

FOOT-AND-MOUTH DISEASE: ARE WE PREPARED?

HEARING BEFORE THE SUBCOMMITTEE ON LIVESTOCK AND FOREIGN AGRICULTURE OF THE COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS SECOND SESSION

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CONTENTS

	Page
Costa, Hon. Jim, a Representative in Congress from California, opening statement	3
Rouzer, Hon. David, a Representative in Congress from North Carolina, opening statement	1
Prepared statement	2
WITNESSES	
Roth, D.V.M., Ph.D., James A., Clarence Hartley Covault Distinguished Professor and Director, Center for Food Security and Public Health, College of Veterinary Medicine, Iowa State University, Ames, IA	5
Prepared statement	7
Hill, D.V.M., Ph.D., Howard T., large animal veterinarian, Iowa Falls, IA; on behalf of National Pork Producers Council	11
Prepared statement	12
Parker, William Stephen "Steve", Director, Meriel Veterinary Public Health, Duluth, GA	15
Prepared statement	17
Wolf, D.V.M., Cynthia B., Assistant Professor and Small Ruminant Veterinary Specialist, College of Veterinary Medicine, University of Minnesota, St. Paul, MN; on behalf of American Sheep Industry Association	28
Prepared statement	30
Sjeklocha, D.V.M., David B., Operations Manager of Animal Health & Welfare, Cattle Empire LLC, Satanta, KS; on behalf of National Cattleman's Beef Association	32
Prepared statement	33
Supplementary material	51
SUBMITTED MATERIAL	
Executive Committee, American Association of Veterinary Laboratory Diagnosticians, submitted letter	52
Kansas Department of Agriculture, submitted statement	53

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THURSDAY, FEBRUARY 11, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON LIVESTOCK AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Subcommittee met, pursuant to call, at 2:01 p.m., in Room 1300 of the Longworth House Office Building, Hon. David Rouzer [Chairman of the Subcommittee] presiding.

Members present: Representatives Rouzer, King, Hartzler, Yoho, Kelly, Costa, Nolan, and Bustos.

Staff present: Caleb Crosswhite, Darryl Blakely, John Goldberg, Mollie Wilken, Patricia Straughn, Stephanie Addison, Mary Knigge, Liz Friedlander, Matthew MacKenzie, Nicole Scott, and Carly Reedholm.

OPENING STATEMENT OF HON. DAVID ROUZER, A REPRESENTATIVE IN CONGRESS FROM NORTH CAROLINA

The CHAIRMAN. This hearing of the Subcommittee on Livestock and Foreign Agriculture of the Committee on Agriculture regarding foot-and-mouth disease: are we prepared, will come to order. I want to welcome everybody here today, and let me say at the outset, I have to pardon myself from our hearing at around 2:20 because we have a Transportation and Infrastructure Committee markup on the FAA bill and we have votes at 2:30, so I will step away temporarily, but I will be back.

But to begin, let me welcome each of you. Thank you to each of our witnesses for being here today. We are going to be evaluating our preparation in the event of an introduction of a highly contagious animal disease known as foot-and-mouth disease, or FMD, and I want to thank everyone for taking their time to be here, and in particular, our witnesses for their participation and valuable insights that I know they are going to provide.

Now I agree with the sentiment expressed by Chairman Conaway last November in the first of the series of hearings on American agriculture and national security, that, in fact, our national security and agriculture are very closely intertwined. The security of our nation depends on our ability to ensure that; first, the food coming into our country is disease and pest-free; second, on our ability to guarantee that farmers and ranchers have the needed policy tools in place to continue producing food and fiber; and third, depends on our ability to meet the nutritional needs of both those within our border and outside of our borders.

FMD, as you know, is a severe, highly contagious viral disease which causes illness in cows, pigs, sheep, goats, deer, and other animals with divided hooves. While not a public health or food safety threat, FMD remains a worldwide concern because of its ability to spread quickly and cause significant economic losses.

I am concerned that an outbreak of FMD in the United States would have catastrophic consequences for the multi-billion dollar livestock industry, delivering a very harsh economic effect that would be felt far beyond just animal agriculture. In fact, I have seen a recent estimate focusing on the pork industry, estimating an annual impact of \$12.8 billion.

While many countries across the globe are dealing with FMD in their livestock populations, fortunately for us, the last case in the United States was in 1929. Because FMD is one of the most difficult diseases to control, and because it still occurs in many parts of the world, the efforts to prevent and manage an outbreak here in the U.S. are robust. The USDA, along with its partners in the states and the industry, has done tremendous work to protect this country from FMD.

We recognize that the size, structure, efficiency, extensive movement inherent to the United States and North American livestock industries will present unprecedented challenges in the event of an outbreak. If FMD were to have an outbreak here, the disease could spread rapidly to all regions of the country through routine livestock movements, unless we detect it early and eradicate it immediately.

Homeland Security Presidential Directive 9 issued by former President Bush provides for a "Defense of United States Agriculture and Food." This directive establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. HSPD 9 directs that the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, and in consultation with the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency, shall work with state and local governments in the private-sector to develop a National Veterinary Stockpile containing sufficient amount of animal vaccine, antiviral or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy, and that will be deployable within 24 hours of an outbreak.

While there has been a considerable amount of work done to defend against FMD, today we have asked this distinguished panel of witnesses from the industry to talk about the progress, the vaccine capabilities we currently hold, and possibilities for continued improvement. I look forward to your insight.

In the near future, we will be continuing this series of hearings, wherein we will be discussing these and other animal and plant health issues with Federal agencies.

[The prepared statement of Mr. Rouzer follows:]

PREPARED STATEMENT OF HON. DAVID ROUZER, A REPRESENTATIVE IN CONGRESS
FROM NORTH CAROLINA

Good afternoon and welcome to today's Livestock and Foreign Agriculture Subcommittee hearing. Today we will be evaluating our preparation in the event of an

introduction of a highly contagious animal disease: Foot-and-Mouth Disease—or FMD. Thank you to everyone for taking the time to be here and I want to thank, in particular, our witnesses for their participation and valuable insights.

I agree with the sentiment expressed by Chairman Conaway last November in the first of a series of hearings on American agriculture and national security—that, in fact, our national security and agriculture are closely intertwined. The security of our nation depends on our ability to ensure that (1) the food coming into our country is disease and pest free, (2) on our ability to guarantee that farmers and ranchers have the needed policy tools in place to continue producing food and fiber, and (3) depends on our ability to meet the nutritional needs of those both within and outside our own borders.

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While there has been a considerable amount of work done to defend against FMD, today we've asked this distinguished panel of witnesses from the industry to talk about that progress, the vaccine capabilities we currently hold, and possibilities for continued improvement. I look forward to your insight.

In the near future, we will be continuing this series of hearings, wherein we will be discussing these and other animal and plant health issues with Federal agencies.

I now yield to the Subcommittee Ranking Member, Mr. Costa, for his opening remarks.

The CHAIRMAN. I now yield to the Subcommittee Ranking Member, Mr. Costa, for any opening remarks.

OPENING STATEMENT OF HON. JIM COSTA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

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

United States agriculture industry, particularly the livestock industry, has been fortunate as foot-and-mouth disease, otherwise referred to as FMD, has not been a threat since 1929. But I think many of our memories are good. We clearly know that in 2001 there was an outbreak in Europe, and there were challenges and there was fear and concerns as it related to what took place, and that is a part of the world in which we have close relations and which we have trade that takes place on a daily basis. We know

it has not been eradicated. And for myself, three generations of a farm family in California, we have been involved in both the dairy and cattle industry for all of those three generations, and I can remember stories of my father and my grandfather about the fears and the concerns when they first began to try to make it work for them, and the lack of protocol and the science and technology then that we now have today that makes a big difference.

Foot-and-mouth disease is a very, very serious disease and would cripple the U.S. livestock industry as we know it if, in fact, such an outbreak were to take place. And therefore, we must be prepared throughout the country and in California, where we have a very significant cattle industry, as well as a dairy industry that last year was over \$7 billion in proceeds at the farmgate. Clearly, the impacts of both the cattle and the dairy industry to California, and to any other part of the country, would be very, very damaging.

The vaccine stockpile is important, but that is only one aspect of trying to ensure that the United States is prepared to handle foot-and-mouth disease if, in fact, such an outbreak were to take place. Several lessons we believe have been learned in terms of animal husbandry and the science that is contained therein, as we try to prepare and provide prevention for other types of contagious issues within our livestock industry, whether we are talking about high-path avian influenza, otherwise referred to as HPAI, are approaching Porcine Epidemic Diarrhea virus, otherwise known as PEDv—I always go through this because I give my staff a bad time when they use the acronyms and I say people never know what you are talking about. Although some of these words might be preferable to use the acronyms. So the fact is they are serious, and they can be devastating if not controlled.

I hope the industries that are represented here today by these witnesses are prepared to talk about steps that they are taking to prevent such outbreaks in ways that we can partner with the United States Department of Agriculture. The USDA, for farmers, ranchers, and dairymen, for the cattlemen and the livestock and pork producers in particular, is a very valued partner, and therefore, that hand in glove relationship is critical as we look at any current activities and as we look at ways to ensure that we protect these industries.

I think it will take a strong continued public-private partnership to ensure that we are adequately prepared to deal with this, or any other related issues, should such an outbreak occur. We pray not.

In closing, it is critical that we protect American animal agriculture against the threat of foot-and-mouth disease. And it is critical that we use fact-based science to ensure that we deal with proper risk assessment and risk management that is always part of the protocol when we are dealing with these issues. Knowing that as many of us grew up the farms, our mothers used to tell us an ounce of prevention is worth a pound of cure, and we are talking about that prevention here today.

The producers who are represented and industry stakeholders know how critical it is to work collaboratively to identify ways to achieve the common goals to detect, control, and contain FMD should it reach the United States.

Thank you, Mr. Chairman. You are quite correct. I think all of us on this Committee believe truly that the production of food and fiber in America is an issue of national security; and therefore, we should treat it as such. So I look forward to hearing the testimony of our witnesses, and I yield back the balance of my time.

The CHAIRMAN. Thank you, Mr. Costa. The chair would request that other Members submit their opening statements for the record so the witnesses may begin their testimony, and to ensure that there is ample time for questions. The chair would like to remind Members that they will be recognized for questioning in order of seniority for Members who were present at the start of the hearing. After that, Members will be recognized in order of their arrival. I appreciate the Members' understanding.

Witnesses are asked to limit their oral presentations to 5 minutes, and all written statements will be included for the record.

I would like to welcome our witnesses to the table. First, we have Dr. Jim Roth, Director of the Center for Food Security and Public Health, Iowa State University, College of Veterinary Medicine. We have Dr. Howard Hill, large animal veterinarian, Iowa Falls, Iowa. Mr. Steve Parker, Director of Meriel Veterinary Public Health from Duluth, Georgia, and Dr. Cynthia Wolf, Assistant Professor, College of Veterinary Medicine, University of Minnesota, St. Paul, Minnesota, and Dr. David Sjeklocha, did I get that right, Sjeklocha? That is not a native North Carolina name, so it takes me a little bit longer. Sorry about that. Operations Manager of Animal Health & Welfare, Cattle Empire, LLC, Santanta, Kansas, on behalf of National Cattleman's Beef Association.

Dr. Roth, we will begin with you.

