry and liquid eggs due to the AI outbreak. In dollars and cents, current table egg prices are up 70 percent from April 2015 prices. U.S. consumers could pay \$8 billion more to buy eggs, which is an increase of at least 75 per-

cent from last year.

The importance of USDA's response efforts to date cannot be overstated, nor can my gratitude for the work that the government and its partners have done thus far. USDA resources have been integral to response efforts. What is more, the individuals and teams that I have worked with on the ground have been highly professional and courteous. They are people who have the best intentions and a true desire to help, and I appreciate that help very much.

Despite the progress being made, the sheer bureaucracy of doing business with the government is challenging family farmers who, like me, do not interact with government bodies every day. I do not have administrative staff to keep up with the changing landscape of rules, work plans, compliance agreements, and the rotating staff inherent to such a recovery process. The red tape is daunting, it is frustrating, and it is financially draining. But, we must push on and work within the framework that has been established for the benefit of me and those like me.

In today's landscape, a response plan aimed at true eradication of the disease must be comprehensive. Biosecurity and containment are indispensable parts of that plan, but they are simply not enough. We need to stop AI and prevent future outbreaks. The fact that the USDA is considering use of a vaccine as a component of a comprehensive response strategy is encouraging. For producers like me, it is difficult to imagine investing the time and money necessary to repopulate our flocks without the assurance provided by an availability of an effective vaccine.

This fact is made even truer in the face of upcoming bird migrations this fall which threaten to reintroduce outbreaks all over this country. Without the long-term protection granted by an eradication approach with a targeted use of a safe and tested vaccine, the path forward for my farm is far from clear.

I am proud to be an American egg producer. I am proud to be a part of an industry that has done its part to feed our Nation, to

support thousands of jobs, and keep small towns vibrant. If there is one message I hope this Committee takes from my testimony, it is this. The threat of AI can take all that away in one fell swoop if we fail to adopt a response plan that both addresses the current outbreak and prevent future outbreaks.

I thank you for your time and for the opportunity to talk with you today and I look forward to answering your questions. Thank

you, Mr. Chairman.

Chairman JOHNSON. Thank you, Mr. Schneider.

I think I will start with you. I think your testimony—and first of all, thank you for your testimony, and we obviously are sorry for your loss. But, what I find interesting about your testimony is I think you share my perspective. I have been very impressed with the quality of the Federal workforce, I mean, just really dedicated individuals doing a great job, which is exactly what you experienced, as well, and that is a good thing. But, frustrated by the problems that you encounter based on the bureaucracy, the rules, what they are trying to follow. So, I just kind of want to followup on that.

First of all, you are a contract producer, correct? Somebody else owns the chickens and you run the operation.

Mr. Schneider. Yes, that is correct.

Chairman JOHNSON. Now, when we met yesterday—and I appreciate you coming in early—you described to me the indemnification process for the actual chicken owners. It took, what, 4 to 6 weeks for them to be indemnified against the loss of the chickens, correct?

Mr. Schneider. That is my understanding, yes.

Chairman JOHNSON. But, you are, as you say, there is no business interruption insurance. You cannot buy this kind of insurance in the open market. This is only provided—and it is a good thing that we have this indemnification through the USDA, but as Professor Gelb was talking about, there is a problem in terms of indemnifying for operational losses as well as trying to recover and doing what you are trying to do to remake your farm, is that correct? Can you describe how much you spent and what your frustration is in the property of the

tion is in terms of being indemnified as the operator?

Mr. Schneider. I think one of the situations that I am running into is that I will be fronting probably close to \$150,000 in terms of depopulation, cleanup, and disinfecting before I am able to start repopulating my complex. It is difficult for me to come up with that kind of cash, and it is difficult to try to make sure that I am dotting all the "I"s and crossing all the "t"s when it comes to the formats that the USDA is going to require me to do when it comes to expenses and identifying which expenses are recoverable for me. Every day goes by, I become a little bit more concerned that some of those expenses might be left out or forgotten or somehow not covered and I stand to lose a lot more money on top of what I am already losing.

Chairman JOHNSON. And, again, if you are not able to repopulate your operation for 8 months, I mean, are you going to be able to start generating revenue any time soon, or is it really you are not

going to generate anything for 8 months?

Mr. Schneider. When I start repopulating, it will be an incremental process. I have the capacity of 200,000 birds on my farm

and I will start incrementally adding flocks to the tune of about 45,000 birds every month, starting in August and October.

Chairman JOHNSON. Now, do you buy those as egg-laying chick-

ens right off the bat?

Mr. Schneider. They are ready to lay. Yes, that is correct.

Chairman JOHNSON. OK. So, you will start generating revenue.

Mr. Schneider. That is correct.

Chairman Johnson. OK. Dr. Clifford, in the private insurance market, you get an insurance adjustor coming out onsite, assessing it, verifying the claim, writing a check sometimes that day or within days, or certainly a week or two. To me, this is a pretty simple claim to adjudicate, particularly the chickens. I mean, here is the program. It is Federal law that the chickens have to be destroyed, and it is Federal law that the indemnification for those owners of those chickens. I would think, OK, we verify that this is AI and the chickens are destroyed, and I do not know why the government cannot write a check literally within a day or two to indemnify, first, the owners of the chickens. Can you tell me why it would take 4 to 6 weeks for the owners of the chickens to be indemnified?

Dr. CLIFFORD. So, with regards to indemnification, we can actu-

ally do that within a week or less.

Chairman Johnson. But, again, that was not the case in this—

Dr. CLIFFORD. No, I understand, sir.

Chairman JOHNSON. OK.

Dr. CLIFFORD. What I was going to say, though, is what we require is a flock plan to be signed, and until that flock plan is signed, we do not pay indemnity. What the flock plan is, is a strategy and plan for that location, specific to that location, with regards to biosecurity and restocking to ensure that we are all doing as much as we can to prevent reinfection. If there is not a signed flock plan before we pay indemnity and they get reinfected after they repopulate, we do not pay indemnity a second time.

So, I think there are things that we can do together to make that a lot quicker process. My heart goes out to Scott and his issues, and we have heard this from many producers. Some of these things

are complex because they have never dealt with them.

So, one of the things that we are doing to combat this in the future is assigning one person to that facility from the beginning to the end to work with the producer and to help them get through these things.

Chairman JOHNSON. OK. So, you are learning from that.

Mr. Schneider, real quick, how long did it take USDA to get out to your operation to inspect and really order the destruction of the flock?

Mr. Schneider. I think the USDA needs to wait until the presumptive positive is actually confirmed by the national laboratory in Iowa before they are able to do anything. And so in my case, we had a presumptive positive, I think it was on maybe a Thursday of the week, and on Saturday evening, it was confirmed by the national laboratory in Ames, Iowa, and I think it was on that Monday, then, that we had USDA people—

Chairman JOHNSON. And how quickly was your flock destroyed?

Mr. Schneider. It took a little—

Chairman JOHNSON. So, Thursday, infected.

Mr. Schneider. Yes.

Chairman JOHNSON. I mean, you saw chickens dying, right?

Mr. Schneider. Right. They were.

Chairman JOHNSON. They died quickly. And then, so, that was Thursday, and you started destroying your flock when?

Mr. Schneider. It was probably the following Thursday or Fri-

day, possibly.

Chairman Johnson. So, Professor Gelb, in your testimony, you said that process should be 24 hours. That is a pretty big gap. There is a fair amount of continuous improvement required here, correct?

Dr. Gelb. Yes, ideally. In Delaware back in 2004, our goal was 24 to 48 hours, in that window. And, in fact, again, that hinges on the identification of the virus. If we go back to Scott's point, that is a very important one, the process. The presumptive positive is made by a local or regional laboratory, a National Animal Health Laboratory Network (NAHLN) member laboratory—that is a mouthful, but it is a USDA, very important, very highly regarded USDA laboratory network system that we have nationally. They are based in Ames, Iowa. The confirmation must come—this is a very important point—from the national laboratory in Ames before it is actually a done deal, so to speak.

Chairman JOHNSON. So, let me just say, so in the current structure, we have these sites. Best case, if you restructured the process, I mean, because sometimes tests take a while.

Dr. GELB. Sure.

Chairman Johnson. Sometimes they have to incubate. What is best case? If you could design the structure, what is the best case in terms of Mr. Schneider calling somebody, you collect a sample. How quickly could you have that confirmed, again, best case, not—I guess, with current structure, but if you really redesigned this thing.

Dr. GELB. Yes. Once the samples are submitted to the local-regional NAHLN laboratory, those results basically are molecular types of tests. They can be completed in about 3 hours. Then those same samples, it is mandated, must be sent to the central lab in Ames for testing and for confirmational testing. So, at the local lab, they are presumptive. We are really waiting for that confirmational testing.

So, frequently, they are going to be sent by overnight delivery, OK, so it might be another 24 hours. So, you are basically waiting, then, that additional 24 hours before you can take action in terms

of initiating flock depopulation.

Chairman JOHNSON. I want to say on this, and I want my Committee members to indulge me a little bit, in your experience—or maybe I will go to Dr. Clifford—how often do you have the initial result differ from the confirmation result? Are there instances of that? So, in other words, the question I am asking is could we rely on the initial result, and it would be destroying the flock of chickens, and all of the sudden, oh, that really was not avian flu?

Dr. Gelb. These regional NAHLN laboratories are basically laboratories of the NAHLN. They are many times, if not all, many times accredited laboratories with very high quality staff. I am giv-

ing you a little more background. All the members that run these molecular tests take proficiency panels once a year, unknown proficiency panels that come from USDA. We are talking about highly qualified laboratories.

Chairman JOHNSON. So, again, so the point is, we could improve this model, so we could destroy that flock of chickens within a day or two, within your guidelines, 24 to 48 hours rather than 7 days, which, again, just increases the likelihood that these outbreaks will not be contained.

Dr. Gelb. Yes.

Chairman JOHNSON. I mean, from my standpoint, for the USDA, if we have to write a law or improve a regulation, there is a real top priority of what we ought to do as a Federal Government to speed that process to limit the damage. I mean, would you agree with that, or—

Dr. Gelb. Yes, I would.

Chairman JOHNSON. OK. I have plenty of other questions, but I

will turn it over to Senator Carper.

Senator CARPER. To our witnesses, you will see our colleagues are coming and going. We serve on three, four, five Committees, and the others have hearings going on, as well. I do, and I will be slipping in and out today.

Senator Tester from Montana has asked to use a little bit of my time and I am going to yield to him and then recover my time.

Thank you.

OPENING STATEMENT OF SENATOR TESTER

Senator Tester. I appreciate that.

Very quickly, Dr. Clifford, is there a vaccine for the avian flu? Dr. CLIFFORD. Yes, sir, there is a vaccine—

Senator Tester. OK. How cost effective is it? What does it cost a bird?

Dr. CLIFFORD. Well, let me, if I may, there is not a well-matched vaccine available today——

Senator Tester. OK, so there is not a—

Dr. CLIFFORD [continuing]. And we are working on well-matched vaccines for the fall.

Senator Tester. All right.

Dr. CLIFFORD. But, you are usually talking pennies per bird——Senator Tester. OK.

Dr. CLIFFORD [continuing]. As far as the cost of vaccine.

Senator Tester. All right. But, we are still researching the potential of a matched vaccine?

Dr. CLIFFORD. There is work ongoing, and I believe that we will have——

Senator Tester. One by fall.

Dr. CLIFFORD [continuing]. Available vaccines by the fall or late fall.

Senator Tester. Mr. Schneider, first of all, thanks for raising cage-free chickens, No. 1, and No. 2, I am sorry about your loss. I am also involved in agriculture of a different kind. I deal with plants. But, I just kind of want to try to figure out where we are going here. With grains and with lentils, we buy insurance. Do you

pay a premium for the insurance we are talking about, or is this part of a disaster program of the USDA?

Mr. Schneider. This is part of the disaster program of USDA. Senator Tester. OK. That is important to know. I mean, we buy insurance, that is heavily subsidized, I might add, by the taxpayer, so it is not totally private sector.

What are you going to have to do to be able to raise chickens? Can you give me four or five things that you are going to have to do on your place so that you can guarantee that the avian flu is not going to come back?

Mr. Schneider. Sure. We have to follow protocols set in place by the USDA

Senator Tester. Yes.

Mr. Schneider [continuing]. For depopulating, for cleaning, and then, finally, for disinfecting.

Senator Tester. OK. And, is there other time elements to those

protocols?

Mr. Schneider. Not necessarily, up until the time which you are completed with your disinfecting. Then you are required for a 21day rest period

Senator Tester. OK.

Mr. Schneider [continuing]. In which time they are doing sam-

Senator Tester. And they are still continuing to do tests to make sure that-

Mr. Schneider. They are doing testing during that 21-day period.

Senator Tester. OK. Very good. And, you are in the middle of that process right now?

Mr. Schneider. I am completing the disinfecting, hopefully this

Senator Tester. And, is it up to you to destroy the chickens or does USDA do it?

Mr. Schneider. It is a reimbursable expense.

Senator Tester. Yes, but do you actually do the job or do USDA people come in and do it?

Mr. Schneider. It depends on whether or not there is a contracted company to come in and do it, or we can as a farm. We can contract to do it, as well.

Senator Tester. In your particular case——Mr. Schneider. We assisted the contracted company.

Senator Tester. OK. Good.

Mr. Currie, in your written testimony, you talked a little bit about foot and mouth disease, and I know this is about avian flu, but how serious is foot and mouth?

Mr. Currie. It is a very serious disease.

Senator Tester. And we are free of that disease in this country, correct?

Mr. Currie. That is probably a question better targeted to Mr. Clifford, but-

Senator Tester. That is good. He is next on my list anyway. [Laughter.]

We are free in this country of foot in mouth-

Dr. CLIFFORD. Yes, sir, we are.

Senator Tester. OK. The USDA just opened up—authorized imports from a number of countries, including Brazil, Uruguay, Argentina—

Dr. CLIFFORD. Yes, sir.

Senator TESTER [continuing]. That are not foot and mouth free countries. Mr. Currie just said it was a very serious disease. Do you guys talk before you open up trade with other countries that have a highly contagious disease?

Dr. CLIFFORD. Do I talk with GAO about doing that? Senator TESTER. Do you talk with Mr. Currie's office?

Dr. CLIFFORD. No.

Senator Tester. OK. So, if that—

Dr. CLIFFORD. Why would I talk to Mr. Currie's office about disease mitigation? They are not veterinarians. We do risk assessments.

Senator Tester. OK, so that is fine. My brother is a veterinarian, so do not take this personally, but—

Dr. CLIFFORD. I know he is. [Laughter.]

Senator Tester. The fact is, is that why did we open up trade with countries that have foot and mouth disease?

Dr. CLIFFORD. Because they are free with vaccination, and what that means is they have not had cases, an active outbreak of foot and mouth disease for years.

Senator Tester. In regions of those countries—

Dr. CLIFFORD. No, in all of the—

Senator Tester [continuing]. Not in those entire——

Dr. CLIFFORD. In the entire country, there has not been a verified case of foot and mouth disease in the entire South America for over 2 years.

Senator Tester. So, why is not Uruguay considered a certified free foot and mouth disease?

Dr. CLIFFORD. They still vaccinate. That is why. And, you can ship beef, boneless beef, safely if you vaccinate and you are free, and we have been doing that for years. We did it from Argentina years before they had an additional case quite a few years ago.

Senator Tester. So, let us go the other direction, then. You are saying that if we had an instance of foot and mouth disease in this country, that it would not hurt our export business?

Dr. CLIFFORD. I did not say that, sir. Of course, it would.

Senator TESTER. We vaccinate.

Dr. CLIFFORD. We base trade on risk mitigation. We do not vaccinate for foot and mouth disease, nor will we vaccinate for foot and mouth disease unless we get the disease. They vaccinate routinely to make sure that they do not have the disease. One of these days—

Senator TESTER. I have it.

Dr. CLIFFORD [continuing]. I think North America will probably—or, the region of Americas will probably be the first continent free of foot and mouth disease within the next 5 to 10 years.

Senator Tester. That would be good. My concern is it stays that way, and from what I hear you say, if we had foot and mouth disease in this country and we were vaccinating, we would actually be in better shape for exports of meat than if we did not have foot and mouth disease and we did not vaccinate.

Dr. Clifford [continuing]. That is not correct.

Senator Tester. Well, now, come on—— Dr. Clifford. I said boneless beef—boneless—from areas of the world that have foot and mouth.

Senator Tester. Got you.

Dr. CLIFFORD [continuing]. Free with vaccination can ship boneless beef-

Senator TESTER. Here is my concern, and you are the doctor and I just raise the animals. My concern is, is what happens if we get foot and mouth disease in this country, and you said it would have impacts on our exports.

Dr. CLIFFORD. It would.

Senator Tester. But, you also believe strongly that the chance of transferring that foot and mouth disease from a country like Uruguay is zero.

Dr. CLIFFORD. I did not say it was zero. I said it was extremely

low risk.

Senator Tester. What would it be, less than 10 percent?

Dr. CLIFFORD. Oh, it is a lot lower than that, but it is-

Senator Tester. Less than 1 percent?

Dr. CLIFFORD. Yes.

Senator Tester. OK. So, nearly zero.

Dr. CLIFFORD. As close to zero as you can get without saying

Senator Tester. Perfect. Thank you very much.

Chairman JOHNSON. Senator Ernst.

OPENING STATEMENT OF SENATOR ERNST

Senator ERNST. Thank you, Chairman Johnson and Ranking Member Carper, and to our witnesses today, thanks so much.

I spent some time with Dr. Clifford yesterday as we met in the Agriculture Committee and discussed a number of these issues, as well. I do want to recognize, we do have a turkey producer from Iowa in our audience today. Mr. Moline, thanks for joining us again today. Good to have you here.

Iowa was hit extremely hard. If you look, a number of us here up at the dais have a little map here, and you cannot really see Iowa too well because out of the millions and millions of birds that have been infected and destroyed, two-thirds of those birds were from Iowa. So, our poultry, our turkeys, have been infected quite heavily, and so this has been a big concern for us for a number of months now. And, the economic impact to Iowa will be about \$1 billion, very significant.

So, Mr. Schneider, I sympathize with you very much. A number of our producers have gone through the exact same thing. I just want to reemphasize, it is not only devastating for these producers, but their employees, those employees' families, and the communities that are supported by these producers. So, thank you for being here today and sharing your story. I appreciate that very much.

Dr. Clifford, I would like to go back and visit a little bit more about the vaccination process. We talked about it a little bit yesterday. Is the USDA working on the vaccination process? If you could explain a little bit about the process, where we are with that. I

know a number of different groups will support vaccinations, some will not. What we want to do is ensure that we are working with trade partners, as well. So, if you could talk about our trade part-

ners, that would be very helpful.

Dr. CLIFFORD. Thank you, Senator Ernst. Yes, what we are doing is developing, actually, a vaccine bank. We intend to go out with a request for proposal soon to ask companies to bid on that. We have several companies that are in process of developing vaccines and we believe that we will have a vaccine bank available sometime this fall, it may be late fall depending upon the companies'

ability to get that vaccine manufactured.

It is a tool in the toolbox, as Dr. Gelb said, that we really need to have to use if we decide it is the right thing to do in a particular situation. So, we are working on those protocols and then we will be reaching out this summer to our trading partners to try to encourage our trading partners, under these conditions, to not shut off trade. And, if we are successful, then that will help us to be able to utilize that one tool, because right now, if we use that tool in our toolbox, they will shut us off and we will lose potentially up to \$3 or \$4 billion additionally in trade. And, they are not talking about a partial shut-off. They are talking about an entire country shut-off.

So, I understand the turkey producers wanting to use vaccines. I can understand the layers and especially outdoor or cage-free birds. So, you have these different groups, from the broilers to the genetics groups that do not want it used because of the impact on trade. So, we are trying to balance all this. We are trying to get our trading partners to support its use in a limited way where it makes sense.

An example of use would be in turkey flocks in Minnesota that have a very close proximity to a lot of lakes and a lot of potential wild waterfowl.