STATEMENT OF JAMES A. ROTH, D.V.M., PH.D., CLARENCE HARTLEY COVAULT DISTINGUISHED PROFESSOR AND DIRECTOR, CENTER FOR FOOD SECURITY AND PUBLIC HEALTH, COLLEGE OF VETERINARY MEDICINE, IOWA STATE UNIVERSITY, AMES, IA

Dr. ROTH. Chairman Rouzer, Ranking Member Costa, and Members of the House Committee on Agriculture, Subcommittee on Livestock and Foreign Agriculture, as the Chairman mentioned, my name is Jim Roth and I am with Iowa State University College of Veterinary Medicine. I want to thank you for recognizing the importance of foot-and-mouth disease preparation, and for the opportunity to speak to you. The introductory comments were very accurate on the situation with foot-and-mouth disease, and the dangers of foot-and-mouth disease.

I will first highlight some challenges for control of FMD in the U.S., briefly mention some significant progress that has been made in preparedness, and then I will discuss the urgent need for a sufficient stockpile of FMD vaccine to protect U.S. agriculture.

As has already been mentioned, FMD is the most important animal disease in the world. It affects cloven-hoofed animals, and we all must remember, it is not a public health or food safety concern. This is a livestock disease. It is a bad livestock disease, but it is not a human health concern. Ninety-six countries in the world have foot-and-mouth disease, so more countries have it than don't have it. So our livestock industry is always under pressure that this

virus could come in from one of those countries by many different ways. The U.S. has had nine outbreaks of foot-and-mouth disease between 1870 and 1929, so in a 60 year period, we had nine outbreaks, and we haven't had one for 87 years, fortunately.

All nine of those outbreaks were controlled by stop movement and stamping out, so in the affected area, they stopped all animal movement. All animals in the infected herd are depopulated, and any herds nearby, and you have to do that very quickly to stop the virus from spreading.

It has become apparent that we can't count on a stop movement and stamping out if we get into a large outbreak, because agriculture has changed quite extensively. We have very large herd sizes that are too large to be depopulated within 24 to 48 hours. If you could depopulate them, carcass disposal would be a massive problem. We have extensive animal movement. It is estimated there are a million pigs on the road every day in trucks, 400,000 to 500,000 cattle, and so there is concern that by the time we find it, the virus may have moved extensively. And we have to be concerned that wildlife can spread this virus. Deer and feral swine, we have 30 million deer, five million feral swine in the U.S. that in many cases move freely between our livestock herds and could spread the disease. So unless an FMD infection is detected very quickly and stamped out, there is a great concern it could spread relatively widely fairly quickly. And of course, foot-and-mouth disease is the main disease limiting trade and livestock and livestock products in the world. We would lose our exports immediately, and that is about \$20 billion a year of beef, pork, and milk exported that we would lose, and that is just the loss in exports.

But progress has been made in changing the plans. The USDA doesn't plan on counting on only stamping out and stop movement. The USDA has been working with states, industry, and academia to address the challenges, how would we address an FMD outbreak, given modern agriculture? And significant progress has been made in developing secure food supply plans to help ensure business continuity for livestock producers and affiliated industries, and provide a continuous supply of safe and wholesome food for our consumers.

One of the outcomes of that was a document that is called, *Phases and Types of Foot-and-Mouth Disease Outbreaks*, and it depends on the magnitude of the outbreak, and the response will change depending on the magnitude. But without sufficient foot-and-mouth disease vaccine, it is likely that we won't be able to stop the outbreak at a small outbreak, and it will progress to a large outbreak. The North American FMD Vaccine Bank is inadequate. It is shared with U.S., Canada, and Mexico, and doesn't have enough doses, so we need an adequate stockpile, and there are methods for producing an adequate stockpile of FMD vaccine. The livestock industry has asked me to draft a white paper on how we could have enough vaccine to adequately manage an outbreak. You need 23 different vaccines. It is not just one vaccine.

So I urge Congress to provide sufficient funding to enable the USDA to work with state officials and livestock industry representatives to develop and implement a plan for establishing an effective

FMD vaccine stockpile to protect American agriculture and the food supply. Thank you.

[The prepared statement of Dr. Roth follows:]

PREPARED STATEMENT OF JAMES A. ROTH, D.V.M., PH.D., CLARENCE HARTLEY COVAULT DISTINGUISHED PROFESSOR AND DIRECTOR, CENTER FOR FOOD SECURITY AND PUBLIC HEALTH, COLLEGE OF VETERINARY MEDICINE, IOWA STATE UNIVERSITY, AMES, IA

Impact of an Outbreak of Foot-and-Mouth Disease (FMD) in the United States and the Urgent Need for an Adequate Stockpile of FMD Vaccine

Chairman Rouzer, Ranking Member Costa, and Members of the House Committee on Agriculture, Subcommittee on Livestock and Foreign Agriculture, my name is Jim Roth and I am the Director of the Center for Food Security and Public Health at the Iowa State University College of Veterinary Medicine. Thank you for the opportunity to speak to you about preparedness for the potential introduction of foot-and-mouth disease (FMD) in the United States. I will first highlight challenges for control of FMD and some of the significant progress that has been made, then focus on the urgent need for a sufficient stockpile of FMD vaccine to protect U.S. agriculture and an approach to begin to build that stockpile.

Challenges for Control of FMD in the U.S.

Foot-and-mouth disease is the most important animal disease in the world capable of crossing national boundaries and devastating animal agriculture (a transboundary disease). FMD affects cattle, pigs, sheep, goats, deer, elk and other wildlife. Ninety-six countries are either endemically or sporadically infected with the disease, therefore there is a constant threat that it will be introduced into the U.S. either accidentally or intentionally. FMD is extremely contagious and can spread rapidly with devastating consequences. You probably remember the outbreak in the United Kingdom in 2001 which is estimated to have cost approximately \$6 billion. The number of livestock and the agriculture economy is much smaller in the UK than the U.S. We learned from their outbreak that we cannot depend on stamping out the disease by killing all infected and exposed animals.

The size, structure, efficiency, and extensive movement inherent in the United States livestock industry will present unprecedented challenges in the event of an FMD outbreak. No country with a livestock industry comparable to that of the U.S. has had to deal with an outbreak of FMD, and the impact would extend far beyond animal agriculture.

Herd Size

The U.S. has some very large herds including feedlots with greater than 50,000 head of cattle, dairies with greater than 5,000 lactating cows, dairy calf ranches with greater than 70,000 head of calves, and swine farms with greater than 20,000 sows. ***These premises are too large to rapidly depopulate to stamp out the disease. If it were possible to depopulate them, carcass disposal would present enormous environmental problems.***

Animal Movement

Once FMD is detected, an essential tool for control is to stop all animal movement in the affected area. Livestock production in the U.S. depends on extensive movement of animals. Approximately 400,000 cattle and one million swine are estimated to be on the road in trucks each day, either being delivered to packing plants or to other stages of production. Approximately 40 million swine are shipped into a new state each year (~110,000 each day). Many of those cross multiple state lines. In an FMD outbreak, State Animal Health Officials may prohibit animals from an FMD positive area from entering their state. Modern swine production depends on extensive animal movement on a regular basis. If animal movement is stopped, animals will need to be euthanized for welfare reasons because facilities will rapidly become overcrowded.

There is also extensive movement of people, feed, manure, and equipment on livestock premises each day. Wildlife, including birds, can spread disease. There are estimated to be more than five million feral swine and 30 million deer in the U.S.; these animals are susceptible to FMD and can often move freely between herds of livestock. ***If FMD infection is not detected quickly, it is likely to spread rapidly due to extensive animal and related movements.***

Diversity of Operations

The diversity of herd size also presents problems in FMD control. In the U.S., 49% of hog operations have fewer than 100 head, whereas 62% of the inventory of swine is on operations with more than 5,000 head. Similarly, 18,800 dairy farms have less than 30 cows; however, 1,800 dairy farms with more than 1000 animals account for nearly 50% of the U.S. dairy cow population. ***An FMD control program will need to include operations of all sizes. Federal and state resources will be quickly overwhelmed.***

Economic Impact of FMD

An outbreak of FMD will shut down exports of fresh beef, pork or dairy products. In 2014, beef exports totaled \$7.1 billion, pork exports \$6.7 billion and dairy exports totaled \$7.1 billion. Approximately 11% of U.S. beef production and 22% of U.S. pork production are exported. In 2003, beef exports dropped due to a single case of mad cow disease (BSE); the cumulative loss in U.S. beef trade is estimated to have been \$16 billion. The increasing export of beef and pork products in recent years significantly contributes to the value of cattle and swine. As exports increase, the industry becomes more vulnerable to the sudden and extended loss of exports that would result from an FMD outbreak. The price for pork and beef will drop dramatically due to the excess product on the domestic market. That will also impact the price of poultry products and the price of grain.

In 2011, Dr. Dermot Hayes and colleagues at the Center for Agricultural and Rural Development at Iowa State University published “Economy Wide Impacts of a Foreign Animal Disease in the United States” which had been funded by the National Pork Board. **They estimated that over 10 years, the cumulative loss due to an uncontrolled FMD outbreak would be \$199.8 billion. Losses estimated include:**

**Pork—\$57 billion;
Beef—\$71 billion;
Poultry—\$1 billion;
Corn—\$44 billion;
Soybeans—\$25 billion;
Wheat—\$1.8 billion.**

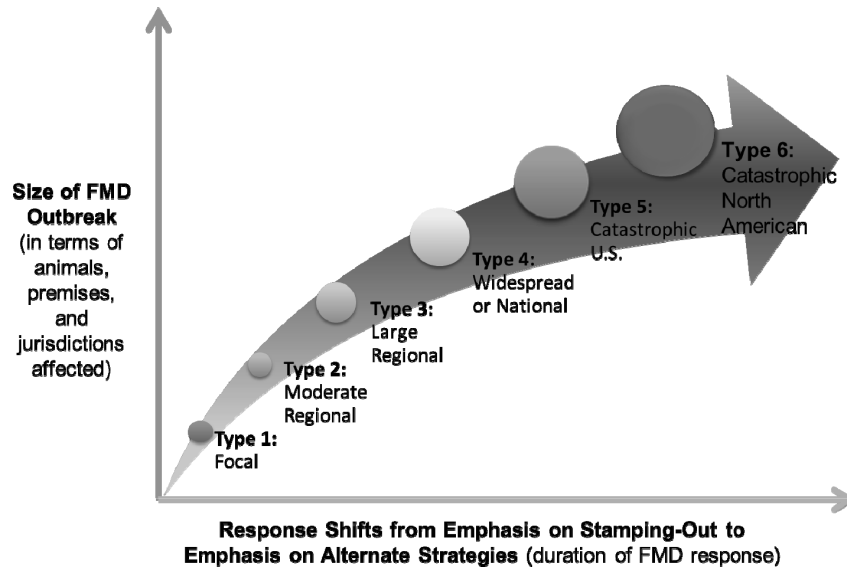
The impact would likely be larger now because of the increase in the value of exports since 2011. Agriculture is a critical infrastructure in the U.S. and is severely threatened by the potential of an FMD outbreak.

Progress That Has Been Made

Because of the challenges outlined above, it became apparent that an FMD outbreak could rapidly get out of control. As a consequence, the USDA has been working with states, industry and academia to address these challenges. Significant progress has been made in developing Secure Food Supply plans to help ensure business continuity for non-infected poultry and livestock premises and affiliated industries in a foreign animal disease outbreak and provide a continuous supply of safe and wholesome food to consumers. The Secure Egg Supply and Secure Turkey Supply plans are credited with enabling premises in Highly Pathogenic Avian Influenza (HPAI) control areas to demonstrate that they are not infected so they could continue to move product to market in the 2015 outbreak in the Upper Midwest. The Secure Pork, Beef and Milk Supply plans are intended to help producers whose farms are not infected with FMD stay in business. However, without adequate FMD vaccine, it will be nearly impossible to keep farms, especially beef and dairy farms, from becoming infected.

The USDA working with states, industry and academia, developed “**Guidelines for Classification of Phases and Types of An FMD Outbreak and Response**”.

Six Types of FMD Outbreak



These guidelines were developed to aid rapid decision making as an FMD outbreak unfolds. Strategies for the response to, and management of, an FMD outbreak will change as the outbreak progresses and will depend upon the magnitude, location, and other characteristics of the outbreak. The response will shift from an emphasis on stamping out in a small outbreak to alternative strategies in larger longer duration outbreaks. Vaccine will be an essential tool to control any outbreak larger than a small focal outbreak. **Without an adequate supply of rapidly available FMD vaccine, it will be very difficult to prevent the outbreak from progressing to a catastrophic North American outbreak** (see: FAD PRoP Strategy Document: Classification of Phases and Types of a Foot-and-Mouth Disease Outbreak and Response available at: www.cfsph.iastate.edu/pdf/phases-and-types-of-an-fmd-outbreak).

Lessons Learned from Recent Foreign Animal Disease Outbreaks

The U.S. has experienced two recent introductions of devastating transboundary animal diseases: Porcine epidemic diarrhea virus (PEDV or Swine Enteric Coronavirus Disease (SECD)) in 2013 and highly pathogenic avian influenza (HPAI) in 2015. Both viruses apparently had origins in Asia; FMD is endemic in most countries in Asia. PEDV spread to 27 states and killed at least eight million baby pigs in the first year. HPAI caused the death of 31.5 million poultry in 2 months in Iowa alone (including approximately 40% of the laying hens in the state) and cost the economy of the state approximately \$1.2 billion; the USDA spent nearly \$1 billion to assist in controlling HPAI. Disposal of the poultry carcasses became a serious problem.

These outbreaks occurred in industries with much more robust biosecurity practices than the beef and dairy industries. An FMD outbreak would dwarf the PEDV and HPAI outbreaks. No one anticipated the introduction of PEDV, so there was no vaccine available. It was more than 15 months before vaccine became available. It is not possible to have an HPAI vaccine available ahead of a new outbreak because of rapid unpredictable changes in HPAI viruses. However, it is possible and essential to have vaccine available at the beginning of an FMD outbreak. Having an adequate supply of FMD vaccine quickly available could greatly limit the extent and duration of an FMD outbreak.

In summary, the size, structure, efficiency, and extensive movement inherent in the United States livestock industry will present unprecedented challenges in the event of an FMD outbreak. It will be nearly impossible to control an FMD outbreak in livestock dense areas without the rapid use of tens of millions of doses of FMD vaccine. At this time, those doses are not available for U.S. use and it would take many months to obtain the volume of vac-

cine needed. Without sufficient vaccine to aid in the response, FMD could rapidly spread across the U.S., resulting in the destruction and need to dispose of potentially millions of animals. It would become an endemic disease in livestock with spread potentially facilitated by deer, feral swine or other free-living animals. A long term, very expensive and extensive control program would be needed and it could take many years to eradicate.

Requirements for an FMD Vaccine Bank

The need for FMD vaccine for the U.S. has been recognized for decades. The U.S. has shared an FMD vaccine bank with Canada and Mexico since 1982 (The North American Foot-and-Mouth Disease Vaccine Bank). The USDA has stated that the amount of FMD vaccine available in the Bank (which is controlled and shared by the U.S., Canada, and Mexico) is far below what would be required for an outbreak in a single livestock dense state. Since the need for vaccine in the U.S. is likely to be much greater than for Canada or Mexico, additional sources of FMD vaccines independent of the North American FMD Vaccine Bank are needed to adequately protect U.S. agriculture.

This was recognized in 2004 in Homeland Security Presidential Directive 9. HSPD 9 directed that a National Veterinary Stockpile be created. The Stockpile was to contain sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy. **The USDA established the National Veterinary Stockpile, however the stockpile has never received sufficient funding to stockpile FMD vaccines; consequently there are no FMD vaccines in the Stockpile.**

The USDA, along with many state and industry officials, recognized that the approach of stamping out and stop movement of animals is simply not possible given the realities of animal agriculture in the U.S. The USDA document "Foot-and-Mouth Disease Vaccination Policy in the United States" (September 2014) illustrates the current capacity of the U.S. to effectively implement vaccination strategy for control of different types of FMD outbreaks (available upon request). It clearly indicates that there is not sufficient vaccine capacity to assist in controlling an FMD outbreak.

A plan to ensure that adequate supplies of FMD vaccine with multiple strains of FMD virus are available in the event of an accidental or intentional introduction of FMD virus into the U.S. is urgently needed.

At the request of the National Pork Board, National Cattlemen's Beef Association, and National Milk Producers Federation I produced a white paper entitled "FMD Vaccine Surge Capacity for Emergency Use in the United States" outlining a potential plan to develop a National Veterinary Stockpile (NVS) with sufficient quantities of FMD vaccine to protect U.S. agriculture, food systems, and the economy. The white paper is available at: www.cfsph.iastate.edu/pdf/fmd-vaccine-surge-capacity-for-emergency-use-in-the-US.

It is possible to have an FMD vaccine stockpile available for immediate use. However, establishing and maintaining an FMD vaccine bank is complex. There are seven distinct serotypes of the virus that are not cross protective and approximately 65 subtypes. Cross-protection varies between strains within a serotype. The World Reference Laboratory for FMD recommends that FMD vaccine banks maintain 23 strains of FMD virus in the vaccine bank. Once the virus in the outbreak is isolated, the serotype can be identified and the correct vaccine selected for use. (See: NAHEMS Guidelines: *Vaccination for Contagious Diseases. Appendix A: Foot-And-Mouth Disease* available at: www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease).

Costs

The white paper contains recommendations that I hope can be considered for implementation and funding to better prepare the U.S. to avoid the worst case scenario which is likely to occur if FMD is introduced into the U.S. without adequate emergency vaccine supplies.

I estimated in the white paper that development of a robust FMD vaccine stockpile could require an investment of up to \$150 million per year for 5 years. This number could likely be reduced with additional planning, the development of new technology vaccines, and negotiation with vaccine companies. The vaccine capability could gradually increase during the 5 years, initially focusing on the most common strains of FMD virus. By the end of 5 years we could have the capability to respond quickly to any strain of FMD virus introduced into the U.S. The stockpile could use a rotating inventory strategy so that vaccine would not expire and need to be destroyed.

Conclusion

I urge Congress to provide sufficient funding to enable USDA to work with state officials and livestock industry representatives to develop and implement a plan for establishing an effective FMD vaccine stockpile to protect American agriculture.

For additional information on FMD see:

http://www.cfsph.iastate.edu/Factsheets/pdfs/foot_and_mouth_disease.pdf
www.cfsph.iastate.edu/pdf/fmd-vaccine-surge-capacity-for-emergency-use-in-the-US
www.cfsph.iastate.edu/pdf/fad-prep-nahems-appendix-a-vaccination-for-foot-and-mouth-disease

The CHAIRMAN. Thank you, Dr. Roth. Dr. Hill.

STATEMENT OF HOWARD T. HILL, D.V.M., Ph.D., LARGE ANIMAL VETERINARIAN, IOWA FALLS, IA; ON BEHALF OF NATIONAL PORK PRODUCERS COUNCIL

Dr. HILL. Good afternoon, Chairman Rouzer, Ranking Member Costa, and Members of the Subcommittee. I am Dr. Howard Hill, a veterinarian and pork producer from Cambridge, Iowa, and I am the immediate past President of the National Pork Producers Council.

As you have heard, foot-and-mouth disease is a very serious disease, an outbreak in this country would be economically devastating to the U.S. pork producers and other food producers. USDA and the livestock industry has been working to develop plans to address a foot-and-mouth disease outbreak. We, the Federal Government, and the industry must be better prepared to deal if we have an outbreak.

As Dr. Roth pointed out, USDA APHIS has changed its policy on managing foot-and-mouth disease from stamping out or depopulating to using vaccine in all but the smallest of outbreaks to limit the spread of this disease. The U.S. livestock industry supported that change, as it is less costly, more humane, and more practical, given the enormous size of the U.S. herd and the movement of livestock around the country. United States simply cannot kill its way out of a foot-and-mouth disease outbreak. But under the current structure of the foot-and-mouth vaccine antigen bank, APHIS does not have the quantity of vaccine needed to implement the new policy, and it currently can't obtain vaccine in a timely manner if there were an outbreak.

U.S. law prohibits foot-and-mouth disease virus from being on the U.S. mainland, so APHIS contracts with foreign vaccine production companies to produce finished vaccine from the antigen that is stored at Plum Island Animal Disease Center off the coast of Long Island. But only a limited number of foot-and-mouth disease strains are covered by the antigen stored at Plum Island. Additionally, based on the current production contract, after 3 weeks, it is estimated there would only be 2.5 million doses of vaccine, and there would be no surge capacity to produce more. United States is the only country in the world that maintains its own antigen bank, requiring shipping of antigen to a foreign manufacturer to have it manufactured into a final vaccine, which is complex and time consuming.

The Foot-and-Mouth Disease Vaccine Bank currently is funded at \$1.9 million, and there have been no requests for a substantial increase in the President's budget, despite Homeland Security Presi-

dential Directive 9, which requires an adequate vaccine stock to be maintained. The livestock industry believes fixing the vaccine bank will require; first, an offshore vendor maintaining vaccine antigen bank that would be available for all 23 strains of the most common foot-and-mouth types currently circulating in the world; second, a vendor-managed inventory of ten million doses, which it is estimated to be needed for the first 2 weeks of an outbreak; and then third, contracting with an international manufacturer or manufacturers for surge capacity to produce at least 40 million doses.

Given the potential economic impact on the livestock industry of a foot-and-mouth disease outbreak and the costs of dealing with it, APHIS has insisted that the industry share in a cost of improving the vaccine bank. From our perspective, it is hard to agree to this until we know what the cost is. Additionally, the type of outbreak and the location where it is will determine which sector of the livestock industry is most seriously affected in the initial phase of an outbreak, and which sector, therefore, should bear the lion's share of any costs.

While several options have been discussed, none would provide significant funds and none have included a way to equitably assign costs to each sector of the livestock industry. More work needs to be done in this area, and we are pleased to hear that APHIS will soon be issuing a request for information for improvement of the vaccine bank that should give us an idea of the cost.

The bottom line, though, is that we need to improve the preparedness for a foot-and-mouth disease outbreak through the development of adequate vaccine bank, and it must be a priority, and NPPC urges this Committee and the Congress to work with the Administration to do that.

I thank you, and I would be happy to answer any questions at the appropriate time.

[The prepared statement of Dr. Hill follows:]

PREPARED STATEMENT OF HOWARD T. HILL, D.V.M., PH.D., LARGE ANIMAL VETERINARIAN, IOWA FALLS, IA; ON BEHALF OF NATIONAL PORK PRODUCERS COUNCIL

Introduction

The National Pork Producers Council (NPPC) is an association of 43 state pork producer organizations that serves as the global voice in Washington, D.C., for the nation's pork producers. The U.S. pork industry represents a significant value-added activity in the agricultural economy and the overall U.S. economy. Nationwide, more than 68,000 pork producers marketed more than 110 million hogs in 2014, and those animals provided total gross receipts of \$23.4 billion. Overall, an estimated \$22.3 billion of personal income and \$39 billion of gross national product are supported by the U.S. pork industry.

Economists Daniel Otto, Lee Schulz, and Mark Imerman at Iowa State University estimate that the U.S. pork industry is directly responsible for the creation of more than 37,000 full-time equivalent pork producing jobs and generates about 128,000 jobs in the rest of agriculture. It is responsible for approximately 102,000 jobs in the manufacturing sector, mostly in the packing industry, and 65,000 jobs in professional services such as veterinarians, real estate agents and bankers. All told, the U.S. pork industry is responsible for nearly 550,000 mostly rural jobs in the United States. The U.S. pork producers today provide 23 billion pounds of safe, wholesome and nutritious meat protein to consumers worldwide.