Senator Ernst. Very good. No, I appreciate that very much.

And, Dr. Gelb, you had mentioned that, of course, the growers, there is an indemnity fund, but some of the growers are not seeing the funds flowing their direction. Do you know of any mechanism where we would be able to follow those dollars and find out—we do want to make sure that if the growers are entitled to a portion of that indemnity payment, that they are receiving that. Do you know of any mechanism that we might be able to engage for followup?

Dr. Gelb. Yes. This is a little bit out of my area, but working with our local trade association, the Delmarva Poultry Industry, Incorporated, and speaking with William Satterfield, the Director of that organization, I think he, for example, could give you a better answer on this.

But, my understanding, as I indicated earlier, the indemnities for contract growers—and there are many contract growers in this country where they do not own the birds. They provide the facilities, the heat, the ventilation, basically, to grow them. But, the birds themselves belong to a poultry company. And, frequently, those indemnities, they just go to the poultry company. Some of the companies will then share some of the indemnity funds with the contract grower.

So, this is kind of a contract grower issue, and I mentioned, also, the interest and current proceedings now in thinking about moving forward with an insurance program that growers could purchase where those funds would go directly to them rather than to the company. So, yes, Senator, you bring up an excellent question, and I am not sure I am really the best one to address it.

Senator Ernst. Thank you.

Dr. GELB. Thank you.

Senator ERNST. Well, I thank you for raising the issue.

And, just one parting point, and I know, Mr. Currie, you work with emergency management, and as we discussed yesterday in the Agriculture Committee, Iowa did have plans in place should this happen. We had a number of landfills that were willing to accept the carcasses of the birds after they were virus-free. But, I tell you, even the best laid plans can go awry, because we had really kind of an uprising amongst the people around those landfills and along those routes that said, how do we know that our birds will not be hit by this virus by moving those birds to these landfills? So, it was a great concern with the people of Iowa that we were not affecting additional farms out there. So, even the best laid plans cannot go the way they are intended.

But, thank you very much to our panel for being here today. We

appreciate it. Thank you, Chairman and Ranking Member. Chairman JOHNSON. Thank you, Senator Ernst. Senator Peters.

OPENING STATEMENT OF SENATOR PETERS

Senator Peters. Thank you, Mr. Chairman, and thank you to the

panelists for your testimony.

This is certainly an issue that is somewhat frightening to a lot of folks, to think that an influenza could hit the poultry industry so quickly, and that so many birds die and have such a massive impact on egg production, and we just think about, certainly, other produce as well, and how these bio threats are so significant.

In fact, Michigan, the State that I am blessed to represent, became the 21st State to confirm a case of avian flu here just recently. I believe it was in wild birds, actually, some geese where it showed up, and I think that is possibly where it all started. I

think we are still trying to figure that out.

But, I guess that leads to my question for you, Dr. Clifford. How closely are you working with the Fish and Wildlife Service? Are they involved in monitoring what is happening with wild birds and the impact it could have on our agricultural sector? Certainly, we will have fall migrations that will be involved with some of these wild birds. So, do you work with the Fish and Wildlife Service, and if so, what are you doing?

Dr. CLIFFORD. Yes, sir, we do. We work directly with them. Our Wildlife Services Division of APHIS leads this effort for us and they work directly with the State Departments of Natural Resources (DNR), the U.S. Fish and Wildlife Service, and other enti-

ties with regards to wild bird surveillance.

We have actually been doing wild bird surveillance for a long time. We began doing a lot more surveillance during the H5N1 occurrence quite a few years ago in Asia, when it became a human health issue and concern, as well, and we increased our surveillance. As that became less of a concern for the United States from the flyways—and we did a lot of testing and monitoring and no cases were found of that H5N1—then we reduced the level of monitoring because of the lack of threat from that particular agent.

Based upon these recent findings, we have increased surveillance in wild birds and we actually have plans out there available that includes Fish and Wildlife, DNRs, and APHIS Wildlife Services on the collection of these samples, and it will occur across all four flyways. In addition, we take samples from up north of Alaska, there in the Bering Strait area where these birds currently are to

see what is happening right now, today.

Senator Peters. Very good. Well, as I looked at the spread of this and looked at the industry and the concentration of the industry, which I think is very interesting I want to direct this question to Dr. Schuchat, probably Dr. Clifford, as well, and Dr. Gelb. The statistic that I think is very interesting is that there are 56 privately held farms that account for about 90 percent of all of the egg production in the United States—90 percent. So, we have some small family farms, but there are not very many small family farms anymore. That has faded away. We have large family farms and we have large corporate farms. And now we have just 56 farms that have 90 percent of the production. So, that is an incredible concentration of animals.

So, I want to kind of get your sense. We have a very large amount of birds in a very small space, and this is not just in poultry, it is in other types of agricultural production, as well. Does that put us at greater risk when it comes to disease, because you have that kind of concentration, or does it not? If you could kind of address that for me as far as what we are looking at in terms of our challenges.

Dr. Schuchat. Yes, I can just briefly comment from the human health perspective, but I think Dr. Clifford will be better. We need biosecurity to be strong at every level, and one level is really what is the geographic location of the establishments. But we need within any establishment, concentrated or not, the right kind of procedures and protocols and the workforce practicing those, because there is risk of spread between the facilities.

So, the specifics of the agricultural practices would be in the USDA arena. What I need to just say is that the workers on those premises and the contractors and so forth who help with remediation really need to be tracked to make sure that they are OK following their exposures and that they do not develop illness that could be a human case of avian influenza.

Dr. CLIFFORD. So, with regards to issues of whether you have intensive farming practices or less so, this virus really does not care. Granted, the more birds you have in a location, the more virus pro-

duction, the wider the spread can occur.

What we need to be thinking about in the way of biosecurity is why this outbreak is different than what we have seen before. This is the first time in North America that we have had a high path AI virus travel through wild birds from Europe and Asia to North America, the first time, and it is because it has adapted itself to these dabbling ducks and it has moved across the Bering Strait. It never happened before in a high path. Low path, maybe, but not

high path.

So, what is different now is we have to consider biosecurity, where it was fine and well and good for what we were dealing with prior to this, we have to consider now that this is different. You have to look where there are wild waterfowl as the entire environment being affected, potentially. It does not mean it is, but you have to consider that as a potential. Every single house that birds exist in, or every single location, you have to think in ways of trying to protect from house to house to house. And it is not about the facility being safe, it is only the safety within each of those houses where those birds are kept, and they have to be looked at as single biosecurity facilities, which is much different than what we have had to do prior.

Senator Peters. So, it is better to have a few large concentra-

tions or more——

Dr. CLIFFORD. It is really more about the biosecurity. But, obviously, in any viral infection, the more birds you have, the easier the virus can spread, the more virus production. That is why it is critically important to get birds put down quickly.

Senator Peters. Right, especially when you have 56 operations

that are 90 percent of all the eggs in America.

Dr. CLIFFORD. These are highly integrated—

Senator Peters. Yes.

Dr. Clifford [continuing]. Operations.

Senator Peters. Dr. Gelb, do you want to mention—

Dr. GELB. Yes. I will kind of answer this from the broiler or the meat-type chicken perspective in Delaware, where, as Senator Carper indicated, it was the birthplace of the modern broiler or meat-type industry in the United States. It has continued to be very productive there and we often brag about the efficiency of our poultry production in Delaware and Delmarva.

But, this concept of having highly density of poultry within a given house, but even more importantly the density of farms in that area, that does facilitate the potential for more rapid transmission. We are dealing with a very contagious virus. We are dealing with a situation where the ventilation fans that are used to maintain the proper environment of the chickens are turned on virtually all the time, and material—dust, other material that is coming out of the air of those barns—will have virus.

And, that virus will travel to some degree, not miles and miles, but in Delaware, within a one square mile area, we might have four or five farms, and each of those farms might have 60,000 to 80,000 chickens on them. They are all contract growers. They may be—and those contracts are probably with—there are four different

integrated operations, four different companies.

So, you have a situation, as Dr. Clifford indicated, where you may have these very large single farms, layer operations, for example, but on some other areas of the country, you have independent facilities owned by different companies, but it is essentially the same thing. Even though maybe the travel on and off those particular farms is different, when birds are taken to market, they are caught, they are put in cages, those trucks take them to what we call processing plants or slaughterhouses, and they may go by 15

different other farms. And, the dust and the feathers are coming

from these live haul trucks, as they are called.

So, there are a lot of complexities here and we really need to kind of think this all through. That is why in Delaware, we are—"concerned" is not the right word, thinking about what might happen here this fall.

Chairman JOHNSON. Thank you, Senator Peters.

A real quick point of clarification for Dr. Clifford. There may be 56 poultry companies, but there are a lot of locations, right?

Dr. CLIFFORD. Sure. I mean, there are 20 States that we would consider to be major poultry producing States across the United States.

Chairman JOHNSON. So, we are not talking about 56 locations. We are talking about probably thousands of locations, correct?

Dr. CLIFFORD. Correct.

Chairman JOHNSON. But, just multiple——

Dr. CLIFFORD. But, there are areas across the country where there are higher concentrations than others.

Chairman JOHNSON. Right. Got you. Great. Senator Baldwin.

OPENING STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you, Mr. Chairman.

This year's avian flu outbreak has had a deep impact in my home State of Wisconsin. The outbreak has wreaked havoc on our farms, where producers have faced the devastating reality of sick and dying birds, I am so pleased that we are joined today by Mr. Schneider of Lake Mills, Wisconsin, to share his story of his farm and livelihood.

The impacts, as we have discussed, of avian flu are really broad on farm workers, on individuals working at processing and packing plants whose jobs depend on those lines running, as well as on the broader farm community, which depends upon demand for grain, supplies and services from our poultry growers. And, so, this avian flu crisis is also a community crisis.

Wisconsin is proud to play a role as host to research labs that are laser focused on the key questions that are in front of us—questions about how the virus mutates, how it is harbored in wild birds, as well as diagnostic labs that help us track its spread and track viral strains as they emerge.

Dr. Clifford, producers in my State have relied on the tireless work that you do, and your team has put in lots of time and energy into addressing this crisis over the past many months. I want to thank you for your leadership.

We know that research labs responding to this virus span several different Federal agencies and are supported, by State labs. Madison, Wisconsin is home to the U.S. Geological Survey (USGS) National Wildlife Health Center and conducts research to determine which wild bird species might carry and spread various viral strains. I want to note parenthetically that I am quite concerned that the lab's aging infrastructure is not allowing it to fully perform as needed during this crisis. This is something that I have paid great attention to.

Dr. Clifford, as you know, this Wildlife Health Center conducts research that supports the industry focused research at USDA. I

am wondering if you could share some general comments about the importance of interagency collaboration and research investments as well as coordination to address this crisis.

Dr. CLIFFORD. I think interagency, across agencies, across States and the industry, the collaboration across all of them is extremely important. I think that was well stated earlier by the testimony of Chris Currie with regards to the importance of collaboration.

We actually collaborate on an ongoing basis with CDC. We work very closely with USGS. We work very closely with the Department of Interior as a whole. The money and funding we provide for the wild bird surveillance, some of that money would go to help support that testing that USGS and others would be doing in collection and testing of those samples. We work with Customs and Border Protection (CBP), the DHS, the Food and Drug Administration (FDA), I mean, a whole host of—Food Safety Inspection Service within our own agency. We have an internal MAC group within the Department of Agriculture that is stood up that brings across all the agencies to help address this issue, as well as with the State agencies.

So, it is critically important that all this is coordinated. As Senator Ernst was talking about with the landfills, there are issues with the Envirionmental Protection Agency (EPA). There are issues with transportation. There are issues with a lot of these things that have to be coordinated across.

There could be issues with availability of water. These foamers that we use for depopulation of birds requires a water source for foaming. You would not think that you would run out of water in certain areas. Certainly in small rural areas, you very well may not have an effective water source. You cannot go take it out of the lake because it has to be filtered water or otherwise it shuts down your machines. You have to have carbon sources for composting and things. So, this really is a massive effort that requires coordination among a lot.

Senator BALDWIN. Thank you, Dr. Clifford.

Dr. Schuchat, the University of Wisconsin hosts a large team of researchers studying pathogens that endanger human, animal, and plant health. We have pioneers in developing research efforts that could potentially help us understand or treat avian influenza viruses.

However, some of these efforts have been put on hold by a Federal pause on gain of function research. This continued research pause is delaying the potential benefits of studying these viruses, including research that could protect human, animal and economic health. When does the CDC plan to issue final guidance on this research to be able to end the pause?

Dr. Schuchat. Yes. I will need to get back with you with the specifics on that, but what I would like to say is that the public safety is really important, and public support for research is very important, and we take very seriously the need to make sure that the scientific experiments that CDC or research partners are doing are done in the safest possible way.

Influenza virus research is critical to make sure that we have safe treatments and effective vaccines and really get ahead of these viruses before we get the kind of problem that we are seeing right now with the avian outbreaks here. And, so, I know that across government, with the National Institutes of Health (NIH), CDC, FDA, the question of the moratorium is important and we can get back with you with the specifics of timing.

Senator Baldwin. I would appreciate that.

Dr. Clifford, I understand that State veterinarians are considering restrictions on the movement of birds and poultry separate from guidance by the USDA. I know that I have heard from farmers in my State who have contracts to deliver birds across State lines. We all clearly share the common goal of containing and eradicating this viral outbreak, but our producers facing substantial economic strain. These uncertainties make things even more difficult to conduct business when it is safe to do so.

Dr. Clifford, what steps is the USDA taking to ensure that quarantine and shipping practices are safe and effective while also fa-

cilitating these contracts and ongoing commerce?

Dr. CLIFFORD. Thank you, Senator. So, within our approach, we have what we call an infected zone and then a control zone. The control zone is around an infected flock. It goes out 10 kilometers.

Basically, products that are negative in that area are tested regularly, and so nothing can move out of those zones unless we permit that product to move. And, there are regular testing requirements for those products within that to be able to be safely moved in and out of those zones. So, that occurs ongoing. We issue, actually, thousands of permits out of those zones to allow that safe movement.

We share that. We have weekly calls with the industry and the States across the entire United States and we explain these things to them. They know how it is happening. Some States have taken additional action because of concern, for example, because of the live bird marketing systems that we have in the United States, and some of those have caused some issues. We intervene on behalf of States such as Wisconsin, Iowa, Minnesota, in that area, to try to help facilitate the movement of those birds into those States and we do the best we can. But, as you know, the States do have oftentimes rights to go above and beyond our requirements, and so we try to work through that with the industry.

Chairman JOHNSON. Senator Carper.

Senator CARPER. Thanks so much. This is a great hearing and we really appreciate your being here and your participation.

I want to come back and revisit the issue of, I will call it crop insurance. We have had a crop insurance program in this country for a long time and it is a shared partnership between the Federal Government, which helps subsidize the crop insurance. We changed it in the farm bill, the last farm bill we passed here. We changed it up some so that it would cover, as I am sure Mr. Clifford remembers, it would cover, I think, fruits and vegetables, if farmers want to participate in that.

And Senator Coons, my colleague from Delaware, I think, offered an amendment adopted and included in the bill that called for maybe trying a demonstration program with respect to insurance for poultry growers and other livestock growers. That was in the bill. I think we adopted it maybe a year or so ago and I do not know if we have had enough time to actually get it up and running. Is that something you are at all familiar with?

Dr. CLIFFORD. Senator, I am aware of the discussions, but I am not involved in the specifics of those. That is kind of outside of my

range of areas of responsibility.

Senator Carper. OK. Well, I will just ask you for the record. We will just ask you to respond for the record. Maybe some of your colleagues there can give us an update to let us know how it is going.

Dr. Clifford. OK.

Senator Carper. And, as Dr. Gelb was saying, in our experience with contract growers and broilers on the Delmarva Peninsula is if there is an avian influenza outbreak, the chickens are owned by the integrators and the Perdues, Mountaires, and companies like that, and the contractors, they do not get indemnified, as far as I know. But, they have, as Mr. Schneider has said, some real costs to bear.

And, I want to go back to something you said, Mr. Schneider, and I will bounce it over to Mr. Clifford. You were very gracious in your comments about the support you have gotten from, we will say, the Federal Government, the Department of Agriculture and others, and we were very encouraged to hear that. You indicated there is a lot of bureaucracy, a lot of red tape, and it can be very

frustrating, time consuming.

I thought I heard you say, Mr. Clifford, that there is an effort to try to identify one person, like a go-to person, for Mr. Schneider or anybody else who might be affected, whether it is in Minnesota or Iowa or Wisconsin or Delaware. Is that something we are actually doing now, where we have, like, one designated person, so you do not, like, call a call center and get switched from person to person to person? Do we have that in effect now, because that sounds like a great idea.

Dr. ČLIFFORD. It is actually in effect, but not in the way that we want it to be finalized for the fall and spring. Right now, it is one person, but because of our rotations of personnel in and out of those areas, because most of these people come from different parts of the United States and we have them on a 3-or 4-week rotation so they can go back home for a period of time before they are rede-

ployed, so——

Senator Carper. OK. It would be great if we could figure out— Dr. Clifford [continuing]. Right now, it is, like, a 3-or 4-week turnaround, so—

Senator CARPER. I understand.

Dr. CLIFFORD. So for the fall——

Senator CARPER. Yes.

Dr. CLIFFORD [continuing]. What we are doing for the fall and spring migrations is we will assign a single person that will stay with that producer for the entire period.

Senator CARPER. Great. One of my favorite sayings, if it is not perfect, make it better—

Dr. ĆLIFFORD. Yes, sir.

Senator Carper [continuing]. And I think you have taken a good idea and made it better.

I would like to ask a question about lessons learned. This would be for Dr. Gelb. Is it Dr. Clifford or Mr. Clifford?

Dr. CLIFFORD. It is Dr. Clifford——Senator CARPER. Dr. Clifford, OK.

Dr. CLIFFORD [continuing]. But it is OK either way.

Senator CARPER. We have a lot of doctors up here. But, I want to ask, can each of you take a minute, Dr. Gelb, Dr. Clifford, and Mr. Schneider—I will call you Dr. Schneider, too—

Mr. Schneider. I have been called worse. Senator Carper. I am sure. [Laughter.]

So have we. [Laughter.]

But, would the three of you just take a minute and share with us maybe one key lesson that we have learned, that you have learned so far from this outbreak, that can better prepare us for further infections, should they occur later this year? And, Jack, would you go first.

Dr. Gelb. Senator, thank you. I have not had any direct experiences in this current outbreak, so we have had some people, experts from the University of Delaware travel and participate in depopulation efforts, because that happens to be one of our real strengths, that we helped develop that technology years ago. So, I

get stories and reports from other individuals.

So, I really feel that biosecurity is really a key issue. I think that has been repeated several times today, an area that—biosecurity is not sexy. It is not something that is easily accomplished. It is a challenge and you sometimes do not see results from it. But, certainly, we know it is not the entire answer, as Mr. Schneider indicated. You can do biosecurity, almost everything right, really, and sometimes it is, maybe it is an act of God if you have the introduction of the virus here. But, I still think biosecurity is a really key weapon in this process.

Senator CARPER. OK. Thanks. Dr. Clifford.

Dr. CLIFFORD. Senator, if I may expand on that for more than one—I would like to hit a few, if I may.

Senator CARPER. Yes. Just do it quickly, please.

Dr. CLIFFORD. Yes. First and foremost, the questions that Senator Johnson, the Chairman, was asking earlier about the time-frame of depopulation due to positive testing at our National Veterinary Services lab, the confirmatory testing, we have already implemented plans quite a while ago to base the depopulation of those birds on presumptive positives by the NAHLN laboratory where it was taken. So, we do not require confirmation anymore. So, that is one lesson learned—

Senator Carper. OK.

Dr. CLIFFORD [continuing]. And one action we have taken.

In addition, one of the things we will be looking at in the future is clinical signs where we already know we have virus in the area,

not even waiting necessarily on a presumptive positive.