Exports add significantly to the bottom line of each U.S. pork producer. U.S. exports of pork and pork products totaled 2.2 million metric tons in 2014, representing more than 26 percent of U.S. production, and those exports add more than \$62 to

the value of each hog marketed. Exports supported about 110,000 jobs in the U.S. pork and allied industries.

FMD a Growing Threat to North America

Foot-and-Mouth Disease (FMD) is one of the most economically devastating foreign animal diseases affecting animal agriculture. It is highly contagious and spreads easily through livestock movement, by wind currents, on vehicles that have traveled to and from infected farms and even on inanimate objects that have come in contact with the virus. It affects all cloven hoofed species, including wildlife such as deer and elk.

Because North America is free of FMD, an outbreak of the disease in the United States would immediately shut off all exports of U.S. livestock, meat and dairy products, creating a precipitous drop in livestock markets. Because U.S. consumers have no knowledge of the disease, there also likely would be serious disruptions in the domestic market because of decreased demand for those products.

FMD is endemic in Africa, Asia, South America and the Middle East. The FMD virus has seven viral serotypes and more than 60 subtypes, with wide strain variability. Managing and ultimately eradicating FMD requires strain-specific vaccines, making vaccination challenging and very expensive. Sporadic outbreaks with different types continue to pop up in countries around the world.

Increased travel and trade between affected countries make the U.S. increasingly vulnerable to introduction of the disease. Now, the United States has to confront the possibility of terrorists using FMD as a weapon to inflict significant damage to the U.S. economy that could also affect food availability.

U.S. Livestock Industry Vulnerable to FADs, Including FMD

The House Agriculture Committee Nov. 4, 2015, held a hearing on American agriculture and national security, which highlighted the vulnerability of the U.S. food supply to the potential for foreign animal disease introduction by terrorists or by accident.

While the United States faces an increasing threat, through multiple sources, of the introduction of FMD into the U.S. livestock herd, there is ample evidence to suggest the safety net in place to prevent such an introduction needs to be improved.

The bipartisan *Report of the Blue Ribbon Study Panel on Biodefense*, co-chaired by former Department of Homeland Security Secretary Tom Ridge and former Sen. Joe Lieberman and released Oct. 28, 2015, highlighted the need for improvements in the U.S. system for protecting the U.S. livestock herd and the nation's food supply from Foreign Animal Diseases (FADs).

Since 2013, several diseases affecting swine have been introduced into the U.S. herd, including Porcine Epidemic Diarrhea virus (PEDv), Delta Corona Virus and Orthoreovirus. Government officials responsible for overseeing port-of-entry inspections and disease risk management have been unable to specifically identify the source or means of introduction of those viruses even though the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) conducted a root cause investigation. If there is an unidentified gap in the U.S. safety net that allowed the recent introduction of these new diseases, it also remains open for FMD.

In USDA's FAD preparation strategy document on the phases and types of an FMD outbreak, Dr. James Roth, professor and researcher at Iowa State University, identified four phases of the disease: (1) confirmation of an outbreak (typically 3 days); (2) surveillance and epidemiological work necessary to provide timely evidence of the extent of an outbreak to support decision making by government officials; (3) recovery from the disease; and (4) freedom from the disease (possibly with vaccination).

He characterized an FMD outbreak as having six types: Type 1, Small Focal; Type 2, Moderate Regional; Type 3, Large Regional; Type 4, Widespread or National; Type 5, Catastrophic U.S.; and Type 6, Catastrophic North American, which includes Canada and Mexico.

Given the structure of the U.S. livestock industry, the likelihood of having a Small Focal or Moderate Regional outbreak is remote. The livestock industry estimates there are approximately one million pigs and 400,000 cattle moved daily in the United States, some over long distances. In addition, there are numerous auctions, fairs and exhibits that concentrate large numbers of animals in a single location, providing the opportunity for one infected or exposed animal to spread disease to many animals. Thus, it seems unlikely that, if the United States had an outbreak, it would be a small focal outbreak that could be controlled without widespread administration of vaccine.

The World Organization for Animal Health (OIE) sets standards for managing and declaring freedom from FMD. Those standards range from “stamping out” (killing all infected and exposed animals) to being free of FMD with vaccination.

Not Enough Vaccine to Address FMD Outbreak

After watching countries such as the United Kingdom, Korea and Japan, whose livestock populations pale in comparison to the United States, struggle to manage an FMD outbreak by killing large numbers of animals, APHIS changed its existing policy on managing the disease from “stamping out” to using vaccine to limit the spread. This policy change was endorsed by the livestock industry as a cheaper and more practical alternative given the enormous size of the U.S. livestock herd and the rapid movement of livestock around the country. The United States simply cannot “kill” its way out of an FMD outbreak!

After reviewing the impacts of the policy change, it became readily apparent under the current structure of the FMD vaccine antigen bank that APHIS did not have the quantity of vaccine needed to implement this new policy, nor could vaccine be obtained in a timely manner in the event of an outbreak.

At APHIS's request, the U.S. livestock industry began a series of meetings with its senior officials to develop a strategy for improving the vaccine antigen bank and vaccine availability. There has been significant progress in FMD preparedness through the development of secure supply plans for milk, pork and beef, and APHIS continues to work with the livestock industry to improve its preparedness capability. Fixing the antigen bank capacity and improving vaccine availability must be a priority in future preparedness efforts.

Current U.S. law prohibits live FMD virus from being introduced onto the U.S. mainland, so foreign production companies are the only source of finished vaccines. It has been suggested that recombinant DNA vaccines that do not use live FMD virus can be produced in the United States, thus avoiding the legal prohibition of having live virus on the mainland. However, current data is not sufficient to determine how quickly, and indeed whether, such vaccines provide protection outside of the laboratory environment and for all species.

The United States likely is years away from the development and commercialization of such novel vaccines. But the U.S. livestock industry must have vaccines that are protective against the strain of FMD that might be in a sample sitting at the Plum Island Animal Disease Center (PIADC) for analysis at this very moment!

The United States is the only country in the world to maintain its own antigen bank, located at the PIADC. The bank maintains antigen for a limited number of FMD strains. APHIS contracts with foreign vaccine production companies to produce finished vaccine from the antigen stored at Plum Island. If an outbreak occurs, the antigen is shipped to Europe to produce vaccine, and the finished product is shipped back to the United States. Based on the current production contract, after 3 weeks, this process would produce only 2.5 million doses of vaccine, and there is no surge capacity to produce more.

Iowa State's Dr. Roth estimates that the U.S. livestock industry would need ten million doses for the first 2 weeks of an outbreak.

The FMD vaccine bank is currently funded at \$1.9 million, and there have been no requests for a substantial increase in the President's budget despite the fact that Homeland Security Presidential Directive 9 (HSPD 9) requires an adequate vaccine stockpile to be maintained.

Although APHIS is the agency charged with managing and controlling FADs, there is no logical reason there could not be mutual cooperation with the Department of Homeland Security on funding an enhanced vaccine bank and improving vaccine availability.

Another factor complicating upgrades to the vaccine bank is it also serves as the North American Bank and thus includes Canada and Mexico. NPPC believes it is appropriate to include those neighboring countries, but the United States should not wait for negotiations with those countries to be completed before making necessary improvements that are so critical to the U.S. livestock industry.

There is concurrence in the livestock industry that fixing the vaccine bank will require the following actions: (1) Contract for an offshore, vendor-maintained vaccine antigen bank that would have available antigen concentrate to protect against all 23 of the most common FMD types currently circulating in the world; (2) Contract for a vendor-managed inventory of ten million doses (the estimated need for the first 2 weeks of an outbreak); and (3) Contract with an international manufacturer(s) for the surge capacity to produce at least 40 million doses.

For more than a year, NPPC and others in the livestock industry have urged APHIS to identify changes needed to modernize the antigen bank and increase vaccine availability by requesting information from vaccine producers to identify the

cost of fixing the vaccine problem. The industry anticipates that the agency soon will make that request.

FMD Outbreak Could Be Economically Devastating

NPPC knows that fixing the vaccine shortage will require a significant increase in budget outlays. However, that cost pales in comparison to the cost of an FMD outbreak. Iowa State University economist Dermot Hayes estimates revenue losses to just the U.S. pork and beef industries from an FMD outbreak at \$12.9 billion per year over a 10 year period; the corn and soybean industries are estimated to lose \$44 billion and \$24.9 billion, respectively. A recent study by Kansas State University estimates cumulative losses to consumers and livestock producers at \$188 billion, with an added cost to the government of \$11 billion for eradication efforts if vaccination is not employed. Depending on the vaccination strategy employed, the study estimates the losses to consumers and producers could be cut by 48 percent.

Given the huge economic impact on the livestock industry of an FMD outbreak and the cost of dealing with it, APHIS has insisted that the industry must share in the costs associated with making improvements to the vaccine bank. While several options have been discussed, none have produced a viable method by which equitable contributions from each sector of the livestock industry could be made. The type of outbreak and its location will determine which sector of the livestock industry is most seriously affected in the initial phase of an outbreak.

None of the options discussed thus far would provide any significant funds, and APHIS has not offered any kind of a plan that would be equitable among components of the industry. Frankly, the industry believes it would be impossible to develop such a plan.

The history of government involvement in disasters like an FMD outbreak is that, once an outbreak occurs, unlimited resources are committed to getting control of the situation. In the case of FMD, there is a clear opportunity to invest in a robust vaccine bank that would limit the economic impact on producers, feed suppliers and consumers and reduce the government's cost for control and eradication of the disease.

NPPC urges the Committee and Congress to work with the Administration to address the alarming gap in the preparedness for an FMD outbreak. Whether the disease introduction is the result of terrorism, careless travelers or carried on traded commodities, the calamitous result is the same: devastation to the U.S. livestock industry.

Mrs. HARTZLER [presiding.] Thank you, Dr. Hill.
Mr. Parker.

**STATEMENT OF WILLIAM STEPHEN "STEVE" PARKER,
DIRECTOR, MERIAL VETERINARY PUBLIC HEALTH, DULUTH,
GA**

Mr. PARKER. Chairman Rouzer, Ranking Member Costa, and Members of the Subcommittee, thank you for the opportunity to provide testimony from the perspective of an FMD vaccine manufacturer.

At Merial, I am responsible for the interface with the government on reportable and animal disease management programs. Merial strives to align our capabilities with the mission of the government to advance solutions against a variety of reportable animal diseases. The current North America FMD Vaccine Bank stockpile is undersized to respond to anything other than a limited scope outbreak. Thoughtful consideration should be given to advancing a funding source that supports building adequate FMD bank stockpiles that are in line with U.S. FMD vaccine use policy.

Even though the current global FMD vaccine demand grossly exceeds the ability of conventional vaccine manufacturers to supply, an optimized vaccine need for the U.S. can be addressed with advanced planning and investment. Expertise in FMD vaccine technology is central to Merial's history. For over 60 years, Merial has produced millions of doses of high quality, high potent FMD vac-

cine. This vaccine is made for government clients in all regions of the world for epidemic disease control efforts, and for government preparedness programs.