On the area of disposal, we need State, local plans in place that we know will work before they occur. Biosecurity, it is based upon new biosecurity. Air filtration systems—these air handling systems in these facilities have to have some type of filtration to reduce the amount of dust and potential for virus particles to enter through the ventilation system itself. Those are just some, but there are others.

Senator Carper. Good. Thanks.

Mr. Schneider, just very briefly. Give us one good take-away, one lesson learned that you think we ought to share with the country.

Mr. Schneider. Well, in addition to all the biosecurity efforts

Senator Carper. Yes.

Mr. Schneider [continuing]. We have just been talking about, I would suggest that the increase of funding for Agricultural Research Service to identify areas that those specific biosecurity protocols need to be implemented to help us prevent this from happening again would be a wonderful place to start.

Senator Carper. OK, good. My time has expired. I hope we will have a chance to ask a few more. Thanks, Mr. Chairman. Thank

Chairman JOHNSON. You will.

Mr. Clifford, real quick, because I want to get into the insurance or the emergency funding. Is there a program in place to indemnify Mr. Schneider as an operator?

Dr. CLIFFORD. There is a program in place that pays right now for the owner of the birds. So, if Mr. Schneider is a contract grower, what we have been doing is working with the companies to make sure that payments do go to the contract growers or contract raisers. I am not sure

Chairman JOHNSON. OK. That is something you try and do working with a law that does not contemplate indemnifying the operator.

Dr. CLIFFORD. Well, actually, sir, what we did in the low path AI situation quite a few years ago in Virginia, it is part of our regulations on low path. It requires the contract growers to be paid. The problem is with this particular high path, that particular regulation is written into the AI rules for low path, not for high path. And, so, we paid the owner of the birds.

Chairman JOHNSON. Correct. So, Mr. Schneider, you have a problem there and we need to work with the Ranking Member to figure out what we need to do to address that, because that is, obviously, devastating for the operator when it is just the owner being paid, and maybe there is an agreement between the owner versus the operator, but that is something that needs to be addressed.

Dr. Clifford, you talked about personnel rotation. How many

USDA offices do we have around the country?

Dr. CLIFFORD. Veterinary Services offices or USDA offices?

Chairman JOHNSON. I mean, where you have qualified personnel to respond to this

Dr. CLIFFORD. Well-

Chairman JOHNSON [continuing]. Because I am surprised we are

rotating personnel versus just having-

Dr. CLIFFORD. We do not have that many trained people to do this. You are talking about animal health technicians and veterinary medical officers. I have about 1,800 people that serve in veterinary services. I am not talking about just any USDA person.

Chairman JOHNSON. But, again, if you are talking about a point person to manage a case, I mean, you really need somebody who is skilled in management, not necessarily in the hard sciences.

Dr. CLIFFORD. No. sir. They need to understand the science as well. In this case, when they are working with them and helping them develop a flock plan and a compliance agreement, they not only need to understand the red tape, as you call it, but also the science.

Chairman Johnson. OK. Well, again, I mean, that could be an interesting discussion to have in terms of—again, if the whole purpose of this is to coordinate an effort with one point person that an owner or operator is dealing with, I think you could certainly have an interesting discussion as to whether or not that person has to be trained in all the—

Dr. CLIFFORD. It is—

Chairman Johnson [continuing]. As opposed to just trained in managing and coordinating the different expertises. But, let me move on.

Dr. Schuchat, I want to talk a little bit about the virus itself and vaccinations. First of all, how robust is the flu virus? I mean, how long can it survive if it gets on a dust particle and gets blown into other farms? I mean, is this a virus that is going to last days, weeks, months? Or is this pretty fragile?

Dr. Schuchat. The virus will not last that long, but the conditions are quite important. So, the colder weather and the dryer weather permits—is favorable to the virus.

Chairman JOHNSON. OK. Talking about—

Dr. Schuchat. So, right now, we are sort of in a quiet period for—

Chairman Johnson. Talking to Mr. Schneider, he said the virus can actually be on a snowflake, as well, and so it will last a little—but, again, are we talking days, then, that the virus will last?

Dr. Schuchat. Yes. I think the issue with the disinfection is to make sure that you have reached everything and that it is not coming back.

Chairman JOHNSON. In terms of the vaccines, so we are concerned about trade, the implications of that. I think, just as Professor Gelb was talking about, of the potential mutation of the virus with vaccines. Can you speak to that a little bit.

Dr. Schuchat. That is right. Influenza changes constantly, and that is why it is so difficult. It can mutate and it can also reassort, so swap parts of its genes with other influenza viruses. And, two of the three H5 strains that we are dealing with, the avian strains in the United States, are these reassortants, where we had high pathogenic H5 avian influenza from Eurasia that swapped out parts of its genes with the low pathogenic avian influenzas that we had here in the United States already.

And, so, the virus is just constantly changing, which makes vaccine development difficult. The vaccines that we have for humans as well as for animals are not as highly effective as some of the other vaccines and the virus can kind of mutate away from or escape from the vaccines.

There is a lot of balance about the avian vaccines. In the human vaccines, of course, we do work to prepare candidate vaccine viruses and have stockpiled vaccine against the original H5 strains from Asia, but those are really preparing for pandemic readiness rather than vaccines that we are using every day.

Chairman Johnson. We are always expecting just a technological miracle to save us from all these things, but again, what you are talking about with the vaccine, those are only going to be a certain percentage effective to begin with. Plus, we have a real problem with vaccine production in this country, do we not? I mean, we have a hard time producing enough vaccine sometimes for human flu. Would we have—I mean, if we start trying to vaccinate, 300,000 chickens, or 300 million chickens, a couple hundred million turkeys, do we even have even close to the capacity for that, and can we ramp it up quickly enough to respond to the changing virus?

Dr. Schuchat. Let me answer about the human vaccines and let Dr. Clifford respond about avian vaccines. The United States has invested an enormous amount in expanding our manufacturing base and the investment in influenza vaccine production and distribution. We actually have had an 80 percent increase in the flu vaccines produced and distributed annually in the past decade as well as a much stronger infrastructure for pandemic vaccine production for humans. But, the animal vaccine production works differently.

Chairman Johnson. No, let me quickly stay on the human vaccine, because I think this is important. We had a pretty robust vaccine production capability, correct, but then it was reduced dramatically, a lot of those lawsuits, that type of thing, and people—it just was not an attractive business to be in, so people—drug manufacturers exited the vaccine business, correct? So, we had to have almost government intervention to try and boost that production in case of a pandemic or in reaction to some of these outbreaks, correct?

Dr. Schuchat. That is right. There has been a lot of U.S. Government investment in stimulating the vaccine industry, both for influenza vaccines, and then actually for routine vaccines, we have a very strong public-private partnership right now where vaccine companies actually are making pretty good profits right now.

Chairman JOHNSON. But, again, I want to go back to sort of the root cause of why we did not have the amount of capacity we really needed for vaccine, is it really was because it was a very unattractive business. People were being sued and people just exited the business, correct?

Dr. Schuchat. Well, I think it was less the suits than the issue of the profitability, because when you are producing drugs, people will take medicines for their whole life, and successful vaccines, you need a couple doses of, perhaps, forever to prevent diseases from occurring. Flu vaccines you have to give every year right now. But, the market was not that favorable. But, things have changed a bit and we are in much better shape for pandemic readiness right now.

Chairman JOHNSON. So, is the manufacturing capacity different for animals versus humans? Dr. Clifford, answer that, please.

Dr. CLIFFORD. Yes, it is, and our Centers for Veterinary Biologics works with the companies here. So, I am not concerned about capacity. It is more economics with the companies, knowing that we would use the vaccine.

Chairman JOHNSON. It is still the same production technique, though, correct, by and large?

Dr. CLIFFORD. By and large, but there are some new techniques

being used, as well, that—

Chairman JOHNSON. Can speed the production and the development?

Dr. CLIFFORD. Yes.

Chairman JOHNSON. So, there is more capacity available for animal vaccines because you just do not really risk the liability problem? Why would we have so much more capacity for animal vaccines versus human?

Dr. CLIFFORD. I really cannot say that from the standpoint of the human side, but we have a lot of companies that are both domestic and international. If they do not have the capacity here, they have approved products that they can move here. So, if it cannot be produced here, it can be produced somewhere else. So, the capacity is there to produce the vaccine.

Chairman JOHNSON. Just a quick question for you, Mr. Currie. You are going to have a GAO audit on this. Dr. Clifford, how do you think the USDA is going to fare in that audit, and I will ask Mr. Currie the same thing. I realize it is a little unfair, but I have had my facility audited. I have a general sense of, this is going to

be a good one, or I might have some problems.

Dr. CLIFFORD. I think they will find some good things and I think they will find some areas that we need to improve on, and I think you oftentimes find that kind of situation. And, some of those lessons learned, we are definitely taking those and working with the industry and States to move those lessons learned so we do not repeat those same mistakes in the fall and spring.

Chairman Johnson. Mr. Currie, do you think you are going to see some improvement from the last time you looked at this thing, that they have already learned from lessons and amended some

things and——

Mr. Currie. Well——

Chairman JOHNSON [continuing]. What is your general sense?

Mr. CURRIE. Yes, sir. I think—well, we know—for instance, we issued a report on the potential response to an outbreak like this in 2007 and made a number of recommendations that touched on, almost to a tee, all of these challenges that we are facing. I do not know if any of us expected it to be this big and this bad. USDA addressed all of those recommendations, and so they are being tested now.

In any emergency, whether it is a natural disaster or an outbreak like this, there are going to be challenges and lessons learned and things we did not expect and after action reporting that we are going to have to study, too, so—

that we are going to have to study, too, so——
Chairman JOHNSON. So, again, there has been a good reaction to your prior report, so, hopefully—but, again, there will always be lessons learned. It is never perfect. Always room for improvement. Senator Carper.

Senator CARPER. Thanks so much.

We have talked about this a couple of times already in the hearing. I want to come back and nail it one more time, and maybe for Dr. Clifford. I am talking about how do we mitigate—let me just back up.

When we have a farm that goes down in Delmarva because of the avian influenza, a lot of times, countries around the world will just say they are not going to take any of our chickens. And, we also have concerns when we hear from countries, and part of the trade negotiations going on right now with the Trans-Pacific Trade Partnership is the use of vaccinations in livestock or birds and to what extent does that impair our ability to sell to a lot of different countries. Some countries just do not want to have animals imported into their countries that have been vaccinated. You know how it is.

How can we mitigate the impact of vaccine-related export bans

that are imposed on the United States? Dr. Clifford.

Dr. CLIFFORD. So, I think one of the ways to do that is to have the plans available to share with certain countries so that they can see those firsthand, how we would use it, and they would have the knowledge that we are not just going to rely on vaccine. In other words, there would be an end game so you are not continuing to use vaccine, because, as already stated, the virus mutates. These vaccines do not remain highly effective for long periods of time. So, other countries, if you use a lot of vaccine, will see that as a weakness to control or eradicate the disease. They have to understand that we are using it only as a tool, and if we can convince them to do that, that would be the first step.

But, if I may just expand on this—

Senator CARPER. Just briefly.

Dr. CLIFFORD [continuing]. Just to Senator Tester's questions earlier about foot and mouth——

Senator CARPER. He asked a lot of questions, did he not?

Dr. CLIFFORD. Yes, about foot and mouth disease.

Senator Carper. I told him he holds the record for asking questions in a 7-minute period.

Dr. CLIFFORD. This is the same thing. We would take no action to put our industry at risk. We care about our mission and we care about American agriculture and we would not do that. But, the fact is, there is a lot of concern out there about the use of vaccine in a country that is free of FMD with vaccination. It is the same thing with high path AI. So, we cannot go around the world and say one thing to one country because of our position and do something different to somebody else.

Senator CARPER. All right. Thanks.

Dr. CLIFFORD. Thank you, sir.

Senator CARPER. You have all heard the term, this is not our first rodeo, or this is not my first rodeo, and when it comes to avian influenza, this is not our first rodeo this year. This one we see from time to time, probably a lot more than we want to.

One of the things we try to focus on in this Committee is not dealing with symptoms of problems, but how do we deal with root causes of the problems. A good example of that is all these people trying to get into our country from Latin America and how do we deal with not just the symptoms of problems on the border, but the root causes of their illegal migration.

Just talk to us about root causes here. Is there any way to address this challenge, this problem with the avian influenza by ad-

dressing not just the symptoms of the problem, but by addressing root causes, or is that just not possible? And, Jack, would you lead off, and then we will just ask the others—

Dr. GELB. Yes. Thank you, Senator.

Senator Carper. I will ask you to be brief, if you will.

Dr. GELB. I think, if you consider the root cause the introduction from wild bird populations, this is a new normal for us, as Dr. Clifford mentioned earlier on. We have not seen this. So, this is a new situation, and what we need to do, if possible, is to institute the biosecurity at the farm level, for example—and this is not only commercial farms, but backyard farmers, which are increasingly important in our country and numerous, as well. So, on several fronts, this is very important.

Senator CARPER. Yes. One of the things we have done in Delmarva, we found that some of our earlier avian influenza outbreaks came not from wild birds, but literally from live bird auctions in

places like New York-

Dr. Gelb. Yes, that is correct.

Senator Carper. They cleaned those up. They have been cleaned

up a lot. That has helped a lot.

Dr. GELB. Yes. USDA has done a wonderful job, along with the State of New York, State of New Jersey, because that metropolitan New York area was once very heavily involved with certain H7 types of avian influenza viruses.

Senator CARPER. OK. Mr. Currie, this is probably not a fair ques-

tion for you. If you want to jump in, please do.

Mr. Currie. No, sir. I mean, as I said, we have not evaluated the current response, but we are very aware of the new challenges and I think there are going to be new challenges identified. Monitoring of wild birds is a challenge, and I know that USDA, I think just last week, issued a couple new strategies to help determine how this should actually be done in wild birds and waterfowl—

Senator CARPER. OK.

Mr. CURRIE [continuing]. So that is just a new element that is going to have to be addressed.

Senator CARPER. Thank you.

Dr. Schuchat, has your name ever been mispronounced, Dr. Schuchat?

Dr. SCHUCHAT. Once or twice.

Senator CARPER. What is the wildest mispronunciation of your name that you recall? [Laughter.]

Dr. SCHUCHAT. I am not really sure.

Senator CARPER. You do not want to go there, huh? [Laughter.] Dr. SCHUCHAT. I did not prepare for that question. I am sorry. [Laughter.]

Senator CARPER. We will hold that to the next hearing.

Dr. Schuchat. Thank you. Yes. I think to step back and generalize a little bit, we think of this as an emerging infection where global threats are local threats and where the human-animal interface is very important. So, with influenza, we are always worried because the virus is constantly changing and we very much are worried about what is happening in the rest of the world. With avian influenza, we obviously are very keen to know what is going on in the animal surveillance as well human surveillance.

Senator CARPER. All right. Thank you.

Dr. Clifford, just very briefly.

Dr. CLIFFORD. Yes. Senator, I think it is important to make one critical point here.

Senator Carper. OK.

Dr. CLIFFORD. This virus came from a virus that was found in 1997 in China and it was in an H5N1 outbreak in Europe and Asia when there was the concern about the human pandemic. We put money around the world into that area. We did not put enough and we did not do the job. If we would have eradicated H5N1 from Asia, this would not have happened today. Senator CARPER. Oh, really? That is a great point.

All right, Scott. I am going to call you Doctor one more time. Dr. Schneider.

Mr. Schneider. That is OK. I kind of like it. [Laughter.]

If I can learn one thing, I think that I am going to be rethinking my entire biosecurity plan on my farm. I am going to be reallocating funds toward increasing the structural, operational, and cultural protocols that I have in place for my farm. Ultimately, it is my problem and it is my farm and I need to do something about it. I am going to be training my employees a little bit better. I am going to be controlling traffic on and off my farm. And, I am even going to take steps to try to control dust. And, I would love to include the use of a vaccine in my toolbox when I come to biosecurity efforts on my farm.

Senator Carper. That was a great response.

I will just close with this thought. I am an old Navy guy. I think in terms of nautical terms. In the Navy, we had to face a big challenge, it is like all hands on deck, and this is all hands on deck, and I am pleased to see that the hands, some of the hands and the minds that are here, represented here today, are focused big time on this and, I think, working collaboratively together, and I commend you for that.

I appreciate very much what you said, Scott, about taking responsibility yourself, and that is clearly what needs to be done.

What I like to say, at Home Depot—I do not know if you have Home Depot in Minnesota, if you have the ad campaign that says, "You can do it. We can help." And, this sort of applies. You can do it, but we can help. We all have a role and a responsibility to play.

It is going to come again. It is going to come again, in maybe a different mutation. It may come again this fall, and we just have to learn from our mistakes, and stuff that works, figure out what works, do more of that, that which does not work, do less of that.

Great hearing. Thank you all very much.

Chairman JOHNSON. Thank you, Senator Carper.

And, one thing we like to do is offer the witnesses one last com-

But, I have to first go to Dr. Clifford. How would we have wiped out that virus in Eurasia?

Dr. CLIFFORD. We talk about one world, one health, and global health security. We have to be able to address these issues and make sure that they are done. We addressed the human pandemic concern, but we basically reduced the funding and support necessary to continue to fight it there.

Chairman JOHNSON. But, how would we have done it? I mean, you can always throw money at something-

Dr. Clifford. How?

Chairman JOHNSON [continuing]. But how would we have done it, when you have migratory birds, and how would we have done

Dr. CLIFFORD. You have to eradicate it from the poultry. It was in the poultry. It was killing the wild birds, but what happened, because of its allowance to continue in the continual lineage, when it became an H5N8, it adapted itself to wild waterfowl and would not kill some of these ducks. That is the problem. So, we had to get rid of it in the poultry so you would stop this exchange of virus back and forth.

Chairman JOHNSON. So, are the protocols in other countries not as rigorous as ours, so they do not destroy flocks, that type of

Dr. CLIFFORD. It depends upon the country, and in Asia, in parts of Asia, people will actually sleep with their birds and may have pigs outside and it is a whole different world.

Chairman JOHNSON. Yes.

Dr. CLIFFORD. But, if we do not help in those cases, many of those kinds of diseases that are of zoonotic potential may come back to this country.

Chairman JOHNSON. That is my point. You are saying we did not spend enough money to eradicate it. I am not sure we could. That was my only question.

Dr. CLIFFORD. Well-

Chairman JOHNSON. But, anyway, I will give you, again, closing comments.

Dr. CLIFFORD. We could have tried.

Chairman JOHNSON. I understand. But, we will start with you, Dr. Clifford.

Dr. CLIFFORD. Again, just thank you, and I think that we have learned lessons and we want this process to be faster. It is critical that we get in there, kill birds quickly, and get the producers back on their feet faster, and that is something we have taken to heart.

Chairman JOHNSON. Thank you.

Dr. Schuchat, and I think one of the reasons that Senator Carper talked about the pronunciation, I actually had a phonetic pronunciation, but we do not have a real good track record ourselves here in terms of—— [Laughter.]

So, if there is a really bad pronunciation, it probably came from

this Committee. But, anyway, Dr. Schuchat.

Dr. Schuchat. Influenza has been around for a really long time and continues to be a major challenge. I think that the big picture here is continued investment in improved vaccines, including the so-called universal influenza vaccine, is really important to get ahead of these kinds of problems for the future. Chairman JOHNSON. Mr. Currie.

Mr. Currie. Yes, sir. I talked about in my opening statement how important coordination and plans are, and it is very easy to sit here and talk about those types of things, but it is very difficult to address a real life situation like this. However, this is somewhat unique in that we have had an outbreak. It seems to be slowing, but we expect and we are worried about the next outbreak. So, we can actually learn many lessons learned, coordination lessons learned, now and figure out what our capabilities need to be in other parts of the country that may be impacted by this. So, we can potentially learn from this quickly and be ready for what we think might be coming in the fall.

Chairman JOHNSON. Professor Gelb.

Dr. Gelb. Thank you, Senator. I think we need to help and protect the Mr. Schneiders of our country. We have seen the number of people involved directly in agriculture fall for many years. We have these large, highly efficient means of producing food and poultry, but I think, really, the producers and the farmers, the family farmers—this is a wake-up call for us, I think, because we have enjoyed the best quality food, safest food supply in the world. Now, we are importing some shell eggs here from other countries. What is wrong with that picture? And, we sometimes get into a problem when we have to import food, not to mention some other kinds of materials—drugs, et cetera. Thank you.

Chairman JOHNSON. Well, first of all, let me say you took the words right out of my mouth. My own background, my parents were both raised on small dairy farms. That tradition of the family farm is dwindling and we cannot allow that to happen, but we also

cannot allow people like Mr. Schneider to remain exposed.

I think in this hearing, I have learned that he is exposed. I thought we had coverage. I thought he was just having a hard time obtaining that coverage. I am afraid he is completely exposed, so I think both Senator Carper and I will certainly work together to see what we can do to help those in Mr. Schneider's position, and not just Mr. Schneider, but everybody affected by this now and in the future. So, that is, I think, the real commitment of this Committee.

It is not necessarily in our jurisdiction, but this is certainly our ability to hold an oversight hearing, to expose that particular problem. As I said before the panelists sat down, this is about getting people to admit we have a problem. I think this is a real problem that needs to be addressed urgently. Mr. Schneider.

Mr. Schneider. One of the things that I think that might be able to help people like me is just in the indemnity payment formula, and one of those things is specific to egg-laying farmers, but the indemnification could be based on the future value of the eggs that

are supposed to be produced from those hens.

That is where the egg industry is just a little bit different than the broilers and the turkeys, whereas over a period of weeks, those animals are raised and then sent to market. In the egg industry, those animals are in my facility for over a year, sometimes even 2 years, and it is the value of those eggs that are going to be produced, that is where, if there was an indemnity payment based on that future value, that would have helped me out an awful lot.

Chairman JOHNSON. No, as we discussed in my office, too, there has to be something like—in my business, I purchased business interruption insurance. If you have a catastrophic loss, and let us face it, you destroy your flock, that is a catastrophic loss, so we have to do something—there has to be some indemnification, some insurance that will keep you in business, business interruption in-

surance. Honestly, I am shocked that we do not have that either

as a government program or in private insurance for that capability. So, again, that is, to me, a real take-away of this hearing. So, again, I just want to thank all the witnesses for your testimony. I will state again, this Committee really does have a great deal of sympathy for your loss, Mr. Schneider, and we are dedicated to doing what we can to help you out of your predicament. But, this hearing record will remain open for 15 days, until July

23 at 5 p.m., for the submission of statements and questions for the record.

This hearing is adjourned.

[Whereupon, at 11:56 a.m., the Committee was adjourned.]

APPENDIX

Opening Statement of Chairman Ron Johnson

"Stopping an Avian Influenza Threat to Animal and Public Health" July 8, 2015

As submitted for the record:

Good morning. I want to welcome and thank our witnesses for being with us today.

As I often say in our hearings, our committee has a mission statement, and that is to enhance the economic and national security of our country. Avian influenza poses a major threat to both our economy because of its potential impact on the poultry industry and, in the long-term, to public health. We will be looking at these issues today.

I want to be clear that this is not a hearing to scare anyone away from buying eggs or turkeys over fears of infection. Our food supply is safe and adequately protected. But it is important for us to examine this threat and the response to the outbreak in detail.

The outbreak of the H5N2 strain this year ravaged egg-laying and turkey facilities through the Midwest. More than 40 million chickens have been lost on account of this virus. That's over 10 percent of the entire egg-laying population. In the turkey industry, 7.8 million birds, over 3 percent of the industry, have been euthanized to stop the spread the outbreaks.

According to Goldman Sachs, this outbreak could cost consumers \$8 billion in higher egg prices, or 75 percent more than last year. That's an extra \$20 on average for every American. It is fortunate that the outbreak has stopped as temperatures across the Midwest have increased. But many states are extremely nervous about a renewed outbreak in the fall as migratory birds begin moving again, potentially bringing the virus back to the Midwest or even taking it down the Atlantic coast, where hundreds of millions of chickens are raised annually.

We have the opportunity now to examine the issues vital to responding to another outbreak, including how testing and depopulating of animals can be improved, the need for a vaccine that industry can use, and how agencies and states are planning for another big hir

Our food supply would undoubtedly remain safe, but the loss of millions more chickens and turkeys would be devastating. The hit to our nation's economy would be in the billions of dollars. On the public health front, the Centers for Disease Control and Prevention has stated that the public health risk from the recent outbreaks has been minimal. That being said, there have been more than 100 of cases of human avian influenza infections worldwide just this year, according to the World Health Organization.

The reality is that at some point, we will face another pandemic resulting from a strain of avian influenza. We need to stay vigilant and ready to mitigate any potential threat to our homeland.

I look forward to hearing your testimony about what the threat of avian influenza has meant to animal and public health, including your experience with the recent outbreaks.

###

Statement of Ranking Member Thomas R. Carper

"Stopping an Avian Influenza Threat to Animal and Public Health" July 8, 2015

As prepared for delivery:

I would like to thank the Chairman and his staff for working with my staff and me on this important and timely hearing on avian influenza. It is my hope that we will all come away from this hearing more confident than ever in the strength and importance of America's poultry industry and better prepared to respond to any further outbreaks should they occur.

The poultry industry is an integral part of our national economy. It supports over a million jobs nationwide and almost \$350 billion in total economic activity. Some of this industry is tied to egg production, which several of our colleagues know very well. Other parts of the industry, as in my home state of Delaware and on the Delmarva Peninsula, focus on the kind of chicken we eat, known as 'broilers.'

As some of you may know, the Delmarva Peninsula – which includes parts of Delaware, Maryland and Virginia – is home to some of the largest broiler chicken producers in the U.S. In fact, Sussex County, Delaware, is considered the birthplace of the broiler chicken industry and produces more chickens than any other county in the United States. The total economic value that this industry brought to Delaware in 2014 was \$2.7 billion dollars. In fact, the meat from our broilers was exported all to nations around the world to tune of nearly \$140 million last year.

Some parts of the poultry industry, particularly in the Midwest, continue to grapple with the devastating impacts of the recent outbreak of avian influenza. We have lost millions of chickens and turkeys to this disease, and the economic losses are staggering.

If that's not bad enough, some of our biggest trading partners have temporarily closed their doors to our poultry exports. In some instances, these bans affect every state that produces poultry products – not just those that have had a confirmed case of the flu.

Thankfully, there is some good news. The frequency of new cases has slowed significantly in recent weeks. Broiler chickens have yet to contract the virus. And as of now, there is no evidence of a threat to human health. We have farmers all across America to thank for much of this fortunate news. Their efforts – and sacrifices – have really made a difference. I'd also like to recognize our federal and state agriculture and public health officials for their hard work. Our friends in academia and industry have also done a great job.

But this is not a time to rest on our laurels. The possibility of a new outbreak, even here along the East coast, is very real. All of us need to remain on high alert. This is especially true as we move into migratory season in the coming months.

Today's hearing provides an important opportunity to better understand the threats posed by avian flu. It will also help us examine the steps so many people are taking to not only put an end to this outbreak, but to ensure new cases don't spring up elsewhere. We should also use this

hearing to identify lessons learned from our response, as well as any best practices that can make a difference in stopping future outbreaks.

I am especially interested in hearing from Professor Gelb about measures we've taken in Delaware and on Delmarva that could be applied nationwide to further contain the spread of virus.

At the end of the day, we all need to work together to stop the spread of avian flu. We must all continue to act with a sense of urgency to assure Americans, along with people all over the world, that our eggs, as well as the meat from our chickens and our turkeys, are safe to eat.

The current outbreak is a serious matter – there is no doubt about that. But we have experts around the country, like those with us today, that have dealt with these issues before and are laser focused on stopping the spread of this disease. With continued hard work, coordination and determination, we can – and will – solve this problem together.

With that, I would like to thank all of our witnesses for being with us today and I look forward to your testimony.

###

Statement of Dr. John Clifford Deputy Administrator Veterinary Services Animal and Plant Health Inspection Service U.S. Department of Agriculture

Before the

Senate Committee on Homeland Security and Governmental Affairs

July 8, 2015

Chairman Johnson, Ranking Member Carper, and Members of the Committee, thank you for the opportunity to testify today on behalf of the U.S. Department of Agriculture (USDA). I serve as the Deputy Administrator for USDA's Animal and Plant Health Inspection Service (APHIS). In this capacity, I am the Chief Veterinary Officer of the United States.

Today, we are facing the largest animal health emergency in this country's history. We are dealing with an unprecedented outbreak of highly pathogenic avian influenza (HPAI) that is taking a heavy toll on the poultry industry. People have lost their jobs and have seen their livelihoods put in grave danger by this outbreak, and our hearts go out to them. I can assure you, however, that this disease has USDA's fullest attention, and we are committed to standing with our producers and industry to get them – and the communities they live in and support – back on their feet.

USDA has been and will be there every step of the way with producers, industry, and our state partners. We've worked closely with them to respond quickly and decisively to this outbreak. More than 400 USDA staff and nearly 3,000 USDA-contracted personnel have been working around the clock in every affected state on the response. We've delivered over \$190 million in indemnification payments to producers to control the spread of disease, and to help them recover from it. Should the need arise, we have the authority to request even further funding. All told, USDA has committed over \$500 million – an amount more than half of APHIS' yearly discretionary budget – in addressing this outbreak. We've seen trade cut off by trading partners concerned about the devastating effects of this disease, causing \$1 over billion in poultry products to be directed to other markets at a cost to producers. We understand the devastating impact this outbreak has had upon all, and we are committed to helping those affected. And we will help protect those producers who have not yet been – and we certainly hope, will not be – impacted by this disease.

The Outbreak

The outbreak started in December 2014. Western Hemisphere migratory birds commingled with Asian birds in the northwestern part of the continent. These birds acquired a variant of HPAI that is currently widespread in Asia. Wild ducks and geese (which have lower mortality for this variant) brought the disease first to the Pacific flyway, and later to the Central and Mississippi

flyways. Initial detections in the United States were in wild birds and backyard flocks, and may have resulted from direct contact with sick migratory birds. As the virus spread through the Midwest, it came into contact with some of the largest segments of the poultry industry; it took an especially heavy toll on turkeys and egg-laying chickens, primarily in Minnesota and Iowa.

APHIS scientists have been conducting an epidemiological investigation into the origins of the disease. Based upon the results of the preliminary investigation the Agency released in June, we believe wild birds were responsible for introducing HPAI into the environment, and from there it was spread into commercial poultry houses. However, given the number and proximity of farms affected by HPAI, it appears the virus is spreading in other ways as well. For instance, one analysis provides evidence that a certain cluster of farms was affected by identical viruses, pointing to possible transmission among those farms. In addition, genetic analyses of the HPAI viruses suggest that independent introductions as well as transmission between farms are occurring in several States concurrently.

Our investigation shows that the virus has been introduced into commercial poultry facilities from the environment (i.e., water, soil, animal feces, air) or from farm-to-farm transmission on human sources such as boots or equipment. After conducting an analysis of over 80 commercial poultry farms, APHIS cannot associate transmission of the disease with any single one of those factors, but it seems clear that lateral spread occurred when biosecurity measures that are sufficient in ordinary times were not sufficient in the face of such a large amount of virus in the environment.

USDA – through the APHIS National Veterinary Services Laboratories – has confirmed HPAI in 21 states, which includes nine states where we identified it in commercial poultry. We have confirmed the disease in 232 total poultry premises, with 211 of those being commercial facilities. As part of our disease control strategy, we've depopulated 7.5 million turkeys and 42 million chickens and pullets. This is approximately 3% of the U.S. annual turkey production, and approximately 10% of the egg-laying chicken population.

USDA's Response to HPAI

USDA has extensive experience in responding to animal disease outbreaks, especially in poultry. In 2003 and 2004, we successfully fought off an outbreak of Exotic Newcastle Disease in the southwestern United States and low pathogenic avian influenza, which spread through the Shenandoah Valley in Virginia. The bulk of our response to the current outbreak has been based upon the existing USDA avian influenza response plans we've developed and refined over the years. These existing plans have allowed USDA and its state partners to respond quickly and decisively to address this outbreak using the authorities given to us under the Animal Health Protection Act and state laws and regulations.

The goals of USDA's HPAI response plans are to (1) detect, control, and contain HPAI in poultry as quickly as possible; (2) eradicate HPAI using strategies that seek to protect public health and stabilize animal agriculture, the food supply, and the economy; and (3) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products. In addition we want to ensure that the

Federal government, producers, States and local governments are well-positioned to effectively respond to future outbreaks. Achieving these goals will allow individual poultry facilities, States, Tribes, regions, and industries to resume normal production as rapidly as possible and minimize losses from future outbreaks. They will also allow the United States to regain disease-free recognition from our trading partners without the response effort causing more disruption and damage than the disease outbreak itself would be where it left unchecked.

The plan has five basic steps when the disease is detected: quarantine, eradicate, monitor, disinfect, and test.

- Quarantining allows us to restrict the movement of poultry and poultry-moving
 equipment into and out of the control area. Simply, we must stop the spread and transfer
 of the disease as much as we can.
- Eradication is part of our "stamping-out" approach to HPAI, which requires the
 depopulation of clinically affected and in-contact susceptible poultry to eliminate the
 disease where it exists and to further reduce the risk of spread. USDA has provided
 indemnification payments to producers for those birds that must be depopulated, which
 helps serve as an incentive for them to report potential infections quickly, which can
 further reduce the potential for virus spread.
- USDA monitors the region to better understand the viral spread. We monitor birds in a
 broad area around the quarantine area to see if there are other incidents to which we must
 respond.
- <u>Cleaning and Disinfection</u> of the premises where affected flocks are located is a key piece toward eradication. We must know that facilities are clean and disease-free before we can allow them back into production.
- <u>Testing</u> is the last step. After the disinfection is complete and before we can release the quarantine, we test the premises and environment to ensure that it is disease-free, so that operations may safely resume.

USDA has the best avian influenza surveillance system in the world. Our program exceeds international standards and allows us to identify the disease, and upon detection, to ramp up our emergency response activities. Our strong surveillance system assures our trading partners that we take disease eradication and control seriously and will be of great benefit to us as we try to resume trade with the foreign trading partners who have cut off access to U.S. poultry and poultry products.

How This Works for Producers

USDA wants impacted producers to get back into business as quickly as possible, and APHIS and its state partners work very closely with those affected.

Following confirmation of HPAI in their operation, a producer will need to develop a flock plan for all premises with confirmed infections or exposure. The flock plan sets out the steps to eradicate the virus and prevent its spread to other flocks. It also specifies the procedures required to get the facility back into production, including requirements for quarantine release. The flock plan will include cleaning and disinfection requirements. The flock plan must be signed by the owners, a State animal health official, and an APHIS official before an indemnification payment can be processed. An APHIS case manager will work with the producers to walk them through the process and the information required to complete all steps.

APHIS will then prepare an appraisal document for indemnification and present it to the producer as quickly as possible. Affected producers need to sign the appraisal document before depopulation can occur. The Animal Health Protection Act limits indemnity to the fair market value of the animal being depopulated; it is not intended to make the producer whole, such as by covering production losses during the time a barn is down for the disease response activities. APHIS economists developed a series of species-specific appraisal calculators that use publicly available prices, costs, and productivity data to develop a value per animal that varies by the age of the animal. The calculators are updated monthly to account for changing feed costs, values, and assumptions.

The value per animal type multiplied by the number of each animal type is used to calculate total indemnity. For HPAI, APHIS provides 100 percent of that indemnity amount. One important distinction: the Animal Health Protection Act limits indemnity to the fair market value of the animal being depopulated.

A compliance agreement must be developed if depopulation, disposal, or cleaning and disinfection will be performed by personnel other than Federal or State officials, and if the producers will request indemnity for those activities. A compliance agreement is separate from the flock plan. The flock plan specifies the necessary procedures for the premises to resume normal production; a compliance agreement indicates what tasks will be completed, who will be responsible for each task, and how much the work is expected to cost. A compliance agreement is comparable to a statement of work -- a plan that lays out the activities to be done and the expected costs to accomplish those activities.

Provided the terms of the compliance agreement are met, USDA will provide funding for those cleaning and disinfection activities, and compensation or indemnification for any items or equipment that are destroyed or damaged as a result of the cleaning and disinfection process.

The Importance of Biosecurity

One of the lessons we've learned is that we all need to be vigilant about maintaining stringent biosecurity measures, especially in the face of a disease outbreak. In June, APHIS released a partial epidemiology report on the Agency's findings about the origins and spread of the virus. While the results of our preliminary epidemiological investigation didn't show a single source of transmission, it did emphasize the importance and need for improved biosecurity. The strength of

our biosecurity efforts depends entirely on all of us – producers, their employees, USDA, and our contractors who are responding to this outbreak.

Part of this involves more outreach to producers. We've made more information about basic biosecurity practices available on our website, and we've shared materials such as a checklist of best practices and information sheets with industry groups for distribution to their members. These recommendations include items such as allowing only essential personnel access to poultry premises and thoroughly disinfecting boots, equipment, and vehicles that enter and exit those locations.

We're also meeting directly with State Veterinarians and industry to discuss the need for more biosecurity. On July 28 and 29, 2015, we'll be holding a stakeholder meeting with those groups to discuss those issues to ensure that our collective biosecurity is more stringent and that we are prepared for any future outbreaks.

We know that proper biosecurity begins at the farm's edge. What this outbreak has taught us is that the biosecurity measures that extend on the farm into each individual barn or facility are equally or, at times, more important than the farm's edge approach. Based on the belief that "an ounce of prevention is worth a pound of cure," we plan to work with our producer and State and local partners to strengthen biosecurity measures. This may require changes to current practices or assumptions, and USDA is engaging our partners in these critical issues.

APHIS appreciates the cooperation of poultry producers in providing the information needed for these epidemiology investigations. APHIS values its partnership with industry and believes that with their continued support and assistance, the agency will be well positioned to learn all it can about this virus. We all have a role in – and a responsibility for – our Nation's agricultural health, and we will work together to ensure that we are in the best position possible to address this disease.

Preparedness for the Fall

USDA is treating the potential threat of more infections in the fall with the utmost seriousness. Although we hope that we will not have additional or more wide-spread outbreaks, it's very likely that wild birds will carry the virus with them when they begin migrating south in the fall. Although states in the Atlantic flyway have not been affected by this HPAI outbreak, it's important that our state and industry partners begin preparations should the disease occur there.

I can assure you that this need for preparedness has the attention of all of USDA. The Secretary is leading these efforts, and has directed USDA to do everything it can to respond to this virus, assist producers, and maintain trade markets. As we look to the fall, we plan to be ready for the challenge.

To that end, we recently concluded a planning workshop with our partners focusing on the worst-case scenarios and the responses needed. We're identifying the resources we would need under various scenarios and how we can better partner with States and industry to manage this disease.

We've encouraged our partners to review the existing avian influenza response plans so they understand what we will expect and what actions we will need them to take should the disease strike. Along those lines, we've urged states and industry to develop site- and county-level specific depopulation plans for landfilling or composting birds. Our experience in the Midwest showed that the biggest roadblock to efficient depopulation (which is key to reducing the spread of the virus) is the lack of ready sites to receive and process dead birds.

Should the disease strike in the fall, USDA and its partners will be ready to tackle it head-on.

Vaccination and Trade Issues

As part of USDA's ongoing response, the Department evaluated the efficacy of current vaccine options for HPAI in addition to the economic impacts of vaccination. Some in the poultry industry asked if USDA would consider allowing the emergency use of vaccines to halt the spread of the disease. In June, after conducting that evaluation, USDA determined that we would not, at this time, allow for the use of vaccines to assist in the eradication of HPAI.