In FMD free countries, vaccine antigen banks are the standard model for emergency response to FMD outbreaks. Efficient antigen bank models match the quality and quantity of bank antigen doses to the disease spread potential in the target livestock population, combined with the manufacturer's ability to rapidly respond to conversion of antigen to vaccine. The North American Bank stores antigen concentrate for production of emergency vaccine. The bank does not store finished vaccine, mainly due to the difference in shelf life of the antigen concentrate, which is 5 years, *versus* the shelf life of finished vaccine at 18 months. FMD antigen banks are the referenced solution that allows FMD free countries to access rapidly, in outbreak situations, large quantity of purified and highly potent vaccine. Within 4 working days of activation of the North America Bank, Merial will produce up to 2.5 million doses of finished vaccine from the North America Bank vaccine antigen concentrate, and make the vaccine available for shipment to the USDA for field distribution. The largest inventory by dose volume and strains in the North America Bank are Merial antigens.

Merial has the broadest world library of FMD vaccine strains. These strains are used to produce single strain or multiple strain vaccines. This capability provides an insurance of protection against the vast majority of strains circulating globally.

As new FMD strains evolve, Merial continues to develop and propose inclusion of those new strains into antigen banks. For a non-endemic country like the United States, the process of constantly updating the library of strains is critical because of the unpredictability of strains in an FMD event.

Merial operates FMD antigen production and vaccine finishing facilities in the UK, the Netherlands, France, and Brazil. As the world's leader in FMD bank management, we maintain vaccine antigen storage facilities in multiple locations for our global clients as a risk mitigation service. Our bank management services provide the cost effective advantages of timely new strain inclusion into banks, perpetual inventory rotation management, inventory buyback options, just in time antigen to vaccine conversion, and risk mitigation of multiple product shipping events.

FMD banks are only a part of the well-developed FMD preparedness plan. Because FMD antigen banks only serve as a temporary measure in the face of outbreaks, optimized FMD preparedness plans should account for a seamless transition to surge production of millions of doses of finished vaccine, once the bank inventory is exhausted. The continuous supply of vaccine is crucial to achieving control and elimination of the disease.

Mr. Chairman, Members of the Subcommittee, Merial has been a partner with the U.S. Government on disease management programs for over 20 years. We stand ready to work together to explore the time and cost needed to supply gold standard conventional FMD vaccines that support continuity of business for U.S. livestock producers. Thank you.

[The prepared statement of Mr. Parker follows:]

PREPARED STATEMENT OF WILLIAM STEPHEN "STEVE" PARKER, DIRECTOR, MERIAL
VETERINARY PUBLIC HEALTH, DULUTH, GA

Foot-and-Mouth Disease Industry Preparedness: Vaccine Capabilities

Testimony Premise Statement: The current North America FMD Vaccine Bank (NAFMDVB) stockpile is undersized to respond to anything other than a limited scope outbreak. Serious consideration should be given to the appropriation amount required for a rightsizing of the stockpiles. However, the industrial capacity needed to produce these large volumes, is not available today anywhere. Global FMD vaccine demand grossly exceeds ability of conventional vaccine manufacturers to supply. This issue can be remedied through planning and investment but will take a few years to implement.

Background: Expertise in FMD vaccinology is central to Merial history as a company. We have produced multiple millions of doses of high quality, high potent FMD vaccines for a multitude of global customers for over sixty years. Some countries rely on local production of FMD vaccines. However, these locally produced vaccines generally cover only regional strains and needs. All past successful examples of FMD control and eradication, *e.g.*, Europe in 1991, the Philippines in 2010, have only been achieved thru application of conventional vaccines at international, high quality standards.

FMD Vaccine Antigen Banks—the solution for emergency situations: In FMD-free countries the vaccine antigen bank model has become the standard solution for emergency response to the risk of FMD introduction.

Established in 1982, the NAFMDVB stores vaccine antigen concentrate for the production of emergency FMD vaccines. The NAFMDVB does not store finished vaccine for two reasons, (1) the shelf life of vaccine antigen concentrate is 5 years *versus* finished vaccine shelf life of 18 months, and, (2) FMD live viruses are on the Federal Select Agent Program prohibiting handling of the virus within U.S. territory, with the exception of Plum Island.

FMD antigen banks are the reference solution that allows FMD-free countries to access rapidly, in outbreak situations, large quantities of purified, highly potent vaccine. The purification of FMD viral antigens provides a "marker" system that allows monitoring of the FMD vaccination program until eradication. The use of highly potent FMD vaccines has been demonstrated to induce cross-protection against certain heterologous challenge infections of FMD strains.

Within a week of activation of the NAFMDVB bank, Merial can produce up to 2.5 million doses of finished vaccine from the NAFMDVB vaccine antigen concentrate, in either single strain or multiple strain vaccine formats, and make the vaccine available to the USDA for field distribution. The largest inventory by dose volume and strains in the NAFMDVB are Merial antigens. Globally, Merial stores more than 120 million doses of antigens for 14 countries.

Merial has the world's broadest library of FMD vaccine strains that can be used either as monovalent vaccine—containing one strain—or polyvalent vaccine—containing several strains. This capability provides an insurance of protection against the vast majority of the strains that circulate globally and that could be introduced into the United States. Merial continues to develop and propose new FMD vaccine strains for inclusion in antigen banks, concurrent with the evolution of the FMD virus globally. For a non-endemic country, like the United States, this is critical because of the unpredictability of an FMD event.

FMD Vaccine Global Industrial Capability Considerations: Merial operates FMD antigen production plants at Pirbright in the UK, Lelystad in the Netherlands and Paulinia in Brazil, as well as vaccine formulation, finishing and packaging facilities in the UK, France and Brazil. As the world's leader in FMD bank management, we also maintain vaccine antigen storage facilities in multiple locations for multiple international clients and countries.

FMD banks are only a part of a well-developed FMD preparedness plan. FMD antigen banks serve as a temporary measure in the face of a disease outbreak. FMD preparedness plans should allow for optimized bank inventories that supply antigen that support vaccine formulation needs for up to 14 to 16 weeks post outbreak. The exhaustion of the bank antigen inventory should then be followed by a seamless transition to production of finished FMD vaccine and the industrial capacity to meet demand capacity. The continuous supply of vaccine is crucial to achieve control and elimination of the disease.

POWERPOINT PRESENTATION

Merial Veterinary Public Health

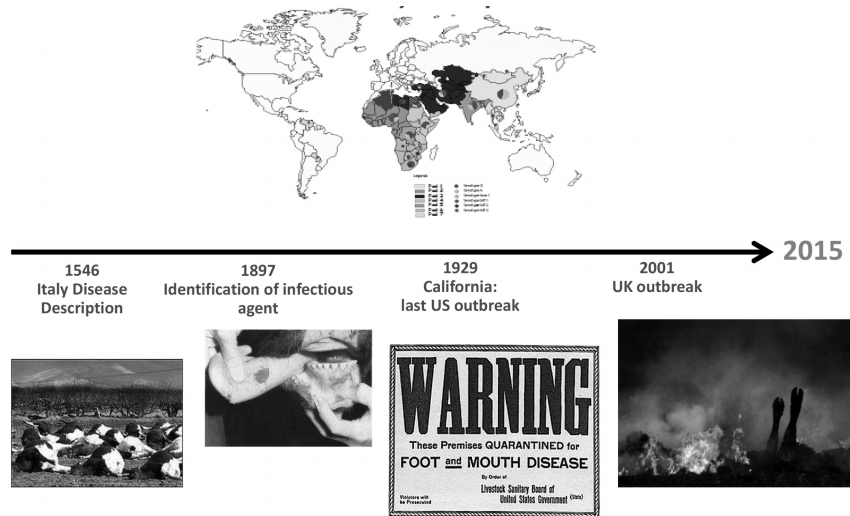
<p>Rabies</p> <p>A fatal infection of the central nervous system of warm-blooded animals and humans</p> 	<p>Foot-and-Mouth Disease</p> <p>A highly infectious viral infection of cattle, pigs, sheep, goats, buffalo, and other ruminants</p> 	<p>Public Private Partnership</p> <p>FMD, Wildlife Rabies, RVF, CSF, BTV, EHD</p> 
<p>Merial VPH works with government agencies in the control of these diseases</p>		
<p>North America Rabies Management Plan (NRMP)</p>	<p>North America FMD Vaccine Bank</p>	<ul style="list-style-type: none"> • USDA-Veterinary Services • USDA-Wildlife Services • Texas State Health Service • USDA-Nat. Wildlife Res. Center • State Agriculture Departments, State Veterinarians, State and Local Public Health Departments • CDC, CFIA, SENASICA, NBAF

Other Merial U.S. Veterinary Public Health infectious and emerging animal diseases areas: Cervid Bluetongue Virus and Epizootic Hemorrhagic Disease, Rift Valley Fever and other reportable animal diseases. VPH collaborates with other Merial entities on Highly Pathogenic Avian Influenza and Classical Swine Fever as related to USDA Foreign Animal Disease (FAD) Planning.

Examples of programs that Merial Veterinary Public Health collaborates with USDA on are: (1) the North America Rabies Management Plan through USDA-APHIS-Wildlife Services and the National Rabies Management Program, and (2) the North America FMD Vaccine Bank through USDA-APHIS-Veterinary Services.

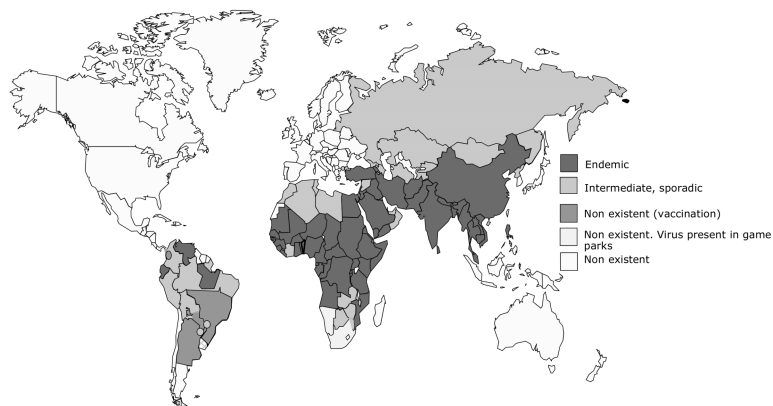
Foot-and-Mouth Disease (FMD)

An Old Disease, But a Present Threat



Foot-and-Mouth disease (FMD) is an old disease. FMD is a present and persistent threat to the U.S. livestock industry. The last outbreak in the U.S. was in California in 1929. Recent outbreaks, in previously non-endemic countries, include the UK, Japan, Taiwan, South Korea, Greece and the Netherlands.

The Importance of FMD



One of the most contagious diseases of cloven-hoofed animals.

- Cattle are most susceptible.
- Pigs are very effective in propagating the disease.

The virus is only present in certain parts of the world

Rarely lethal, but negatively impacts animal productivity (milk, meat, draft power)

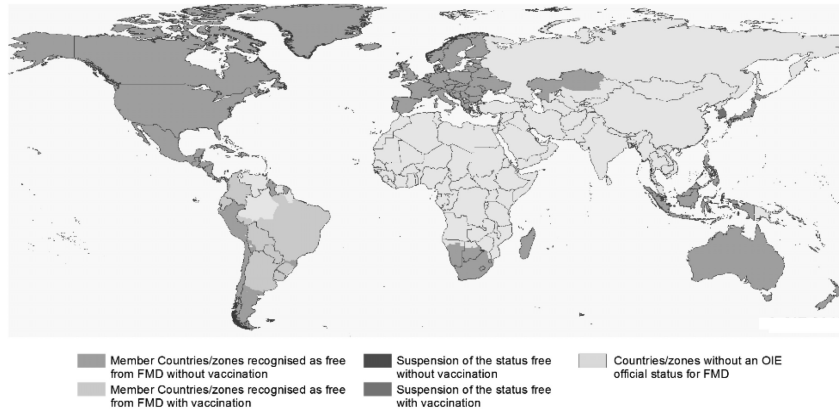
Disease Control Methods:

- Sanitary: culling/mass slaughter, stop animal movement, disinfection.
- Medical: mass vaccination:
 - Need for Inter-governmental and Governmental FMD Control Programs.

FMD—OIE Official Status

OIE Member Countries Official FMD Status Map

Last Update May 2051



[<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/en-fmd-carte/>]

[©OIE 2015.]

FMD outbreaks in countries previously free from FMD has major effects on the ability to trade animal protein internationally. FMD free countries experiencing outbreaks may respond initially with strict restriction of animal movement and livestock transportation methods.

Virus Transmission Routes



The FMD virus is easily transmitted (direct contact, transboundary means of introduction of virus, aerosolized virus transmission introduced via respiratory or oral routes, virus in infected milk, or on clothing, trucks, in feed etc.).

Case Study—The South Korea Outbreak

Historical situation

- South Korea historically "FMD free w/o vaccination"
- Increased frequency of FMD incursions from neighbouring, endemic countries over past decade
- Stamping out policy, average direct cost ~ US\$165M per incursion before restoration of "FMD free" status



November 2010 outbreak

- Unprecedented magnitude
- Culling of ~3.5 million animals (3.3M pigs /140K cattle)



- January 2011: decision to change control policy into vaccination of the whole susceptible animal population (10M pigs, 3M cattle), culling only unvaccinated animals in new outbreaks.
- Change of country status to "endemic with vaccination".



The South Korea FMD outbreak in 2010 was initially addressed by culling animals. The disease was not controlled and the decision was made to mass vaccinate.

Indirect & Direct Impact

Mass Culling and Burial of Pigs in Korea (Nov. 2010–Feb. 11)



- Direct costs (3.3 millions pigs + 140 000 cattle): \$2 Bn
- Total costs: ~\$8 Bn

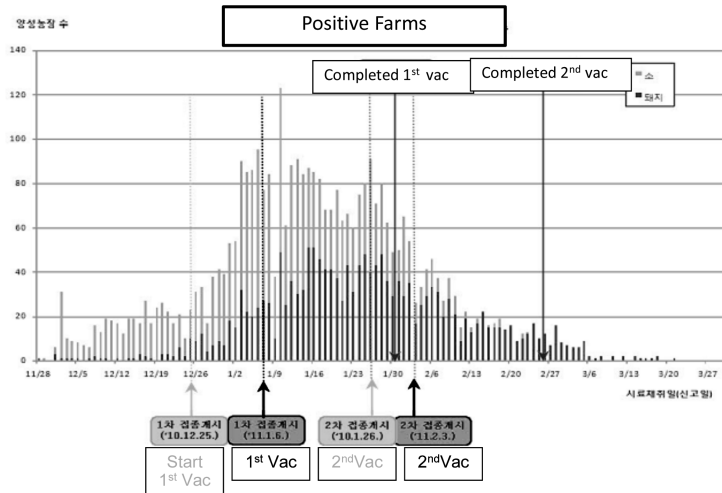


The South Korean livestock industry suffered massive loss due to culling. The South Korean Government incurred huge direct and indirect costs in the culling effort. Consider this event and compare to cost of what the U.S. has recently been through with HPAI.

The South Korea Outbreak: Vaccine Impact

Nov. 10–Mar. 11—FMD Outbreak Evolution

- Reduction in cattle outbreak cases 2 weeks after completion of 1st vaccination round
- Reduction in pig outbreak cases 3 weeks after completion of 1st vaccination round

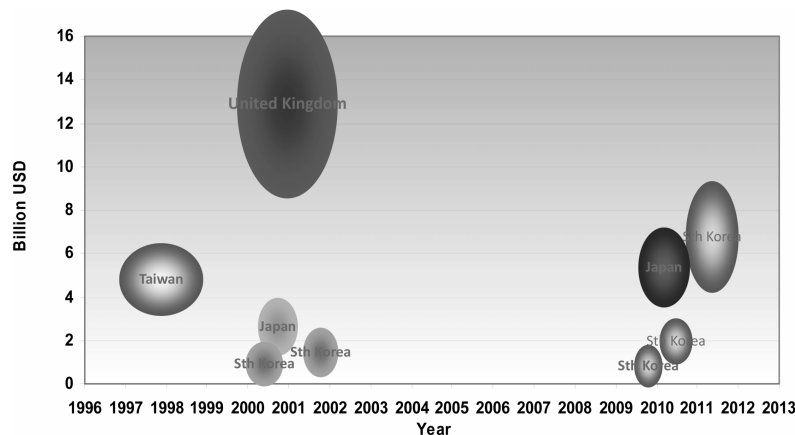


When mass vaccination campaigns were initiated in South Korea, animal outbreaks with FMD were brought under control.

The South Korea situation, as a case study for the United States, continues to evolve as the introduction of new FMD strains from border countries prove challenging. Meriel partners with the South Korean Government on FMD vaccine supply agreements. Meriel monitors the local epidemiology of new emerging virus strain to develop vaccines adapted to evolving disease conditions.

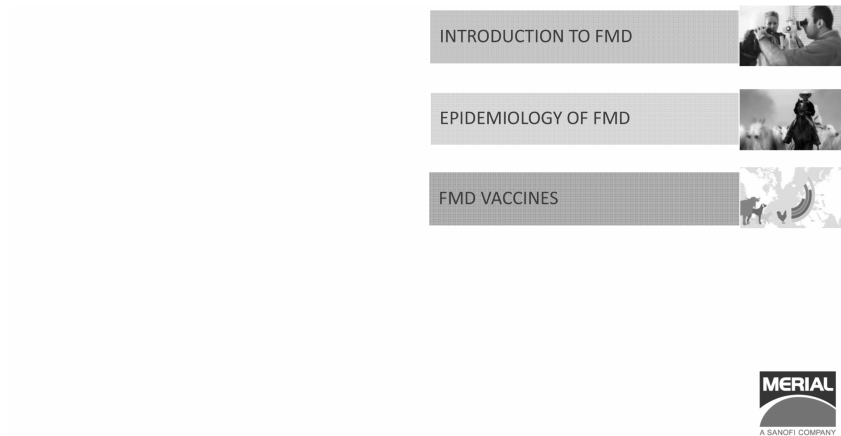
FMD Cost of Incursion—Control

FMD Outbreak Economic Impact—Major Incursions Into Disease Free Countries

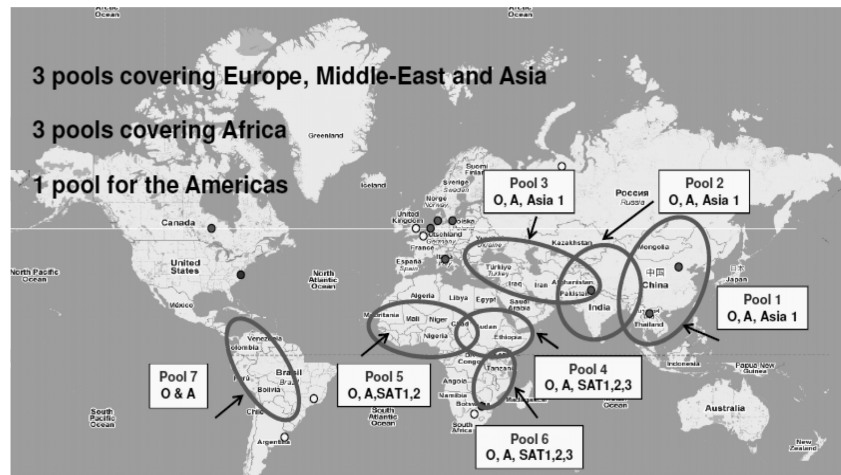


The UK, in 2001, did not implement a vaccination program of control for disease eradication. Costs associated with the UK FMD outbreak, as compared to countries that used vaccine as part of a control effort, were magnitudes of degree greater.

Epidemiology & Vaccine Recommendations

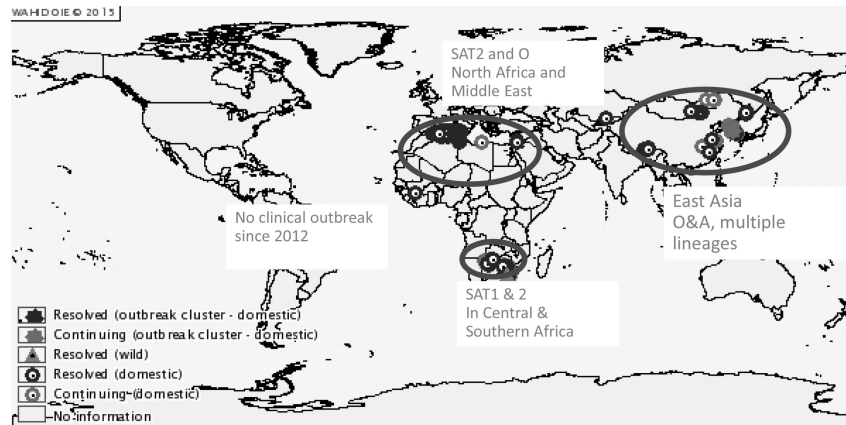


FMD Epidemiology Trends Per Pools/June 2015



- OIE Reference Laboratories And Collaborating Centres ● FAO Additional Reference Centres ● Regional/National Reference Centres
- At a global level, seven FMD epidemiologic regions are recognized containing specific viral variants (seven “virus pools”), requiring specific vaccines targeted against these variants.
 - Vaccine demand is different in each of these regions (no common product profile).

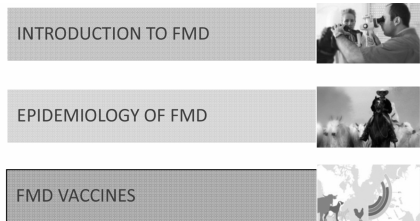
Recent FMD Outbreaks (Jan. 14–Sep. 15)



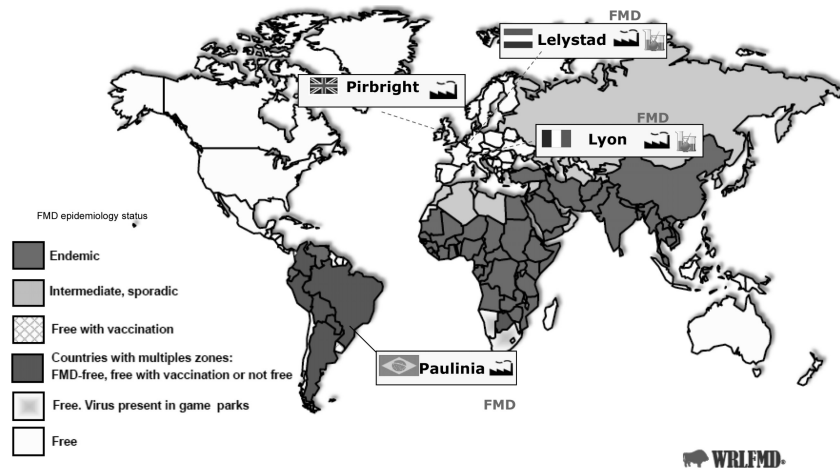
Outbreaks reported to OIE. Courtesy WRL.

Tracking of recent FMD outbreaks show activity in the Middle East, South Africa and East Asia. New FMD strains are emerging in the Middle East and East Asia that warrant strain adaptation for new vaccine development.

FMD Vaccines & Vaccination



Meriel FMD Vaccine Sourcing



Meriel's industrial capabilities to produce FMD vaccine are broad based and global in scope.

The global industrial demand for high quality conventional FMD vaccine exceeds manufacturer's ability to supply. It is generally accepted that the industrial capacity to build antigen bank inventories or to supply endemic markets beyond current agreements does not exist at this time.