Right now, we do not have a closely matched vaccine to the outbreak H5N8 or H5N2 HPAI viruses. USDA's Agricultural Research Service (ARS) is evaluating a current vaccine in chicken and turkey protection studies against our specific outbreak viruses. In addition, ARS has developed a reverse genetic H5 vaccine seed strain that antigenically matches the field virus and it is undergoing the same protection studies. Only the most efficacious vaccines should be considered for field use as any infection in the vaccinated population would still require the entire barn to be depopulated.

Aside from questions about its effectiveness, USDA believes that if a vaccine were used, some additional trading partners would ban all U.S. exports of poultry and eggs and not necessarily just those from the states currently affected by HPAI until they could complete a full risk assessment. The loss of these markets could cost U.S. producers at least \$3 billion in trade revenue with uncertain reductions to the mortality rate of birds from this disease.

In the weeks and months ahead, we will continue to support efforts to develop more effective vaccines. ARS scientists are working diligently on a better vaccine based on the specific genetics of this strain of the virus. We have said that we may reevaluate our vaccination decision as more effective vaccines are developed and ready for use, carefully considering both the efficacy of the vaccine and the potential trade impacts. If used, vaccines will serve as an additional tool in our eradication efforts and will be targeted in the states and poultry sectors where they can be most effective.

USDA has been working very closely with our trading partners to minimize the effects of this outbreak on producers. The World Organization for Animal Health (OIE) guidelines encourage a regionalized approach to animal diseases, and we have urged our trading partners to adopt that approach, just as we would with them should they be struck by an animal disease. Despite the OIE guidelines, 18 trading partners have suspended imports of all U.S.-origin poultry and poultry products. However, 38 trading partners have adopted a regionalization approach, limiting

imports of poultry and poultry products only from those states or counties affected. We speak with our partners regularly, and are already working with them to restore market access from the areas where the outbreak was limited and has been controlled. We'll continue to work with them to restore full market access as quickly as possible as the overall outbreak subsides.

Conclusion

There are a few key points I want to leave you with. There have been no human infections from these viruses and the risk to the general public is low. It's also important to understand that our food supply is safe. Properly prepared and cooked poultry and eggs are safe to eat.

I think despite the difficulties we've faced, we've had some good news. In recent weeks the number of new detections has slowed to a trickle, and more and more farms have begun to repopulate with new poultry. The restocking guidelines we and our state partners have put in place give us the assurance that the premises and the local environment are free from the disease, and that we have enhanced biosecurity measures in place to reduce the threat of recontamination. Most importantly, successful restocking is a sign that our techniques and approaches in confronting this disease can and do work. That might not seem like much consolation for the producers who've lost so much, but it should provide reassurances to those nervous about the potential approach of the disease through wild waterfowl come fall.

I really want our producers to understand that they have USDA's support. Our experience in quickly and successfully responding to previous animal disease outbreaks and the lessons we've learned from the Spring on this outbreak will inform our response and allow us to minimize the effects of this disease going forward. Every day, we are further refining our prevention, detection, and response based on the latest science and the lessons from this outbreak. We will continue sharing what we learn with our state and industry partners through regular conversations and meetings. We will also continue to work with Congress to ensure that we have the necessary tools and resources to fight this disease. Together, we will meet this challenge and protect the health of the Nation's poultry.



Stopping an Avian Influenza Threat to Animal and Public Health

Anne Schuchat, MD (RADM, USPHS)
Director, National Center for Immunization and Respiratory
Diseases, Centers for Disease Control and Prevention U.S.
Department of Health and Human Services



For Release upon Delivery Wednesday July 8, 2015 Expected at 10:00 a.m.

Introduction

Good morning Chairman Johnson, Ranking Member Carper, Members of the Committee. I am Dr. Anne
Schuchat, Director of the National Center for Immunization and Respiratory Diseases at the Centers for Disease
Control and Prevention (CDC).

Today, I am here to discuss the potential human health implications of the outbreaks of highly pathogenic avian influenza (HPAI) H5 in U.S. domestic, captive, and wild birds and the steps CDC is taking to prepare for one or more human infections with these viruses. Influenza viruses are unpredictable and constantly changing. Influenza viruses in animals provide a reservoir of viruses that can contribute to the emergence of novel influenza viruses with pandemic potential for humans. When a novel influenza virus emerges that can infect and spread readily among people with little or no immunity against the virus, a pandemic can occur. The viruses currently circulating in U.S. birds are novel viruses against which people have little or no immunity — but thus far they do not seem to be able to easily infect humans. Regardless, the circulation of H5 influenza in U.S. birds is of concern to public health, and from a CDC perspective requires vigilance and preparedness.

Over the last decade with the support of Congress, we have made great strides in our ability to detect, respond to, and mitigate influenza virus threats. At CDC we have enhanced surveillance and diagnostic capabilities to rapidly detect new influenza viruses. Our systems provide the scientific basis for vaccine virus strain selection — both for each season's influenza vaccine as well as for pre-pandemic influenza vaccines. We diligently monitor for genetic changes in the circulating viruses, and identify how those genetic changes affect disease, transmission, and/or severity. CDC invests resources in seasonal influenza surveillance systems, laboratory capacity, and vaccination efforts that help prepare for and inform pandemic responses.

Avian H5 Influenza

Avian influenza viruses are influenza type A viruses that circulate in birds. These viruses commonly infect wild birds worldwide and can also infect domestic poultry, other birds, and some other animal species. Avian

influenza A viruses are classified as either low or highly pathogenic viruses, based upon pathogenicity of the virus in chickens, as well as molecular criteria.

In December 2014, the United States Department of Agriculture (USDA) confirmed the presence of highly pathogenic avian influenza (HPAI) H5 viruses in domestic, captive, and wild birds in the United States. As of June 18, 2015, USDA reports that HPAI H5 viruses have been detected in 21 U.S. states, 15 states have experienced outbreaks in domestic poultry or infections in captive birds, and six states have detected H5 in wild birds only. The HPAI viruses detected include an H5N8, reassortant H5N2 and a reassortant H5N1 virus. Reassortment is the process through which two or more influenza viruses can swap genetic information by infecting a single human or animal host. When reassortment does occur, the virus that emerges will have some gene segments from each of the infecting parent viruses and may have different characteristics than either of the parental viruses. These viruses were not detected among domestic poultry or birds in the United States prior to December 2014.

Human Health Implications

CDC considers the human health risk to the general public from HPAI H5 outbreaks in U.S. birds to be low at this time. Thus far there have been no human infections with domestic HPAI H5 viruses associated with the ongoing outbreaks among birds in the United States. Initial laboratory studies at CDC suggest these viruses do not possess molecular properties associated with adaptation to mammalian hosts and do not cause severe disease in animal models as other HPAI H5 viruses have caused severe disease in people in other parts of the world. In general, human infections with avian influenza A viruses are rare. When they have occurred elsewhere in the world, person-to-person spread has been extremely rare. Most of these human infections with avian influenza A viruses occurred in people who had close, prolonged, unprotected contact with infected birds or the excretions/secretions of infected birds (e.g., droppings, oral fluids). Sustained person-to-person transmission with avian influenza A viruses has not been documented to date anywhere in the world.

We must remain vigilant and be prepared: other HPAI H5 viruses, such as the Eurasian H5N1 and H5N6 have resulted in severe illness or death in humans. It is possible that human infections with HPAI H5 viruses may occur in the United States. With more infections occurring in birds in the United States, there are more opportunities for exposures to these viruses. CDC is preparing not only for the possibility of human infections in the United States, (despite limited human transmission to date) but also for the unlikely event that one or more of these viruses could acquire the ability to spread efficiently among people.

CDC Activities

CDC has made significant investments in seasonal and pandemic influenza preparedness and control, and our efforts are only one part of the broader U.S. Government effort toward pandemic preparedness.

The U.S. Department of Interior and the U.S. Department of Agriculture are the lead Federal Departments for response to outbreaks in wild birds and domestic poultry respectively. HHS and CDC are closely coordinating and collaborating with these Departments to provide guidance for the people working on the frontlines of the animal response, to better understand the genetic and antigenic properties of the viruses, to prepare for the possibility of spread of these new viruses to and among people, and to develop medical countermeasures such as human vaccines.

Public Health Guidance

CDC has issued specific public health guidance related to prevention, detection, and response for H5 viruses currently circulating in birds in North America. Although CDC considers the risk to the general public from these newly-identified US HPAI H5 viruses to be low, people with close, prolonged, unprotected contact with infected birds or the excretions/secretions of infected birds may be at greater risk of infection. Until more is known about these newly-identified HPAI H5 viruses, public health recommendations are largely consistent with guidance for novel influenza A viruses associated with severe disease in humans (e.g., HPAI H5N1 viruses that have caused human infections with high mortality in other countries). First, CDC has worked with USDA and the

Department of Labor's Occupational Safety and Health Administration (OSHA) on the development and posting of guidance on the proper use of personal protective equipment for those who work or have close contact with infected flocks or contaminated environments. Second, CDC has developed guidance for clinicians and public health professionals on the collection and testing of clinical specimens from patients who may be infected with HPAI H5 viruses. Finally, CDC has developed influenza antiviral prophylaxis and treatment guidance for persons exposed to or possibly infected with HPAI H5 viruses. In addition to the proper use of personal protective equipment, antiviral medications can be an important tool in reducing the risk posed by H5 viruses to humans. CDC recommends their use in the treatment of human infections with avian influenza A viruses, and recommends that physicians and other health care providers consider prescribing them to persons with exposure to HPAI H5 viruses circulating in North American birds. Chemoprophylaxis is not routinely recommended as a control measure for personnel involved in culling non-infected or likely non-infected bird populations, or for personnel involved in handling sick birds or decontaminating affected environments (including animal disposal) who properly used personal protective equipment. To help ensure health care providers have access to antiviral drugs, CDC issued guidance to state preparedness directors allowing the use of Federally-subsidized antivirals stockpiled at the state level, as well as directions for requesting antivirals from CDC's Strategic National Stockpile (SNS). CDC will continue updating and issuing guidance related to human health as the situation evolves.

Epidemiologic Response

CDC has long-standing protocols in place for field investigations and contact tracing in the event of a suspected novel influenza case. CDC is working with state public health officials and USDA to ensure that these protocols are appropriately tailored to the current avian response efforts. CDC has equipped and trained public health laboratories to be capable of detection of novel influenza strains, including recent H5 strains. States use CDC developed and distributed molecular diagnostic assays. CDC is working with FDA to refine assays to make them sensitive to hypothetical future variants of circulating viruses. These assays will be distributed to state public

health laboratories. CDC is working with FDA to refine and distribute assays to state public health laboratories that would be sensitive to hypothetical future variants of circulating viruses.

Vaccine

Seasonal influenza vaccines will not protect against avian influenza. CDC is conducting evaluations in its laboratory to determine how H5 influenza vaccines currently in the federal stockpile may be used to offer some protection against H5 viruses circulating in birds in the United States. Simultaneously, CDC has already developed a candidate vaccine virus (CVV) specific to a strain currently circulating in birds in the United States, and shared it with FDA. This candidate vaccine virus is available to manufacturers and other public health partners should production of vaccine become necessary.

Laboratory investigations

CDC is collaborating with USDA and other partners working on the domestic response to avian H5 outbreaks to evaluate virus specimens and genetic sequence information. Together, we are working to better understand and characterize these viruses with the goal of evaluating their potential to cause a pandemic. CDC uses several types of laboratory studies to evaluate avian influenza A viruses for the risk they might pose to humans. We conduct genetic analysis, through which we evaluate a virus' genome to look for mutations that may indicate mammalian adaptation, and other markers such as those that would indicate the possibility of resistance to antiviral drugs. We also use animal models and human cell culture models to understand how the virus infects and transmits in mammals.

The ever-changing nature of influenza viruses requires that CDC and its public health partners remain vigilant regarding novel influenza threats. The impact of the H5 circulation on agriculture is substantial, but we also take seriously the potential risks to human health posed by circulation of new H5 viruses in U.S. birds. I appreciate the opportunity to update you on our assessment of human risks and the preparedness efforts we have taken, and look forward to your questions.



United States Government Accountability Office

Testimony
Before the Committee on Homeland
Security and Governmental Affairs,
U.S. Senate

For Release on Delivery Expected at 10:00 a.m. ET Wednesday, July 8, 2015

BIOSURVEILLANCE

Additional Planning, Oversight, and Coordination Needed to Enhance National Capability

Statement of Chris Currie, Director, Homeland Security and Justice

and

Steve D. Morris, Director, Natural Resources and Environment

GAO Highlights

Highlights of GAO-15-664T, a testimony before the Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

Naturally-occurring infectious disease or the intentional use of a biological agent to inflict harm could have catastrophic consequences. For example, the recent outbreak of naturally-occurring highly pathogenic avian influenza affecting will birds and poultry in the Midwest and on the Pacific coast presents a serious threat to the economy and trade, and underscores the importance of maintaining effective food and agriculture diseases surveillance systems. Biosurveillance aims to detect such events as early as possible and to enhance situational awareness related to human, animal, and plant health.

Since 2010, GAO has issued a number of reports that discuss the importance of effectively conducting biosurveillance across the human, animal, and plant domains. This statement discusses prior GAO reports and the status of recommendations related to (1) federal; state, and local biosurveillance efforts, and (2) efforts related to food and agriculture disease surveillance.

This testimony is based on previous GAO products issued from 2010 through 2013 related to biosurveillance, along with selected updates conducted from November 2014 through June 2015. For these updates, GAO reviewed agency responses and documents provided in response to its recommendation follow up efforts, such as the July 2012 National Strategy for Biosurveillance.

View GAO-15-664T. For more information, contact Chris Currie at (404) 679-1875 or curriec@gao.gov and Steve D. Morris at (202) 512-3841 and morriss@gao.gov.

July 8, 2015

BIOSURVEILLANCE

Additional Planning, Oversight, and Coordination Needed to Enhance National Capability

What GAO Found

In June 2010, GAO reported that there was neither a comprehensive national strategy nor a designated focal point with the authority and resources to guide development of a national biosurveillance capability. Further, in October 2011 GAO reported that states and local agencies faced challenges in developing and maintaining their biosurveillance capabilities, such as obtaining resources for an adequate workforce, and that the federal government had not conducted an assessment of state and local jurisdictions' ability to contribute to a national biosurveillance capability. To help ensure the successful implementation of a complex, intergovernmental undertaking, GAO recommended in 2010 that the White House's Homeland Security Council direct the National Security Council Staff to develop a national biosurveillance strategy, and further recommended in 2011 that the strategy consider nonfederal capabilities. The White House issued the National Strategy for Biosurveillance in July 2012, which describes the U.S. government's approach to strengthening biosurveillance. However, the strategy did not fully respond to the challenges GAO identified. For example, it did not establish a framework to prioritize resource investments or address the need to leverage nonfederal resources. The White House was to issue an implementation plan within 120 days of publishing the strategy. GAO has reported that it is possible that the implementation plan could address issues previously identified, such as resource investment prioritization; however, the plan has not been released as of June 2015.

In August 2011, GAO reported that there was no centralized coordination to oversee federal agencies' efforts to implement Homeland Security Presidential Directive 9 (HSPD-9) on the nation's food and agriculture defense policy, which includes food and agriculture disease surveillance. GAO also found that the Department of Agriculture (USDA) had no department-wide strategy for implementing its HSPD-9 responsibilities. Therefore, GAO recommended that the National Security Council Staff and the Department of Homeland Security resume their efforts to coordinate and oversee implementation, and that USDA develop a department-wide strategy. In response, the National Security Council Staff began hosting interagency working group meetings, and DHS has worked to develop a report on agencies' HSPD-9 implementation efforts, which officials stated will be finalized by late summer 2015. As of February 2015, USDA had conducted a gap analysis of its HSPD-9 implementation efforts but had not yet developed a department-wide strategy. Further, GAO reported in May 2013 that USDA's Animal and Plant Inspection Service (APHIS) had broadened its previous disease-by-disease surveillance approach to an approach in which the agency monitors the overall health of livestock and poultry, but had not yet integrated this approach into an overall strategy aligned with the nation's larger biosurveillance efforts, such as efforts called for in HSPD-9. GAO recommended that APHIS integrate its new approach into an overall strategy aligned with national homeland security efforts, and develop goals and measures for the new approach. In June 2015, officials stated that APHIS has begun to develop some measures, but noted that resource constraints limit their ability to assess their new approach to disease surveillance. Fully integrating its new approach into an overall strategy aligned with broader homeland security efforts, as GAO recommended, will better position APHIS to support national efforts to address threats to animal and human health.

United States Government Accountability Office

Chairman Johnson, Ranking Member Carper, and Members of the Committee:

A catastrophic biological event, such as a naturally occurring pandemic or a terrorist attack with a weapon of mass destruction, could cause thousands of casualties, weaken the economy, and threaten national security. Biosurveillance aims to detect such events as early as possible and to enhance situational awareness and decision making by gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health. The recent outbreak of highly pathogenic avian influenza in the Midwest and on the Pacific coast underscores the importance of maintaining effective animal and plant surveillance systems within the broader context of biosurveillance, as the disruption of the agriculture or food production systems can present a serious threat to the national economy, trade, and human health. Although the current strain is only affecting birds at this time, prior influenza strains have had devastating effects on humans. For example, as we reported in 2011, the Department of Health and Human Service (HHS) estimated that there were as many as 89 million U.S. cases of H1N1 influenza from April 2009 to April 2010.1

Effective preparation for, detection of, and response to a major biological event of natural, accidental, or intentional origin requires effective coordination and cooperation among different federal agencies, levels of government, nongovernmental organizations, and the private sector. At the federal level, HHS is the federal agency with primary responsibility for disease surveillance in humans. The Department of Agriculture (USDA) is the primary federal agency with responsibility for pest and disease surveillance in animals and plants as well as safety of meat, poultry, and processed egg products. As the agency with lead responsibility for protecting against and responding to threats and hazards to the nation, the Department of Homeland Security (DHS) is concerned with the prevention of bioterrorist attacks as well as preparing the nation to

¹See GAO, Influenza Pandemic: Lessons from the H1N1 Pandemic Should Be Incorporated Into Future Planning, GAO-11-632 (Washington, D.C.: June 27, 2011).

²Although USDA's Food Safety and Inspection Service is responsible for ensuring the safety of meat, poultry, and processed egg products, HHS's Food and Drug Administration is responsible for ensuring the safety of virtually all other food. For more information on efforts needed to improve federal oversight of food safety, see GAO, *High-Risk Series: An Update*, GAO-15-290 (Washington, D.C.: Feb. 11, 2015).

Select Worldwide Disease Occurrence: Avian Influenza

Avian influenza
According to the Department of Agriculture, since nid-December 2014, there have been several ongoing highly pathogenic avian influenza incidents along the Pacific, Central, and Mississippi Flyways, impacting about 50 million widt birds and poultry. The Centres for Disease Control and Prevention considers to be low and no human infections have been detected as of June 2015. However, similar viruses have infected people. For example, beginning in the early 2000s, an outbreak of avian influenza spread from China to nearly 800 cuntries, reaching a peak in 2006. Nearly 500 human cases were reported for this outbreak, with almost 300 fatailites. The outbreak, with almost 300 fatailites. The outbreak is resulted in the death and destruction of millions of wild and domestic birds through 2015. birds throughout Asia, Europe, Africa, and the Middle East.



Source: GAO, Department of Agriculture, and Centers for Disease Control and Prevention (photo) | GAO-15-664T

respond to biological events in order to minimize human and economic losses. The responsibility and capacity for collecting most biosurveillance information and carrying out most health-monitoring activities reside within state and local jurisdictions or with private sector entities—such as hospitals and other private health care providers.

Since 2010, we have issued a number of reports that discussed the importance of conducting biosurveillance across the human, animal, and plant domains. This statement describes the status of our prior recommendations related to (1) federal, state, and local biosurveillance efforts, and (2) efforts related to food and agriculture disease surveillance. This statement is based on GAO's prior work issued from June 2010 through May 2013 on various biosurveillance efforts, along with selected updates conducted from November 2014 through June 2015.3 To conduct our prior work, we reviewed relevant presidential directives, laws, regulations, policies, and strategic plans; surveyed states, and interviewed federal, state, and industry officials, among others. More information on our scope and methodology can be found in each of the reports cited throughout this statement. To conduct our updates, we reviewed agency responses and documents provided in response to our recommendation follow-up efforts, such as the July 2012 National Strategy for Biosurveillance.