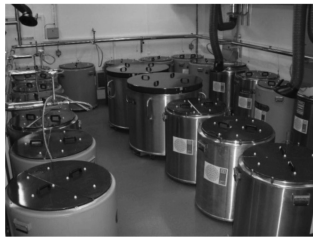
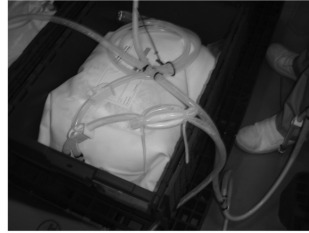
Additional to the manufacturing capabilities, Meriel maintains FMD Research and Development project in Europe and North America.

FMD Vaccines

- Non-purified, low potency vaccine for mass vaccination campaigns in endemic countries
 - Purified, high potency marker vaccines for disease control/eradication programs
 - Aqueous for ruminant only
 - Oily adjuvant for ruminant and swine
- Meriel produces FMD vaccines for specific vaccination program needs.

Merial FMD Vaccine Supply Alternatives

- **Bulk & Concentrates** for technology transfer in control/eradication programs



- **Antigen banks** for Disease Free Countries

Merial offers alternatives, in addition to finished vaccine for endemic disease situations, for FMD vaccine supply. Merial can provide bulk vaccine concentrate for local finishing and packaging. Merial also offers vaccine antigen concentrate banks as a way for disease free countries to build vaccine supply inventory by the stockpiling method.

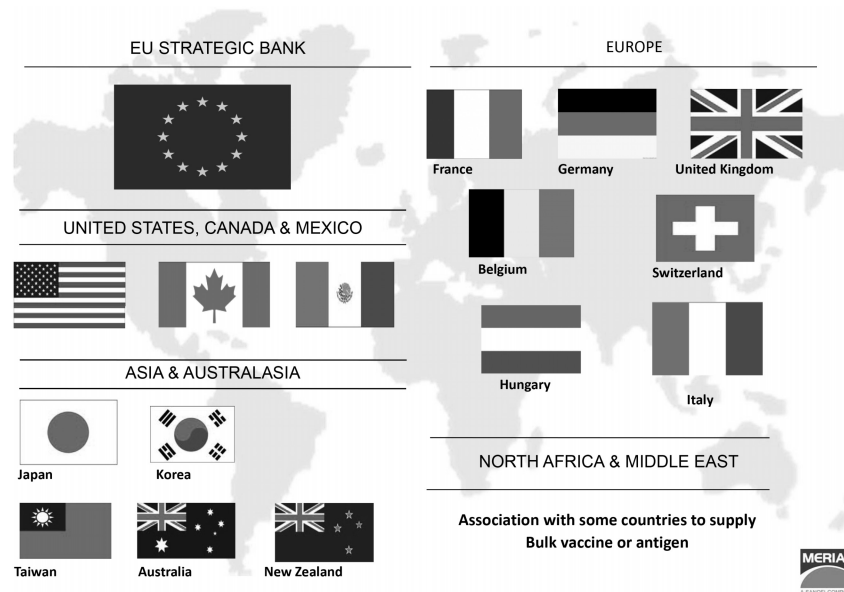
FMDV Antigen Banks—Storage



Straw	P1	P2	P3	P4	P5	P6
1		P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
2	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
3	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
4	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
5			P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
6	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071
7	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071	P1-1180P071

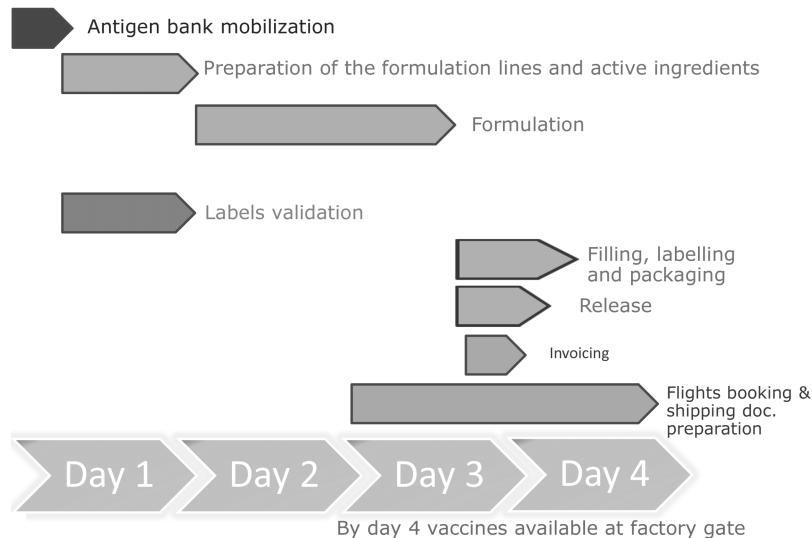
- Antigen banks are stocks of immunogenic materials ready to be formulated into vaccines in case of introduction into FMD-free country
- FMD virus antigen are highly concentrated and stored over liquid N₂ (-130C) to guarantee a shelf life of 5 years
- Banks include strains from major topotypes
 - FMD antigen storage banks provide an efficient means to build stockpiles ahead of potential disease outbreaks.

FMD Antigen Banks Supplied by Merial



Merial maintains and manages many antigen bank stockpiles for many countries and NGOs. Merial has been a partner to the North America FMD Vaccine Bank since the 1990s and represents the majority of inventory doses in the NAFMDVB.

Antigen Bank Mobilization Process



Typically, once Merial is notified by a country partner of the need to mobilize their bank antigen stockpile, it takes 4 days to formulate, fill, label, package and release the finished vaccine for shipment to the country of need.

WRL FMD Bank Recommendations: 7/15

Annex 3

RECOMMENDATIONS FROM WRLFMD® ON FMD VIRUS STRAINS TO BE INCLUDED IN
FMDV ANTIGEN BANKS (FOR FMD-FREE COUNTRIES) – March 2015

Note: Virus strains are NOT listed in order of importance

High Priority	<ul style="list-style-type: none"> ○ Manisa ○ PanAsia-2 (or equivalent) ○ BFS or Campos A24 Cruzeiro Asia 1 Shamir A Iran-05 (or A TUR 06) A22 Iraq SAT 2 Saudi Arabia (or equivalent i.e. SAT 2 Eritrea)
Medium Priority	<ul style="list-style-type: none"> A Eritrea SAT 2 Zimbabwe SAT 1 South Africa A Malaysia 97 (or Thai equivalent such as A/Sakolnakorn/97) A Argentina 2001 ○ Taiwan 97 (pig-adapted strain or Philippine equivalent)
Low Priority	<ul style="list-style-type: none"> A Iran '96 A Iran '99 A Iran 87 or A Saudi Arabia 23/86 (or equivalent) A15 Bangkok related strain A87 Argentina related strain C Noville SAT 2 Kenya SAT 1 Kenya SAT 3 Zimbabwe

NB: Discussions are currently underway to adopt a risk-based approach for different FMD viral lineages to identify priority vaccines for use in Europe and other FMD-free settings.

The World Reference FMD Bank in the UK updates their FMD antigen bank strain recommendations quarterly.

Mrs. HARTZLER. Thank you, Mr. Parker.
Dr. Wolf.

**STATEMENT OF CYNTHIA B. WOLF, D.V.M., ASSISTANT
PROFESSOR AND SMALL RUMINANT VETERINARY
SPECIALIST, COLLEGE OF VETERINARY MEDICINE,
UNIVERSITY OF MINNESOTA, ST. PAUL, MN; ON BEHALF OF
AMERICAN SHEEP INDUSTRY ASSOCIATION**

Dr. WOLF. Thank you to this Subcommittee for the opportunity to speak with you on behalf of the American Sheep Industry regarding preparedness for FMD. My name is Cindy Wolf. My family and I raise sheep and beef cattle in Minnesota, and we sell direct to a variety of end-users. For the past 32 years, I have also been employed as a small ruminant veterinarian at the College of Veterinary Medicine at the University of Minnesota.

A few things about the sheep industry are important relative to FMD, and I would like to point those out. Basically in this country, sheep and goats move around the country daily, crossing several state lines in about every type of vessel made. We hope they have health certificates, but I wouldn't count on it. The sheep are sold for human consumption at a wide range of body weights and ages, dependent on the custom of the end-user. While we have some concentration in our country regarding sheep production, we do have a tremendous amount of small numbers moving around in the Northeast United States processed in a variety of different ways.

The odd thing about sheep is they are very subtle when they are infected with clinical signs. First, you can't really notice it. This is in contrast to pigs and cattle. And second, for much of the year, sheep are covered with wool, making it even harder to see these lesions, and also, their normal behavior is that they tend to move with their heads low, so seeing these lesions makes that even more difficult.

So one thing we learned from the UK outbreak in 2001 is that sheep carried and distributed the virus around the country throughout marketing channels, spreading it to other livestock, before the disease was recognized. So the direction we are going in this country regarding early detection animal traceability, movement restrictions, and vaccination is essential to averting a very large outbreak.

My close friend, Dr. Don Hoenig, who was the State Veterinarian in Maine for 27 years, if I could quote him, he said, "A major development in our response planning is the acknowledgment that if an outbreak becomes widespread, a large scale FMD vaccination strategy will need to be implemented." I believe that it is imperative that as a country we continue along this path, moving away from the singular approach of stamping out FMD to one of control that relies upon cooperation to produce and deliver timely, effective vaccination, communication, and education.

To accomplish FMD control where business continuity will be possible, we will need to adequately fund vaccine banks to ensure there is at least one functional FMD vaccine bank at all time, if not more, and that that bank is ready to launch into production upon a second's notice. Part of such contract will need to include making the most likely serotype or serotypes available, rapid production of the needed number of doses, and preexisting licensure of manufacturing processes so the vaccine will be legal to use in the U.S. Also, we—stakeholders and government—will need to continue the readiness development process so if we need to execute a control plan, we will know how to immediately find the herds and flocks that need to be vaccinated; we will know how to acquire the ancillary supplies, so ten million needles, syringes, special ear tags, the handling equipment that we know from other disease examples, we don't necessarily have in place; the manpower. How are we going to ID these vaccinates? While we have a plan, but can we make these 2.5 million ear tags or ten million ear tags in a weeks' time? And how are we going to ensure that whole farms are vaccinated as rapidly as possible, because sometimes these sheep are on thousands of acres at any one time.

While this will not be a small investment, the cost of not having a vaccine preparedness plan in place, given the risk is extremely high, and it is essential to the security of U.S. agriculture and the country that we are fully prepared and ready to produce the potentially needed doses of the appropriate serotype in an extremely rapid timeframe.

And last, it is my holistic approach as a veterinarian, we need to continue to bolster our efforts at any and every entry point into the U.S. so we rely on improved screening techniques and additions to the Beagle Brigade, and we continue to educate and remind the public about not bringing in food or other ag products from foreign

Thank you for your support.

[The prepared statement of Dr. Wolf follows:]

PREPARED STATEMENT OF CYNTHIA B. WOLF, D.V.M., ASSISTANT PROFESSOR AND SMALL RUMINANT VETERINARY SPECIALIST, COLLEGE OF VETERINARY MEDICINE, UNIVERSITY OF MINNESOTA, ST. PAUL, MN; ON BEHALF OF AMERICAN SHEEP INDUSTRY ASSOCIATION

Impact of an Outbreak of Foot-and-Mouth Disease (FMD) in the United States and the Urgent Need for an Adequate Stockpile of FMD Vaccine

Chairman Rouzer, Ranking Member Costa, and Members of the House Committee on Agriculture, Subcommittee on Livestock and Foreign Agriculture, my name is Cindy Wolf. My family and I raise sheep and beef cattle in Minnesota. We sell directly to consumers, restaurants, auction markets and to a lamb cooperative. For the past thirty-two years, I have also been employed as small ruminant veterinarian at the College of Veterinary Medicine at the University of Minnesota. Thank you for the opportunity to speak to you about our preparedness for the potential introduction of foot-and-mouth disease (FMD) into the United States.