The work upon which this testimony is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

³GAO, Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader, GAO-10-645 (Washington, D.C.: June 30, 2010); Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture, GAO-11-652 (Washington, D.C.: Aug. 19, 2011); Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy, GAO-12-55 (Washington, D.C.: Oct 31, 2011), and Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry, GAO-13-424 (Washington, D.C.: May 21, 2013.)

Background

Selected Worldwide Disease Occurrence: Foot-and-Mouth Disease
According to the Department of Agriculture, a 2001 outbreak of foot-and-mouth disease in the United Kingdom resulted in the slaughter and disposal of millions of animals and economic losses conservatively estimated at \$14.7 billion.

Foot-and-mouth disease is a highly contagious viral disease of cloven-noofed animals such as cattle, swine, and sheep, and does not have human health implications.



GAO, Department of Agriculture (photo) | GAO-15

Homeland security presidential directives (HSPD) have called for HHS, USDA, DHS, and other federal agencies to take action to strengthen biosurveillance, including food and agriculture disease surveillance. For example, HSPD-9: Defense of United States Agriculture and Food, issued in January 2004, directed HHS and USDA, among others, to develop robust, comprehensive, and fully coordinated biosurveillance and monitoring systems for animals, plants, wildlife, food, human health, and water. Further, DHS was to lead, integrate, and coordinate implementation efforts among federal departments and agencies to protect critical infrastructure, including agriculture. HSPD-10: Biodefense for the 21st Century, issued in April 2004, established the four pillars of biodefense: (1) threat awareness, (2) prevention and protection, (3) surveillance and detection, and (4) response and recovery.5

Pursuant to these presidential directives, as well as federal laws, many federal departments and agencies pursue missions and manage programs that contribute to a national biosurveillance capability. Table 1 describes selected federal departments and agencies with surveillancerelated responsibilities.

⁴The White House, *Homeland Security Presidential Directive* 9: Defense of United States Agriculture and Food (Washington, D.C.: Jan. 30, 2004).

⁵The White House, *Homeland Security Presidential Directive* 10: *Biodefense for the 21st Century* (Washington, D.C.: Apr. 28, 2004).

| Department | Component | Surveillance-related responsibilities | |
|--|---|--|--|
| Department of Health and Human Services | Centers for Disease Control and Prevention (CDC) | CDC is the lead federal agency for human health surveillance and develops strategies for conducting surveillance of diseases in humans, including coordinating with other agencies to monitor zoonotic diseases, which can be transferred between animals and humans. | |
| Department of Agriculture | Animal and Plant Health Inspection Service (APHIS) | APHIS is responsible for implementing and conducting national measures to detect, control, or eradicate certain livestock and poultry diseases (such as diagnostic testing), including in animals at slaughterhouses, stockyards, or other points of concentration. APHIS is also responsible for emergency response to an economically devastating or highly contagious animal disease—for example, by determining the veterinary and other expertise needed to respond. ⁸ | |
| Department of Homeland Security | Office of Health Affairs (OHA) | As the lead agency for national biosurveillance coordination, OHA provides medical, public health, and scientific expertise in support of the Department of Homeland Security's mission to prepare for, respond to, and recover from all threats. | |
| Department of the Interior | National Wildlife Health Center (NWHC) | The NWHC, a science center of the United States Geological Survey, was founded in 1975 to provide the technical assistance necessary to identify, control, and prevent wildlife losses from diseases as well as conduct research to understand the impact of diseases on wildlife populations, and devise methods to more effectively manage these disease threats. | |

Source: GAO analysis and NHWC Strategic Plan | GAO-15-664T

*For further information, see GAO, Federal Veterinarians: Efforts Needed to Improve Workforce Planning, GAO-15-495 (Washington, D.C.: May 26, 2015).

There are two White House councils that provide oversight over the development and implementation of policy related to biosurveillance. The National Security Council was established by the National Security Act of 1947 and serves as the President's principal forum for considering national security and foreign policy matters with senior national security advisers and cabinet officials. ⁶ The Homeland Security Council was established following the terrorist attacks of September 11, 2001, by executive order in October 2001 to ensure coordination of the homeland security—related activities of executive departments and agencies, as well as effective development and implementation of homeland security

⁶50 U.S.C. § 402.

Page 4

GAO-15-664T

Selected Worldwide Disease Occurrence: Salmonelia, United States, 2008

Salmonella, United States, 2008
in 2008, a salmonella outbreak occurred in 43 states and the District of Columbia, with 1,500 persons reportedly ill with the outbreak strain. The initial investigations identified tomates as the likely source. As the outbreak continued, additional investigations showed much of the outbreak was due to jatapeno and Serrano peppers grown and packed in Mexico and distributed in the United States. According to the Department of Agriculture's Rural Cooperative, the tomatic industry sustained an estimated loss of \$100 million or more.



de: GAO | GAO-15-664T

policies.7 In May 2009, the staff serving the Homeland Security Council and National Security Council were merged as the National Security Council Staff, but both councils continue to exist by statute. The Homeland Security Council was maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such a biosurveillance.

We have previously reported that in an era of rapid transit and global trade, the public health and agricultural industries, as well as natural ecosystems including native plants and wildlife, face increased threats of naturally occurring outbreaks of infectious disease and accidental exposure to biological threats.8 Some diseases, such as some strains of influenza, are known as zoonotic diseases and can be transferred between animals and humans.9 Influenza pandemics occur when a new influenza virus emerges and spreads around the world, and most people do not have immunity. Although human influenza pandemics have been rare in the United States, they have had devastating effects. For example, as we reported in 2011 and 2013, HHS estimated that the 2009 H1N1 pandemic in the U.S. led to as many as 403,000 hospitalizations and 18,300 deaths from April 2009 to April 2010, and HHS had over \$6 billion available for influenza pandemic activities from a 2009 supplemental appropriation.10

Selected Worldwide Disease Occurrence: Anthrax

In 2001, anthrax was intentionally spread in 2001, animax was intentionally spread through the postal system by sending letters with powder containing anthrax to the U.S. Capitol. Of the 22 infected persons, 5 died. The Environmental Protection Agency spent S2T million for clean up of Capitol Hill and the U.S. Postal Service was appropriated hundreds of millions of dollars to clean up affected facilities.



 $^7 \rm See$ Exec. Order No. 13,228, 66 Fed. Reg. 51,812 (Oct. 10, 2001). The establishment of the Homeland Security Council was subsequently codified in statute with the enactment of the Homeland Security Act of 2002. Pub. L. No. 107-296, § 901, 116 Stat. 2135, 2258 (codified at 6 U.S.C. § 491).

8GAO-10-645

⁹For more on avian influenza, see GAO, Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response, GAO-07-652 (Washington, D.C.: June 11, 2007).

¹⁰See Pub L No. 111-32, 123 Stat. 1859, 1882-86 (2009). The United Nations' World Health Organization declared the H1N1 influenza outbreak to be a pandemic in June 2009, which was the first such declaration in over four decades. See GAO-11-632 and GAO, Influenza: Progress Made in Responding to Seasonal and Pandemic Outbreaks, GAO-13-374T (Washington, D.C.: Feb. 13, 2013).

The White House Has Developed a National Biosurveillance Strategy, but More Action Is Needed to Enhance Federal and Nonfederal Capabilities

The National
Biosurveillance Strategy
Does Not Yet Identify
Resource and Investment
Needs

Although the White House developed the National Strategy for Biosurveillance in July 2012, this strategy does not include information that identifies resource and investment needs as we previously recommended.¹¹ In June 2010, we found that there was no integrated approach to help ensure an effective national biosurveillance capability and to provide a framework to help identify and prioritize investments. Without a unifying framework; structure; and an entity with the authority, resources, time, and responsibility for guiding its implementation, we concluded that it would be very difficult to create an integrated approach to building and sustaining a national biosurveillance capability. National and agency strategies note that coordination is important because a national biosurveillance capability relies on the ability of a complex interagency and intergovernmental network to work together and meet an ever-evolving threat. Specifically, we found there was neither a comprehensive national strategy nor a designated focal point with the authority and resources to guide the effort to develop a national biosurveillance capability. We have previously found that developing effective national strategies and establishing a focal point with sufficient responsibility, authority, and resources can help ensure successful implementation of complex interagency and intergovernmental undertakings, such as providing a national biosurveillance capability. 12

¹²See GAO, Combating Terrorism: Selected Challenges and Related Recommendations, GAO-01-822 (Washington, D.C. Sept. 20, 2001), and Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

Page 6 GAO-15-664T

¹¹GAO-10-645.

We made two recommendations to the White House's Homeland Security Council, which has taken some actions to address them, as shown in table 2.

| Table 2: Recommendations from | n GAO-10-645 and Agency Actions Taken to Address Them | |
|-------------------------------|---|--|

| GAO's recommendation | Agency actions taken to address recommendation | Status of recommendation and, i open, what remains to be done |
|--|--|---|
| The Homeland Security Council should direct the National Security Council Staff to establish a focal point to lead the development of a national biosurveillance strategy. | The National Security Council Staff convened an interagency policy group that guided the completion of the National Strategy for Biosurveillance in July 2012, which addresses the intent of our recommendation. | Status: Closed as implemented. |
| The Homeland Security Council should direct the National Security Council Staff to develop a national biosurveillance strategy that clarifies roles and responsibilities, provides goals and performance measures, and identifies resource and investment needs, among other elements. | In July 2012, the White House issued the National Strategy for Biosurveillance. However, our review of the strategy determined that the strategy alone did not fully meet the intent of our recommendation because, among other things, it did not provide the mechanism we recommended to identify resource and investment needs, including investment priorities. ^a The National Strategy for Biosurveillance stated that an implementation plan was to be completed within 120 days of the strategy's issuance. However, as of June 2015, an implementation plan has not been released | Status: Open To fully address this recommendation, the implementation plan would have to sufficiently address the need to help identify and prioritize resource and investment needs. |

Sources: GAO-10-645 and GAO analysis of agency documents and information. | GAO-15-664T

*See GAO, Biosurveillance: Observations on the Cancellation of BioWatch Gen-3 and Future Considerations for the Program, GAO-14-267T (Washington, D.C.: June 10, 2014).

The National
Biosurveillance Strategy
Does Not Address Key
Challenges for Nonfederal
Efforts or the Need to
Leverage Nonfederal
Resources

The National Strategy for Biosurveillance also does not address issues we raised related to state and local biosurveillance efforts, and that we previously recommended. In October 2011, we reported that nonfederal capabilities should also be considered in creating a national biosurveillance strategy. 13 Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to strengthen and leverage nonfederal partners could improve efforts to build and maintain a national biosurveillance capability. Moreover, efforts to build the capability would benefit from a framework that facilitates assessment of nonfederal jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise. In 2011, we found that although the federal government did provide some resources to help control disease in

Page 7

GAO-15-664T

¹³GAO-12-55.

humans and animals in tribal and insular areas, there were no specific efforts to ensure that states and local agencies can contribute to the national biosurveillance capability. In addition, we noted that the federal government had not conducted a comprehensive assessment of state and local jurisdictions' ability to contribute to a national biosurveillance capability. While the size, variability, and complexity of the biosurveillance enterprise makes an assessment difficult, we concluded that the federal government would lack key information about the baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise until it conducts an assessment of nonfederal biosurveillance capabilities.

We further reported in October 2011 that state and local officials identified common challenges to developing and maintaining their biosurveillance capabilities such as (1) state policies in response to state budget constraints that restricted hiring, travel, and training; (2) obtaining and maintaining resources, such as adequate workforce, equipment, and systems; and (3) the lack of strategic planning and leadership to support long-term investment in crosscutting core capabilities, integrated biosurveillance, and effective partnerships. For example, state and local officials we surveyed had reported facing workforce shortages among skilled professionals—epidemiologists, informaticians, statisticians, laboratory staff, animal-health staff, or animal-disease specialists. Many of the challenges that state and local officials identified were similar to issues we reported regarding biosurveillance at the federal level. We noted that many of the challenges facing the biosurveillance enterprise were complex, inherent to building capabilities that cross traditional boundaries, and not easily resolved.

To address these issues, and building on our June 2010 recommendation to develop a national biosurveillance strategy, we called for such a strategy to also address the key challenges we identified in nonfederal biosurveillance, as shown in table 3.

Table 3: Recommendations from GAO-12-55, and Agency Actions Taken to Address Them

GAO recommendation

GAU recommendation The Homeland Security Council should direct the National Security Council Staff to, as a part of its development of a national biosurveillance strategy, ensure that the strategy (1) incorporates a means to leverage existing efforts that support nonfederal biosurveillance capabilities, (2) considers challenges that nonfederal jurisdictions face, and (3) includes a framework to develop a baseline and gap assessment of nonfederal jurisdictions' capabilities.

Agency actions taken to address mendation

In July 2012, the White House released the National Strategy for Biosurveillance and was also to complete a strategic implementation plan within 120 days of the strategy's issuance. However, from our review of the strategy, susuance. However, from our review of this strategy, we determined that this strategy did not address the issues we raised related to state and local biosurveillance and did not meaningfully address the need to leverage nonfederal resources. As of June 2015, the implementation plan has not

Status of recommendation and, if open, what remains to be done

to federal biosurveillance, it is possible that the implementation plan, when released, will meet the intent of our recommendation. However, until this plan is released, this recommendation remains not fully implemented.

Sources: GAO-12-55 and GAO analysis of agency documents and information. J GAO 15-664T

More Oversight and Coordination Are Needed to Ensure That Federal Food and Agriculture Surveillance Efforts Align with National Policy

Federal Oversight and Coordination of the Nation's Food and Agriculture Defense Policy Could Be Enhanced

As part of the national biosurveillance capability, the maintenance of effective animal and plant surveillance systems is critical to detecting and enhancing the situational awareness of biological events that might disrupt agriculture and food production systems, such as highly pathogenic avian influenza. Although DHS, the White House's Homeland Security Council, and USDA have made efforts to improve the coordination and implementation of federal food and agriculture defense policy, additional actions are needed. In August 2011, we found that there was no centralized coordination to oversee the federal government's overall progress implementing HSPD-9 on the nation's food and

agriculture defense policy, responsibilities for which are distributed across several agencies. ¹⁴ As we reported in 2011, these federal responsibilities include the development of surveillance and monitoring systems for animal, plant, and wildlife disease, food, public health, and water quality, as well as other responsibilities related to awareness and warning, vulnerability assessment, mitigation strategies, response and recovery, and research and development. Prior to 2011, the White House's Homeland Security Council had conducted some coordinated activities to oversee federal agencies' HSPD-9 implementation by gathering information from agencies about their progress. DHS supported these activities by coordinating agencies' responses to the White House on their progress. However, at the time of our 2011 review, the White House and DHS had discontinued their efforts.

Per HSPD-9, DHS is responsible for coordinating agencies' overall HSPD-9 implementation efforts. In addition, the White House's Homeland Security Council was established by executive order in 2001 to ensure the effective development and implementation of homeland security policies, including HSPD-9. Because there was no centralized coordination to oversee agencies' HSPD-9 implementation progress at the time of our 2011 review, it was unclear how effectively or efficiently agencies were using resources in implementing the nation's food and agriculture defense policy, including surveillance efforts. We concluded that without coordinated activities to oversee agencies' implementation efforts, the nation may not be assured that crosscutting agency efforts to protect agriculture and the food supply are well designed and effectively implemented in order to reduce vulnerability to, and the impact of, terrorist attacks, major disasters, and other emergencies.

We also reported in August 2011 that USDA's component agencies had taken steps to implement the department's HSPD-9 responsibilities, but USDA did not have a department-wide strategy for implementing its numerous HSPD-9 responsibilities. For example, component agencies had taken steps to implement the four HSPD-9 response and recovery efforts for which USDA has lead responsibility, such as APHIS's development of the National Veterinary Stockpile. However, according to USDA officials, the department assigned HSPD-9 responsibilities to its component agencies based on their statutory authority and expertise and

Page 10 GAO-15-664T

¹⁴GAO-11-652.

allowed individual agencies to determine their implementation and budget priorities.

To address these issues, we made four recommendations to DHS, the White House's Homeland Security Council, and USDA, and each agency generally concurred with its respective recommendations. Since we made these recommendations, in August 2011, these entities have taken some actions to address them, as shown in table 4.

Table 4: Select Recommendations From GAO-11-652, and Agency Actions Taken to Address Them

| GAO recommendation | Agency actions taken to address recommendation | Status of recommendation and, if open, what remains to be done |
|---|---|--|
| Security (DHS) should resume its efforts to coordinate agencies' overall Homeland Security Presidential Directive (HSPD)-9 implementation efforts. | DHS officials stated in May 2015 that DHS is in the process of finalizing a report on agencies' efforts to implement HSPD-9. Officials indicated that the report is going through an interagency review process and will likely be finalized by late summer 2015. Further, officials added that there are several DHS interagency working groups that meet regularly and discuss topics related to HSPD-9. Although participation in these groups helps to keep DHS aware of related efforts, they do not comprehensively coordinate agencies' overall HSPD-9 implementation efforts. | Status: Open |
| | | To fully address this recommendation, DHS should finalize its report on agencies' efforts to implement HSPD-9, which we believe will provide federal decision makers with critical information needed to assess how well the nation is prepared for major emergencies. |
| The Homeland Security Council should direct the National Security Council Staff to establish an interagency process that would provide oversight of agencies' implementation of HSPD-9. | National Security Council Staff officials stated in December 2013 that they, along with the White House's Office of Science and Technology Policy, have cohosted meetings of an interagency working group that is chaired by DHS. The officials stated that they plan to continue to oversee agencies' implementation of HSPD-9 through this working group. These actions address the intent of our recommendation. | Status: Closed as implemented. |
| The Homeland Security Council should direct the National Security Council Staff to encourage agencies to participate in and contribute information to DHS's efforts to coordinate agencies' implementation of HSPD-9. | National Security Council Staff officials stated that they also used the interagency working group to encourage agencies to participate in and contribute information to DHS's efforts. DHS officials stated in November 2013 that, throughout the previous 18 months, the National Security Council Staff had invested effort and expressed interest in the interagency working group and have been involved in discussions about DHS's assessment of agencies' implementation of HSPD-9. These actions address the intent of our recommendation. | Status: Closed as implemented. |

GAO-15-664T

GAO recommendation

Agency actions taken to address recommendation

Status of recommendation and, if open, what remains to be done

The Department of Agriculture (USDA) should develop a department-wide strategy for implementing its IRSPD-9 responsibilities. Such a strategy would include an overarching framework for setting priorities, as well as allocating resources.

USDA officials stated in 2012 that the department intended to develop a comprehensive homeland security strategy to oversee its agencies' implementation of homeland security activities, including responsibilities outlined in HSPD-9. However, USDA officials told us in November 2013 that, because of limited staffing and resources and competing priorities, they were not able to develop a strategy in 2013. In February 2015, USDA officials stated that they had conducted a gap analysis with USDA's component agencies to determine USDA's successes and challenges with HSPD-9 implementation.

Status: Open
We continue to believe that until it
completes a department-wide
strategy for implementing its HSPD9 responsibilities, USDA cannot be
reasonably assured that its
agencies' efforts align with
departmental priorities, that it has
effectively allocated resources, and
it is fulfilling its HSPD-9
responsibilities.

Sources: GAO-11-652 and GAO analysis of agency documents and information. (GAO 15-664T

APHIS Developed a New Approach for Livestock and Poultry Surveillance, but Has Not Integrated These Efforts into an Overall Strategy with Performance Measures We reported in May 2013 that APHIS had developed a new approach for its livestock and poultry surveillance activities, but had not yet integrated these efforts into an overall strategy with goals and performance measures aligned with the nation's larger biosurveillance policy. 15 Under its prior approach, APHIS focused its disease surveillance programs on preventing the introduction of certain foreign animal diseases and monitoring, detecting, and eradicating other reportable diseases already present in domestic herds. Under this previous approach, information about nonreportable diseases, including those that are new or reemerging, was not always captured by the agency's disease surveillance efforts. We reported in 2013 that under its new approach APHIS had begun to broaden its approach by monitoring the overall health of livestock and poultry and using additional sources and types of data to better detect and control new or reemerging diseases. For example, APHIS has been monitoring for the presence of pseudorabies—a viral swine disease that may cause respiratory illness and death—at slaughter facilities, but under the new approach, it has proposed monitoring these facilities for a range of other diseases as well.

Although APHIS had a vision for its new approach, we found that it had not yet integrated that vision into an overall strategy with associated goals and performance measures aligned with the nation's larger biosurveillance efforts. At the time of our 2013 review, APHIS had developed a number of planning documents related to the agency's

¹⁵GAO-13-424.

Page 12 GAO-15-664T

capabilities for disease surveillance in livestock and poultry, but these documents did not specifically address outcomes the agency seeks to accomplish or have associated performance measures. Moreover, none of APHIS's surveillance plans indicated how they individually or collectively supported national homeland security efforts called for in HSPD-9 or other national policies to defend the nation's food and agricultural systems against terrorist attacks, major disasters, and other emergencies. We concluded that without integrating its new approach to livestock and poultry surveillance activities into an overall strategy with goals and measures aligned with broader national homeland security efforts to detect biological threats, APHIS may not be ideally positioned to support national efforts to address the next threat to animal and human health. To address this issue, we made a recommendation to APHIS, with which APHIS concurred and is taking action to address, as described in table 5.

Table 5: Recommendations from GAO-13-424, and Agency Actions Taken to Address Them

GAO recommendation

As the Animal and Plant Health Inspection Service (APHIS) develops goals and measures for its new approach to disease surveillance in livestock and poultry, the agency should integrate the agency's vision into an overall strategy that guides how its new approach will support national homeland security efforts to enhance the detection of biological threats.

Agency actions taken to address recommendation

Agency actions taken to address recommendation.

APHIS has begun to develop measures to assess surveillance efforts for critical diseases affecting food, animals, and agriculture, and has begun to integrate surveillance efforts. For example, officials stated in June 2015 that APHIS has begun to integrate agency efforts with those of that APHIS has begun to integrate agency efforts with those of the Department of Homeland Security, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the National Animal Health Laboratory Network, a consortium of state-funded testing and diagnostic veterinary laboratories. Activities include sharing personnel, jointly carrying out pilot projects, and signing collaboration agreements. However, officials also reported that resource constraints obstruct APHIS's efforts to electronically integrate various sources of surveillance information and that constrained funding would further limit APHIS's ability to assess its new approach to animal disease surveillance.

Status of recommendations and, if open, what remains to be done

Status: Open
We continue to believe that
integrating its new approach to
livestock and poultry surveillance
activities into an overall strategy
aligned with broader national
homeland security efforts will better
position APHIS to support national
efforts to address threats to animal
and human health.

Sources; GAO-13-424 and GAO analysis of agency documents and information. | GAO 15-864T

Chairman Johnson, Ranking Member Carper, and members of the committee, this completes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

Dr. Jack Gelb, Jr. Director Avian Biosciences Center University of Delaware jgelb@udel.edu July 8, 2015

U.S. Senate Committee on Homeland Security and Governmental Affairs "Stopping an Avian Influenza Threat to Animal and Public Health"

Introduction and Current Situation

Highly pathogenic (HP) avian influenza (AI) and the virus that causes it, avian influenza virus (AIV) is a major threat to the U.S. poultry food supply. While not a public health risk at present, the H5N2 HPAI virus is of concern. The current situation represents a new challenge to U.S. animal agriculture. Our country has not experienced an introduction of a HPAI originating directly from wild birds. Although the disease is now on the decline in the hard-hit Midwest region, through the efforts of many, we are faced with developing improved measures to more quickly recognize and respond to the disease to minimize its impacts.

HPAI has resulted in mortality in our wild waterfowl populations, certain species of which are known to harbor and spread the virus during their migrations along the Pacific, Central and Mississippi flyways. Only wild birds of the Atlantic flyway remain free of AI as far as we know at the present time. But predictions are that HPAI will come East during the southern waterfowl migration this Fall. Poultry are accidental hosts, becoming infected following direct or indirect contact with waterfowl or their droppings on land or contaminating water (ponds, wells, etc. used for poultry water sources). However, there is also a growing body of evidence suggesting terrestrial wild birds, which have not been consider conventional vectors in the past, may play a "bridging" role in the transmission of avian influenza into poultry farm facilities or perhaps to humans.

Since December 2014, USDA has reported H5 AI virus detections in 21 states in commercial poultry, primarily in egg layer type chickens and turkeys, privately owned backyard flocks, and wild birds.

Approximately 42 million commercial egg layer chickens on 210 farms have died from the disease or have been euthanized to end animal suffering and control the spread of the disease. In Minnesota alone, turkeys numbering more than 9 million on 108 farms have died. Numerous backyard poultry flocks have also been lost, representing additional financial and emotional stresses on small flock owners.

The H5N2 strain has evolved to become the predominant AIV responsible for the losses in the Midwest. However, earlier in the outbreak in the Western states, other H and N combinations (H5N8, H5N1) were involved, and molecular sequencing and

analysis of those other AI viruses demonstrated genetic interrelationships among all of the AI viruses. It is important to appreciate that AI viruses are adaptable and changeable. Career scientists studying AI know this better than anyone. AI virus does not follow rules so there are few clear-cut answers to some questions. This has theoretical implications and more importantly, practical applications. The good news is, we have many disease response tools already at our disposal that will hopefully provide the basis to successfully addressing HPAI control in the future.

Low Pathogenicity H7N2 Avian Influenza in Delmarva in 2004

Profitable Agriculture but Disease Risks

My experience with AI stem's from in Delaware and the larger Delmarva region, Delaware is the birthplace of the modern meat chicken (broiler) industry in the U.S., dating back to the early 1920s. Delmarva, consisting of Delaware (Del), the eastern shores of Maryland (mar), and Virginia (va) is one of the most productive and efficient broiler chicken production regions in the world. Approximately 20% of the broiler-finished product is exported from Delmarva and represents a significant portion of business profitability. At any point in time, approximately 100 million broiler chickens are being raised in the region. Sussex County Delaware is the most densely populated county in the U.S. Seventy percent of the farm income in Delaware is tied to poultry, including the production of corn and soybean for feed ingredients. Moreover, the so-called multiplier effect that accounts for direct and indirect infusions to the ag economy bring the annual value of poultry to \$3.2 billion, and 13,500 jobs. All of this is impressive, especially for a state the size of Delaware, but it places great emphasis on preventing highly contagious diseases such as AI. AI is a potential business-ending event for farmers and poultry companies.

In February 2004, the University of Delaware (UD) Poultry Diagnostic Laboratory at Georgetown received a call from a poultry farmer reporting unusual mortality in his flock near Harrington. Our UD staff veterinarian obtained samples and real time RT-PCR testing was used for the first time during an outbreak to identify AI, in this case a H7 virus. The farm was immediately quarantined by the Delaware State Veterinarian to restrict all movement of poultry, people and equipment. As per USDA protocol, the diagnostic samples were sent to the USDA National Veterinary Services Laboratory in Ames, Iowa. The Delmarya emergency incident command system (ICS) was activated on Day 2 to implement the Delmarva emergency response plan. The H7 findings were confirmed the next day and the virus was further identified as H7N2, and was suspected to be low pathogenicity (LP). The flock was humanely depopulated on Day 3 using the USDA-approved carbon dioxide gassing method, and the chickens were composted inside the AI positive poultry houses to prevent possible spread to nearby AI-free farms. Meanwhile a second chicken farm 5 miles from the index farm was found AI positive, quarantined and depopulated on Day 5. Region-wide AI surveillance testing of approximately 2000 poultry farms, performed by UD and USDA identified one additional farm on the eastern shore of Maryland about one month after the index case. The on-farm

response was identical to the other two AI positive farms, and no further cases were ever detected. The origin of the LP H7N2 AI viruses was determined to be the live poultry markets in the metropolitan New York City area. Wild waterfowl were not implicated in the outbreak. Epidemiological evidence showed the index case in Delaware and the 3rd case in Maryland both had ties to these markets. Restrictions by several countries were levied for several months against poultry exports from Delaware and Maryland as a result of the LPAI event.

Lessons Learned in 2004

Biosecurity, Biosecurity, Biosecurity...

According to Wikipedia, "Biosecurity" as a term was coined first by the agricultural and environmental communities. It is defined as a "set of preventive measures designed to reduce the risk of transmission of infectious diseases in crops and livestock...Another site, horseandrider, com goes further and states that "People can spread diseases as they move within a facility and from one facility to another." Indeed, humans are highly efficient transmitters of disease by carrying AI virus on our clothing and shoes, farm equipment and other vehicles that become contaminated with wild bird or poultry droppings. AI virus may be present in manure at high concentrations and be viable for days to weeks depending on ambient temperatures and relative humidity. Unfortunately, biosecurity practices are not consistently applied on farms where animals and crops are produced. This is a major gap that must be addressed by farmers and the animal production companies. There are many aspects to improved biosecurity; having farm-dedicated clothing and shoes for farmers, limiting visitors to essential personnel, and mandating clean clothing including the use of disposable plastic shoe covers. Poultry litter and manure management, and dead poultry disposal are also critical elements of biosecurity programs.

The ICS leaders in 2004 identified several areas of improvement. Two specific areas that were particularly emphasized were...

Although the rapid depopulation (within 48-72 hours) of AI positive flocks was thought to be a critical element in the successful outcome, the need for faster depopulation procedures with a consistent goal of 24 hours after presumptive identification of an AI positive farm was recommended.

Also recommended was to take actions based on the local diagnostic lab positive findings, without waiting the additional 24 hours for the USDA NVSL findings to be reported.

Consideration of the use of a total depopulation strategy restricted control (quarantine) zones in areas with high farm densities. In this scenario, all farms, even those testing AI negative in the same zone with one or more AI positive farms,

would be depopulated to reduce risk of spread outside the zone. ICS leaders were particularly supportive of the approach in the event of a HPAI outbreak.

Seek an insurance program that would specifically benefit poultry farmers that suffer AI losses.

Please see section "Potential Action Items for 2015 and Beyond" for details.

Current Avian Influenza Programs at UD's Avian Bioscience Center (ABC)

The mission of the ABC is to support poultry production nationally and internationally through teaching, research and outreach. ABC scientists address real-world practical avian influenza (AI) needs by collaborating with USDA, poultry non-profits, U.S. states, and countries around the world to share information. I also oversee our University of Delaware Poultry Health System that is a member of USDA's National Animal Health Laboratory Network (NAHLN). Our diagnostic lab is responsible for ongoing AI virus surveillance testing and reporting.

Below are some of the AI programs of the ABC.

- USDA supports the ABC Emergency Poultry Disease Certificate course that has trained 121 participants from 64 countries from 2009 2015.
- In conjunction with the U.S. Poultry and Egg Association, UD's Dr. Benson and Professor Alphin sponsored a series of web-based training sessions this year on topics including "On Farm Biosecurity", "Guidelines for Depopulation" and "Foam Depopulation". Over 500 participants took part in these trainings.
- Benson, Alphin and now retired UD scientist George Malone developed the foam-based technology for emergency poultry depopulation several years ago. This technology was approved by USDA and is widely used in the U.S. for floor-reared poultry.
- Since 2013, Benson and Alphin have trained over 80 USDA contractors in the "3D's" depopulation, disposal, and decontamination. These activities require rapid deployment of response personnel and equipment to affected locations. The 3D response is part of the USDA National Veterinary Stockpile program.
- Since 2006, the ABC has cooperated with the Delaware Department of Agriculture to provide training for emergency depopulation of poultry to state participants in Delaware, Maryland, Virginia, West Virginia, Pennsylvanian and the state of Washington.
- This year, UD extension agent William Brown with assistance from University of Maryland Extension, and regional poultry company

- veterinarians, hosted a series of On-Farm biosecurity seminars for poultry farmers in Delaware and Maryland.
- My research group, working in collaboration with Dr. Erica Spackman of the USDA Agricultural Research Service (ARS) showed that testing one larger pool of specimens from individual poultry for AI was as sensitive testing two smaller samples per flock. The research lead to reducing the cost of AI molecular testing by approximately 50% per flock.

Potential Action Items for 2015 and Beyond

1. <u>Develop and implement educational outreach biosecurity programs designed to help farmers prevent and respond to avian influenza (AI) on their poultry farms.</u>

Poultry farmers are on the front line and prevention of all diseases is a major goal. Their ability to recognize the symptoms of AI and initiate biosecurity measures is crucial.

The educational programs should have web-based, as well as face-to-face delivery options. Initial focus to be on programs for commercial poultry farmers, followed later by development of programs for backyard and hobby flock owners.

Suggested Elements of the Program

- Implement improved "everyday, non-emergency" biosecurity programs to limit exposure to all "off farm" infectious disease threats including AI. The effort will pay dividends by reducing the introduction infectious diseases of all causes.
- Recognize potential foreign animal diseases, AI and virulent Newcastle
 Disease (VND), at the earliest stages and report suspicions to a resource
 person (state animal health official, poultry company representative,
 farmer's consulting veterinarian, university extension agent, etc.). AI control
 may be viewed as similar to successful cancer outcomes. Early recognition by
 the farmer is key to successfully controlling AI.
- Define and implement an "emergency" biosecurity plan following recognition of AI. The plan must be well conceived and practiced in advance. All movement of people and animals coming on and off the farm must cease immediately, including farm equipment and other vehicles. Visitors, contractors, and their vehicles must not be permitted on the farm. "No access" signage should be posted and farm gates, if available, must be closed to restrict access. Additional instructions will come from the state animal health official's office on further farm actions and procedures.

- Facilitate collection, and handling of affected poultry for purpose of obtaining
 high quality diagnostic samples for testing by a U.S. Department of
 Agriculture (USDA) National Animal Health Laboratory Network (NAHLN)
 laboratory. Fresh dead poultry mortalities to be placed in double plastic
 sealed bags and deposited in a clean, labeled trash can with secure lid at the
 end of the farm driveway. A trained AI surveillance sample team will collect
 specimens and take them to the lab for testing. Farmer is responsible for
 disposal of remaining contents of the trashcan in a biosecure manner.
- 2. Revise federal emergency response plan to more effectively and successfully control HPAI and thus limit exposure of healthy poultry and humans to virus.
 - Allow "presumptive" Al testing results generated by local USDA National Animal Health Network Laboratories (NAHLN) to be the official USDA basis for initiating the depopulation of Al positive flocks. Al infected flocks release massive quantities of Al virus via the respiratory and fecal routes. Transmission to nearby Al-free farms is a high risk as long as poultry are alive. At present, the timing of decisions to depopulate positive flocks and to later indemnify farmers, or the companies that own their poultry, rest with the "confirmation" of the local lab test results by USDA's National Veterinary Services Laboratory in Ames, IA. In reality, delaying depopulation presents an unnecessary, risky practice that can tip the scales towards transmission to nearby farms, other animals and humans.
 - Depopulate HPAI positive flocks within 24 hours of a presumptive positive result by the local NAHLN lab to limit transmission for reasons stated previously. Of particular concern are large commercial farms using power ventilation (fans) to maintain air quality, but this in itself can aid transmission. Preferred procedures for emergency depopulation of commercial farms include the use of carbon dioxide (CO2) gas or foam. In the event of limited resources to perform depopulation with CO2 or foam, other means of depopulation may need to be used.
- 3. <u>Provide an insurance program for poultry farmers who contract with poultry companies to raise their flocks.</u>

The insurance program would compensate contract farmers for losses due to AI and VND. USDA has hired the consulting company, Watts & Associates, to explore possible creation of a Business Interruption Insurance Program for farmers who lose income because of disruptions to their businesses, because of AI and another foreign animal disease known as exotic Newcastle disease. In the event a farm is confirmed as HPAI positive, a government order is issued to destroy the poultry to eradicate the virus. Indemnity is paid by the federal government to the owners of the birds, the poultry company, not the contract farmer who raises them. The poultry company may make some partial payment to the farmer for the time he or

she raised the birds, but nothing is guaranteed. Moreover, cleaning and decontaminating the farm will take a month or longer before the next flock of poultry is delivered so the farmer can be without income for an extended period of time.

4. <u>Vaccination for controlling AI in poultry requires careful, in depth consideration of the pros and cons.</u>

The poultry industries in the U.S. are divided on the vaccination issue. On one side, the hard-hit layer and the turkey companies in the Midwest are leaning towards favoring vaccination. The broiler companies, which has not yet suffered losses, are against vaccination because more of their business is export dependent. Many countries will restrict import of U.S. products even if poultry products come from unaffected, AI-free states.

Pros

AI vaccination will reduce losses due to HPAI, by preventing serious disease and mortality in infected flocks. However, the efficacy of AI vaccination is limited, as discussed below.

Cons

Restricted export trade has already been an economic consequence of AI in the U.S. The fear is that vaccination will not improve the likelihood of the removal of these restrictions.

Research has demonstrated AI vaccines are only partially effective, not unlike human influenza vaccines. While AI vaccines reduce mortality, they do NOT prevent infection with the virulent HPAI virus that may be present on the farm. So over time, vaccines place selective pressure on virulent HPAI viruses to cause them to further mutate and circumvent the immunity provided by vaccine. As this happens, vaccines become less effective.

An added cost of poultry production accompanies the use of AI vaccines. Development manufacturing, purchasing and administration add obvious production costs. Additional costs of monitoring vaccine usage via blood testing to determine if the vaccinated flock has or has not been infected with the virulent HPAI virus are required. These costs will likely be passed on to the consumer.

Farmers may become complacent with their biosecurity efforts when vaccines are used, because mortality and severe disease will be reduced or eliminated. Meanwhile, the virulent HPAI virus may still be infecting the flock and could potentially spread to and cause mortality on a farm that is not using AI vaccination.

How will the American consumer react? Will meat or eggs from HPAI farm be labeled differently from other poultry products? If HPAI virus was zoonotic, what

impact would this have? There is a risk that consumers will find other sources of meat protein and forgo poultry products.

5. Research on terrestrial wild birds and AI – Understanding the potential role of terrestrial wild birds in AI and evaluating ways to reduce their contact with poultry.

Suggested Elements of the Program:

- Raise all commercial poultry indoors at all times to limit exposure to wild birds and AI virus exposure. Most commercial poultry are raised in indoor facilities. However, poultry in organic production programs must be given access to outdoors where the risk of Ai exposure is greater.
- Facilitate controlled laboratory research to determine the susceptibility and shedding patterns of terrestrial wild bird species to the H5N2 HPAI virus to assess their possible role as carriers and transmitters of the HPAI using the currently circulating H5N2 virus. If lab research shows specific terrestrial species are susceptible and can transmit the virus to uninoculated cage mates, field surveillance studies targeting those species could be performed to further identify risk.

Terrestrial species are often observed in poultry houses. Their role in introducing and transmitting AIV to poultry and possibly humans or other hosts is unknown. There is a limited body of evidence suggesting these birds may play a role in disease transmission. Published research has shown certain species of finch, sparrow, as well as starlings and parakeet can be experimentally infected with a specific low path (LP) and HP AI viruses. Further research using the currently circulating AIV H5N2 strain and perhaps other American AIV strains is needed to define the risk.

 Facilitate research using safe bird deterrent products. Wild bird deterrents might be useful to reduced terrestrial birds intrusion into poultry houses. Senate Homeland Security and Government Affairs Committee HPAI Hearing Scott Schneider Testimony

Chairman Johnson, Ranking Member Carper, and members of the committee.

Thank you for inviting me to discuss the impact of Highly Pathogenic Avian Influenza (AI) on poultry and egg producers. I appreciate the opportunity to be a part of developing a comprehensive solution to recover from the current outbreak and prevent the future spread of the disease.

My farm is my livelihood. My flock of 200,000 cage-free egg layers did more than produce a product that helped meet American consumer demand. My flock and my farm fed my family, paid my bills, and enabled me to help my 10 plus employees feed their families and pay their bills, too. I always have played by the rules and ensured pristine conditions for my employees and my birds. I have done my part to keep the American egg industry competitive. But as producers from around the world know all too well, hard work and strictly following regulations does nothing to protect against Al.

My flock of 200,000 egg layers has been reduced to zero in the face of the AI outbreak. My short-term prospects have been grim, and the middle- and long-term prospects are challenging especially in the face of future AI threats. Although containment and biosecurity efforts have been admirable, survival of my family farm and the American egg industry at large depends upon meaningful protection against future outbreaks.

Al will cost my farm a minimum of \$500,000 in revenues before this year is over — a sizable blow for any operation, but an almost unimaginable financial hit for a smaller producer such as myself. My farm will be completely out of production for at least four months and generate no new revenue. My current plans call for gradual repopulation over the four months to follow, building my flock back toward its pre-Al size. When all is said and done, under a best-case scenario, I am facing a minimum of eight months with either zero or heavily reduced revenues and surviving by using my life's savings. In addition to the direct loss of revenue, I am also "fronting" payment for some of the costs of remediation and containment efforts until the USDA is able to reimburse me.

Of course, my farm is just one of the many operations devastated by Al. To date, more than 48 million birds have been infected by the disease in 220 operations in 20 states¹. Al has killed more birds in the egg sector than in any other to this point. The reported loss from the current outbreak has set egg layer inventories back by more than a decade². Prior to the current outbreak of Al, there were roughly 303 million egg layers in the United States. Over the past six months, about 35 million have been lost³. That loss is hurting American egg supplies and driving up prices, as indicated by the USDA's 4.1 percent reduction of forecasted 2015 egg production⁴. It has even led to the importation of shell eggs from Europe. This is an extreme situation very seldom seen in our industry.

 [&]quot;Update on Avian Influenza Findings," USDA, accessed July 1, 2015,
 http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa_animal_disease_information/sa_avian_health/c

t_avian_influenza_disease. avian_heat t_avian_influenza_disease_information/sa_avian_heat t_avian_influenza_disease. Bird Flu-Induced Supply Shock Sends Egg Prices Soaring into Record Territory," Informa Economics edition EG15-06, June 10, 2015.

³ *Egg Shortage Scrambles U.S. Food Industries, "US News & World Report, accessed July 1, 2015, http://www.usnews.com/news/articles/2015/06/12/egg-shortage-amid-avian-flu-outbreak-scrambles-us-food-industries."

industries.

4 "US 2015 Egg, Turkey Production Expected to Fall," The Poultry Site, accessed July 1, 2015, http://www.thepoultrysite.com/poultrynews/35261/cme-us-2015-egg-turkey-production-expected-to-fall/.

Senate Homeland Security and Government Affairs Committee HPAI Hearing Scott Schneider Testimony

Consumers are also hurt. We have seen significant increases in the price of eggs and products made with dry and liquid eggs due to the Al outbreak.

In dollars in cents, current table egg prices are up 70 percent from April 2015 prices ^{5 6}. U.S. consumers could pay \$8 billion more to buy eggs, which is an increase of at least 75 percent from last year7.

Outside of table eggs, a third of all eggs in the U.S. are broken for liquid products that go into products ranging from baking mixes and sauces to pasta and ice cream. Prices for breaking eggs are up 141 percent from April 2015⁸, and, as with fresh shell eggs, this market will remain high for the foreseeable future. Food companies around the world are experiencing price impacts and supply limits relative to the disease.

In short, the financial impact of AI is being felt acutely, everywhere from breakfast tables in Wisconsin to the bottom line of food companies around the globe. These impacts - on producers, jobs and prices - add up to an economic dynamic that cannot be overlooked. The impact of AI on the American economy will continue to grow, resulting not just in higher prices for consumers, but also job losses, depressed commodities markets, and the loss of billions of dollars for American farmers. Government coffers will also feel the pinch. According to the U.S. Poultry and Egg Association, the poultry and egg industry in the U.S. provides more than 1,814,200 jobs that pay \$100.2 billion in wages, generate over \$469.6 billion in annual economic impact, and about \$32.9 billion in taxes9. Those numbers are jeopardized by Avian Influenza

The importance of USDA's response efforts to date cannot be overstated, nor can my gratitude for the work that the government and its partners have done thus far. USDA resources have been integral to response efforts. What's more, the individuals and teams that I have worked with on the ground have been highly professional and courteous - people who have the best intentions and a true desire to help. I appreciate their help.

Despite the progress made, the sheer bureaucracy of doing business with the government is challenging family farmers who, like me, do not interact with government bodies every day. I do not have administrative staff to keep up with the changing landscape of rules, work plans, compliance agreements, and the rotating staff inherent to such a recovery process. The red tape is daunting, frustrating, and financially draining. But we must push on and work within the framework that has been established for the benefit of me and those like me.

Looking further down the road, I have questions about the future of our industry. First, in anticipation of repopulating, I as a producer am wondering what will I do differently this time around to protect my farm from reinfection. I, like all producers, will make changes especially in the area of structural, operational, and cultural biosecurity efforts. However, I worry about the effectiveness of solely employing improved biosecurity protocols, particularly given the fact that this outbreak hit farms with highly sophisticated biosecurity programs already in place that require significant resources to develop, maintain, and practice.

 ⁵ "Urner Barry's Price-Current," Number 125-Volume 159, Urner Barry, June 29, 2015.
 ⁶ "Urner Barry's Price-Current," Number 070-Volume 159, Urner Barry, April 10, 2015.
 ⁷ "Egg Consumers Face \$8 Billion Bill From Worst U.S. Bird Flu," Bloomberg, accessed July 1, 2015, http://www.bloomberg.com/news/articles/2015-05-21/egg-consumers-may-face-8-billion-bill-from-worst-u-s-bird-flu.

^{9 &}quot;Industry Economic Data, Consumption, Exports, Processing, Production," US poultry and Egg Association, accessed July 1, 2015, https://www.uspoultry.org/economic_data/

Senate Homeland Security and Government Affairs Committee HPAI Hearing Scott Schneider Testimony

In today's landscape, a response plan aimed at true eradication of the disease *must* be comprehensive. Biosecurity and containment are indispensable parts of that plan, but they are not enough.

We need to stop AI and prevent future outbreaks. The fact that the USDA is considering the use of vaccines as a component of a comprehensive response strategy is encouraging. For producers like me, it is difficult to imagine investing the time and money necessary to repopulate our flocks without the assurance provided by the availability of an effective vaccine. This fact is made even truer in the face of upcoming bird migrations this fall, which threaten to reintroduce outbreaks all over the country.

Without the long-term protection granted by an eradication approach with the targeted use of safe and tested vaccines, the path forward for my farm is far from clear. Is it fiscally responsible for me to rebuild my flock and restart my operation if I know full well that, without access to reliable vaccines, I stand a chance of losing it all again? On the other hand, how can I NOT repopulate when my farm is my source of income and I have a debt against its value to repay? There are no complete answers but I must try to do the best I can with the tools I have at my disposal. This is why I and my industry need a reliable vaccine as part of our biosecurity practices.

I'm proud to be an American egg producer. I am proud to be part of an industry that has done its part to feed our nation, support thousands of jobs, and keep small towns vibrant. If there is one message I hope this committee takes from my testimony, it is this: The threat of AI can take that all away in one fell swoop if we fail to adopt a response plan that both addresses the current outbreak and prevents future outbreaks.

I thank you for your time, and for the opportunity to talk with you today. I look forward to answering your questions.

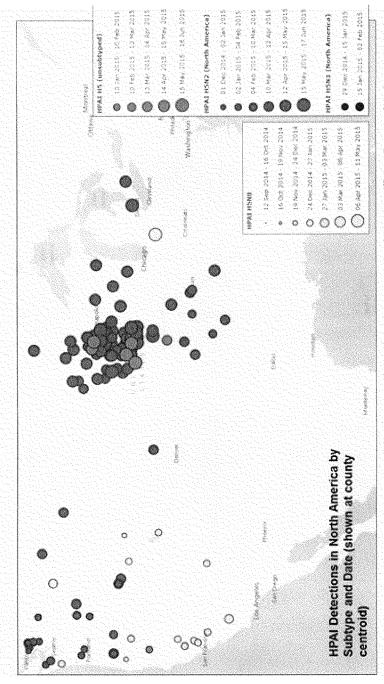
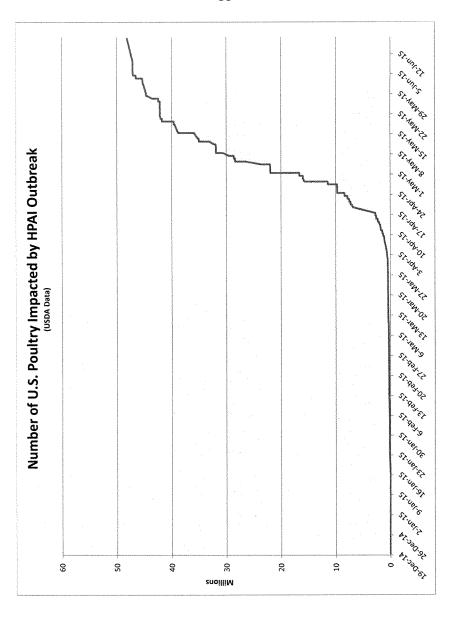


Chart produced by the Department of Homeland Security, National Biosurveillance Integration Center





Senate Committee on Homeland Security and Government Affairs Hearing on Highly Pathogenic Avian Influenza

July 6, 2015

Chairman Johnson, Ranking Member Carper, and Members of the Committee:

Since December 2014, Highly Pathogenic Avian Influenza has infected and killed more than 49 million birds nationwide. The impact has been particularly profound in the Midwest, where producers in lowa, Minnesota, Nebraska, and 12 other states have seen their flocks decimated. Although the spread of this devastating outbreak is beginning to slow, the travel path of migratory birds returning in the fall is poised to spur the continued spread of Avian Influenza.

The economic impact of this outbreak has been thoroughly documented, and has reached well beyond poultry producers. As a result of dwindling flocks, prices for whole eggs are up 70 percent – an unprecedented increase. According to Goldman Sachs, this means consumers could spend an additional \$8 billion on eggs. Prices for liquid and dried eggs, ingredients that go into a variety of food products ranging from baking mixes and ice cream to pasta and sauces, are up 219 and 190 percent respectively. Further effects are being felt every day by ancillary industries, including animal feed, trucking, and more.

The path forward – toward reliable supply for consumers and efficient and profitable operations for producers— is challenging. As flocks depopulate, many producers are working as an interim solution to source eggs from foreign trading partners, while all consider the question of whether resumption of operations is practically achievable while facing the threat of re-infection.

For producers, our current position is one of ongoing and continuing risk. Cleanup is well underway and is being carried out efficiently, but repopulation cannot begin in earnest until we are safeguarded against the return of the disease in a manner that reaches beyond enhanced biosecurity and a cycle of eradication and cleanup. Without lasting protection against future outbreaks, the future of the \$44 billion American poultry industry is in sincere jeopardy.

The United States Department of Agriculture (USDA) recently accepted comments regarding the limited use of vaccines as a means of combating the devastating disease with which we are currently faced. We support USDA's deliberate steps to assess vaccines and their efficacy. A comprehensive, effective response and prevention solution must include the use of limited, efficacious and geographically targeted vaccines. Delaying a final decision on vaccines until the fall is ill advised, and in practice, may limit our ability to return to operation.



Although producers recognize the need to proceed cautiously and with full awareness of the circumstances surrounding the industry's response to Avian Influenza, many of us strongly support the use of a proven vaccine. I am aware of one production platform that has been successfully tested on the H7 strain of Avian Influenza. Although the current strain is different, I understand that the vaccine (produced by lowa-based Harrisvaccines) has been amended to suit the current H5N2 outbreak. Additionally, Ceva Santé Animale (CEVA) is a global company based in France that has developed a product called Vectormune. The efficacy of Vectormune has been demonstrated through various field and laboratory experiments conducted by CEVA as well as independent research institutes. I am enthused about these vaccines' capacity to serve a role in our industry's comprehensive response to the threat of Avian Influenza.

I respectfully ask for your assistance in approving field trials of a vaccine for H5N2, and eventually approving the limited use of vaccines.

Furthermore, Rembrandt greatly appreciates that USDA is devoting substantial time and resources to the project of fairly compensating affected farmers. With respect to "start of lay" or capitalization costs, we believe that USDA is close to arriving at a formula that adequately captures those costs. We are concerned, however, that the Department's fair value formula does not accurately reflect the harm that farmers will suffer as a result of losing their egg production revenue streams. Without delving too deeply into the mathematical minutiae, we would like to explain our primary concerns with that piece of the formula

First, as a result of USDA restrictions on re-populating dictated by its eradication strategy, and due to the nature of the egg production business requiring stategered layer placement to ensure consistent egg production, affected farmers will not be able to immediately re-populate farms to ordinary capacity. This unplanned down-time and the corresponding substantial lost income will compound the severe and immediate hardship farmers will be experiencing from the loss of the destroyed hens. Nevertheless, the Department's current indemnity formula does not account for these losses. Additionally, instead of using gross margin, the Department is using retained earnings as the baseline to calculate fair value. In addition to being a less precise mathematical undertaking, using retained earnings as the baseline seems inconsistent with the notion that farmers should receive the full fair market value of future lost egg production. Moreover, we are concerned that the Department is relying on data from the U.S. Bureau of Economic Analysis for its calculations, as we believe that the Bureau data does not reflect the current, on-the-ground financial realities of affected egg farmers. Finally, while affected farmers are deprived of income for months and even years, they will not be relieved of the substantial burden of paying fixed costs, such as utilities, taxes, and labor. Currently, the Department's formula does not take account of this additional financial strain on farmers.

Rembrandt fully understands the challenges the Department is facing in attempting to contain the HPAI outbreak while administering the indemnity program, and we appreciate the careful attention the Department has devoted to the indemnity program thus far. We are optimistic that we can continue to work with the Department to arrive at



an indemnity formula that addresses the above concerns and ensures that affected farmers are fairly compensated for the lost income they will suffer as a result of the outbreak.

Respectfully,

Dave Rettig President and Co-owner Rembrandt Enterprises Rembrandt, Iowa

University of Wisconsin-Madison Statement to the Senate Committee on Homeland Security and Governmental Affairs

Highly pathogenic bacteria and viruses found in nature present great risk to the health of the American people, economy, and agricultural enterprise. For instance, between late 2014 and mid-July 2015, an outbreak of highly pathogenic avian influenza type H5N2 was responsible for the deaths of more than 48 million birds in the United States, including two million in Wisconsin, primarily impacting commercial domestic food producing chickens and turkeys and their eggs. The economic impacts are yet unknown.

While no human infections involving that virus were reported as of mid-July 2015 in the U.S., similar viruses in Europe and Asia have killed more than 800 people over the last decade.

Researchers at the University of Wisconsin-Madison are dedicated to the study of several of these pathogens, often known as select agents, with the aim of better understanding how they work in order to bolster efforts to prevent, thwart, monitor, and treat them - and to otherwise protect the nation. Some, at the Wisconsin Veterinary Diagnostic Laboratory and the School of Veterinary Medicine, are at the frontlines of diagnosing disease and working with farmers, state and federal agencies, and veterinarians in the region, as well as the public, to respond to outbreak and minimize the spread of disease, as they have done for H5N2.

Continued state and federal support is critical for the future of these endeavors. Responding to outbreaks requires adequate facilities, equipment and highly-trained staff. Charting a way forward to understand disease and disease risk also requires a dedicated research environment and reliable funding.

The University of Wisconsin-Madison is home to the one of the largest academic Select Agent Programs in the country and also one of the most highly regarded. Studying select agents is not a zero-risk endeavor and UW-Madison takes the privilege of conducting this research with the utmost seriousness. The institution seeks to comply with federal regulations and oversight governing select agent work and has a proven track record of cooperation, dedication to safety, and transparency. All select agent work, including so-called gain-of-function studies, must be performed with an appropriate level of regulation and oversight, transparency, and biosafety and biosecurity, as these are crucial to protect the public and those who do the work.

However, it is also critical to maintain a select agent research environment free of undue burdens that can substantially impede efforts and serve as barriers to meaningful progress. At UW-Madison, as at other institutions across the U.S., a federal funding pause has halted some types of gain-of-function select agent research, including those involving influenza viruses. The ban may delay the potential benefits of studying H5N2 and other highly pathogenic influenza viruses, including the incremental gains in basic scientific knowledge that underlie fundamental discoveries. These studies could otherwise advance our understanding and help protect people, animals and the economy.

At UW-Madison, gain-of-function research on pathogens like H5N2 is conducted at the Influenza Research Institute (IRI), a \$12.5 million facility built specifically for these types of studies and among the most highly scrutinized laboratories in the world. Nearly every year since the facility was constructed - during annual inspection and maintenance of the Biosafety Level 3-Agriculture laboratory - UW-Madison has invited elected officials from all levels of government, local and national journalists, City of Madison and Dane County public health officials, university administrators, local and federal law enforcement agents, biosafety and biosecurity professionals, and others for tours of the IRI and to meet with its researchers. In fact, a representative from Senator Ron Johnson's office, Terri Spanbauer, attended an IRI tour in 2013.

The University of Wisconsin-Madison is also considered a model among select agent institutions for its creation more than a decade ago of the Biosecurity Task Force, an independent body that provides a voluntary and additional level of oversight for select agent research at UW-Madison. The Biosecurity Task Force, which meets almost monthly, is a consortium of stakeholders including university law enforcement, university health officials, university legal services, state representatives from the Wisconsin Veterinary Diagnostic Laboratory and the Wisconsin State Laboratory of Hygiene, IT security officials, University Communications, and others.

With a top-tier Select Agent program, a record of safety and transparency, a critical place at the frontlines of disease response, and a willingness to perform above and beyond federal regulations governing select agent research, the University of Wisconsin-Madison believes this work can and should be conducted responsibly, and that doing so is crucial. UW-Madison appreciates the attention paid to these issues and calls on leaders in Congress to push for a quick resolution to the current pause impacting progress in the study of highly pathogenic influenza and other select agents that present a natural threat to the health and safety of our nation and world, as well as continued funding to sustain this work.

1. Update on the avian influenza findings: Poultry findings confirmed by USDA's National Veterinary Services Laboratory. <a href="http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth/sa_animal_disease_i nformation/sa_avian_health/ct_avian_influenza_disease/lut/p/a1/IZLbUoMwElafxYte0m_wJFOpda88Hq3bUwg0TQoCMkDAhbac-vfSg084oau5299vk3_yLfLRGviBbnhDNpSDZlfbbwXQ5Nis9MCejVWcAk_uX4cKdO3g5tirAq4C7UXdsOXMAsFwTJv3euO90FgCT9m_9r8hHPhW60CnysJHyMqBSaCZ0kPFQE_bVvQEkCuVFBLOmmPEZE8JxkQcplptPLTMRLRkoWcBFLIR-HOJW3nlgvnupzosKyDRPv5LPxlKagPEJeaHZiaJvMwG6LGBYNsUFsYhumHcVRRKmDsXMeHn44XfjT8FflaNCrkOH8wzINTzjzZ6Duf49AjQavEun8qKJjodU_p57-YSdMtbhbJNW1RKfGwQ20rnXpVL5wCa1rXHrtIz8L7GwfD2KSTlbHVfW6lsRu9apiMVNMTreqSqdaF-VtAxqw2-2aiZRJxppU5g34riWVpUbraxIV-XPu4r3x9uQCtrPENfxwv-vefAABmm6q/?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_foc_us%2Fsa_animal_health%2Fsa_animal_disease_information%2Fsa_avian_health%2Fsa_adetections_by_states%2Fct_ai_pacific_flyway_Accessed_July_20, 2015.

 \bigcirc