Sheep Industry Demographics

I included two images in my written testimony, one showing the numbers of sheep by state in the U.S. and the other one roughly shows sheep movement. Sheep (and goats) move across the continental U.S. daily traversing several state lines in about every type of vessel made. We hope that most of them have Certificates of Veterinary Inspection but I wouldn't count on it. Sheep sold for human consumption have a wide range of bodyweights and ages dependent on the customs of the end-user.

Since FMD transmission can be airborne, there are millions of livestock at-risk along routes of commerce if even one animal should be infected. Young lambs are generally concentrated for a few weeks to a few months while they are being fed prior to processing. The highest concentration of these lambs at any given point in time but mostly in the fall through the spring is in feedlots or crop aftermath on the front range of Colorado, California, Arizona, and Oregon. The larger commercial lamb feedlots (including grazing operations) range in size from 20,000 to 80,000 head in one-time capacity. Lambs entering commercial feedlots tend to come from larger-scale breeding flocks. There are approximately 80,000 sheep producers in the U.S. and there are sheep in every state. In general terms, 80 percent of the breeding ewes are owned by 20 percent of the producers.

All Sheep and Lamb Inventory in the United States: January 1, 2016



United States Total: 5.32 million head.

Source: *Sheep and Goats* (January 2016), USDA National Agricultural Statistics Service.

Sheep Marketing Channels & FMD Risk

If FMD were to be found in one or more of the larger commercial feedlots, temporary movement restrictions, tracebacks, vaccination, *etc.*, would be relatively straight forward because of geographic concentration. However, there are sheep in transport every day of the year and they are crossing multiple state boundaries through rural America much of the time with stops along the way. Nearly all of the sheep in traditional interstate commerce are ear-tagged back to their flock of origin as required by the cooperative state-Federal national scrapie eradication program.

Many auction barns that buy and sell sheep also have other species in the same facility. This presents a large disease exposure risk especially in a species whose FMD clinical signs are rather subtle.

Sheep Movement



Sheep the Silent Carriers and Risk to Other Species

There are a few things about sheep and goats that are unique regarding FMD clinical signs and diagnoses. For example, sheep can be infected with FMD and not present remarkable clinical signs as seen with pigs and cattle. Besides the clinical signs being more subtle, for much of the year many sheep are covered with wool and tend to move with their heads low so seeing FMD lesions from any distance would be difficult.

Lessons Regarding Sheep and Other Species from the Outbreak in the UK

One of the lessons learned from the 2001 FMD outbreak in [the] UK was that sheep were carrying and distributing the virus across the country and throughout marketing channels, spreading it to other livestock before the disease was recognized. Therefore early detection, animal traceability, movement restrictions and vaccination is essential to averting a very large outbreak in the U.S. Veterinarians break down the stages of FMD infection into phases that describe virus progression with phase one being initial infection and the beginning of clinical signs. From a practical standpoint, by the time someone sees a sheep in what they believe is phase one, there are other animals somewhere that are in stage five or full presentation of clinical signs and all of these infected animals have been spreading virus to susceptible animals. Immune response to the vaccine takes several days once the vaccine is given therefore a large and inclusive vaccination program needs to be done very quickly if a case is diagnosed.

Vaccine Needs

My close friend and colleague who was the State Veterinarian for Maine for the 27 years, Dr. Don Hoenig has said the following. "In the past 13 years, I've been involved in national and regional efforts to enhance and improve our preparedness and response to FMD. Our response plans have been dramatically upgraded. State, Federal, and industry stakeholders have held countless meetings and training sessions and conducted numerous tabletop and on-farm, functional exercises to test our plan. A major development in our response planning is the acknowledgement that, if an outbreak becomes widespread, a large-scale FMD vaccination strategy will need to be implemented. Unfortunately, preemptive vaccination is not feasible or practical since there are seven serotypes of FMD virus and over 65 subtypes. Predicting which of these viruses might come to the U.S. is impossible."

I believe that it is imperative that as a country we *continue* to move away from a singular approach of stamping out regarding FMD control to one that relies upon cooperation to produce and deliver timely effective vaccination, communication, and education. To accomplish FMD control where business continuity will be possible, we will need to adequately fund vaccine contracts to ensure there is at least one functional FMD vaccine bank(s) maintained and ready to launch into production. Part of these contracts will need to include making the most likely serotype(s) available, rapid production time of needed number of doses, and pre-existing licensure of manufacturing processes so vaccine will be legal to use in U.S. Also we (stakeholders and government) will want to continue the readiness development process so the executors of the control plan know how they will immediately find the herds and flocks needing to be vaccinated, acquire ancillary supplies (needles, syringes, special ear tags, handling equipment), manpower, ID vaccinates, and ensure whole farms are vaccinated as rapidly as possible. While this will not be a small invest-

ment, the cost of not having a vaccine preparedness plan in place given the risk is extremely high. It is essential to the security of U.S. agriculture and the country that we are fully prepared and ready to produce potentially needed doses of the appropriate serotype in an extremely rapid timeframe. It is our responsibility to protect agriculture as a component of our country's critical infrastructure of which this one part.

Last, we need to continue to bolster our efforts at airports and border crossings with improved screening techniques and additions to the Beagle Brigade. We must continue to educate and remind the public about not bringing in food or other agricultural products from foreign countries as well as livestock producers to be vigilant and proactive regarding suspect cases.

Conclusion

The American Sheep Industry appreciates the support of this Committee in furthering a plan to bolster our preparedness for a FMD outbreak.

Mrs. HARTZLER. Thank you, Doctor.
Dr. Sjeklocha.

STATEMENT OF DAVID B. SJEKLOCHA, D.V.M., OPERATIONS MANAGER OF ANIMAL HEALTH & WELFARE, CATTLE EMPIRE LLC, SATANTA, KS; ON BEHALF OF NATIONAL CATTLEMAN'S BEEF ASSOCIATION

Dr. SJEKLOCHA. Mrs. Hartzler, Mr. Chairman, Ranking Member Costa, and Members of the Subcommittee, thank you for the opportunity to be here today.

Foot-and-mouth disease is an extremely contagious viral disease of cloven hoofed animals and some wildlife species. The United States has not experienced an FMD outbreak since 1929, yet FMD is still a significant threat to American cattle producers. International travel and trade pose a substantial risk for FMD by providing pathways for the virus to enter the United States. FMD can be transmitted over long distances by animal products, people, and other vectors. FMD is considered a potential agent for agricultural terrorism. The size, structure, efficiency, and extensive movement inherent in the United States livestock industry will have unprecedented challenges in the event of an FMD outbreak.

An FMD outbreak in the United States would result in immediate closure of most, if not all, of our foreign export markets. For the sake of perspective, as the result of a single BSE case in 2003, we saw our beef exports decline by 2 billion pounds from 2003 to 2004. We still do not have access to several critical markets, such as China.

While international trade is a concern, we also expect to see significant impact to U.S. beef producers due to the depopulation, restrictions on cattle movements, and a potential shutdown of overall cattle trade in the affected regions. Models demonstrate that the impact to the beef industry could be in excess of \$50 billion. Overall, there is a lack of capability to rapidly depopulate cattle and dispose of carcasses for large feedyards. A 2007 FMD exercise involving feedyards in the Texas Panhandle established that it would be a logistical challenge to depopulate 50,000 to 75,000 head of cattle within 72 hours, and then dispose of them within 96 hours. With over 3½ million animals within a 100 mile radius of that exercise, 75,000 head of cattle is only a small portion of the region's susceptible livestock population.

Vaccination of cattle against FMD has been practiced with relatively positive immunity results. Cattle are considered to be the

highest priority for emergency FMD vaccine use. If the disease is under control in cattle, it should not persist in other species. In 2001, rapid vaccination of all the cattle in Uruguay brought that FMD outbreak under control rapidly.

Limitations with FMD vaccinations do exist. Vaccines provide only serotype specific protection. There are seven distinct serotypes of the FMD virus, and more than 65 strains. Vaccination against one serotype may fail to fully protect against other strains within the serotype.

Novel FMD technologies are currently under development, using subunit and recombinant DNA. These vaccines do not utilize live FMD virus, and can be safely produced on the U.S. mainland. ARS scientists at Plum Island have developed leaderless FMD vaccines that will allow safe production of FMD vaccine on the U.S. mainland, and protect livestock against clinical disease, as well as prevent virus shedding and virus transmission.

Although work has started for commercialization of the leaderless FMD vaccine, the cost and timeline for vaccine production remains highly uncertain. NCBA actively supports a development of novel FMD vaccine technologies, and also requests immediate steps be taken to update the current FMD vaccine supply composed of conventional vaccine technology.

Established in 1982, the North American FMD Vaccine Bank currently holds vaccine antigen concentrate for use by Mexico, Canada, and/or the United States. A single livestock dense state in the United States would deplete this bank's supply of antigen. The funding that USDA has for the supply of FMD vaccine in the National Veterinary Stockpile is insufficient to provide adequate FMD vaccine supplies. An FMD outbreak in South Korea depleted the banks of FMD vaccines from around the world in order to vaccinate a population roughly $\frac{1}{2}$ the size of the livestock population in Iowa.

USDA has funded the development of the secure food supply plans and incorporated the use of FMD vaccines as an important tool. Currently, the beef industry is involved in a collaborative effort with USDA, state animal health officials, and academic partners to develop a secure beef supply plan to manage movements of non-infected cattle in the event of an FMD outbreak, provide business continuity for producers, transporters, and processors, and to maintain a continuous supply of safe and wholesome beef for consumers.

We request that the Committee work with USDA and encourage them to budget the funds needed for the update and modernization of the National Veterinary Stockpile of FMD vaccine. Thank you for the opportunity to be here today, and we look forward to working with you to ensure that the United States is prepared for an outbreak of FMD.

[The prepared statement of Dr. Sjeklocha follows:]

PREPARED STATEMENT OF DAVID B. SJEKLOCHA, D.V.M., OPERATIONS MANAGER OF ANIMAL HEALTH & WELFARE, CATTLE EMPIRE LLC, SATANTA, KS; ON BEHALF OF NATIONAL CATTLEMAN'S BEEF ASSOCIATION

Foot-and-Mouth Disease Preparedness

Mr. Chairman, Ranking Member Costa, and Members of the Subcommittee, my name is Dr. Dave Sjeklocha. I am a veterinarian and the Operations Manager for Animal Health and Welfare for Cattle Empire, LLC. Cattle Empire is owned by the

Brown family and is located in southwest Kansas. The company consists of five feedyards, ranging in size from 18,000 head capacity to 87,000 head capacity, for a total one-time capacity of approximately 240,000. In addition, there is a farming and ranching operation associated with Cattle Empire.

I grew up on diversified farming and ranching operations in Iowa and Missouri and received my degree from Kansas State University's College of Veterinary Medicine. Before joining Cattle Empire I spent several years as a practicing veterinarian in Nebraska, Colorado, Kansas, Texas and Oklahoma with a focus on beef cattle production management and medicine. I am an active member of the American Veterinary Medical Association, the Academy of Veterinary Consultants and the American Association of Bovine Practitioners. In 2011, I was recognized as the Beef Cattle Institute's "Beef Cattle Veterinarian of the Year" from Kansas State University and in 2013 recognized as the AVC's Consultant of the Year.

NCBA is the nation's oldest and largest trade association representing America's cattle producers with a strong and united voice in our nation's Capital. On behalf of NCBA's membership, I appreciate the opportunity to share with you more background on Foot-and-Mouth Disease (FMD), our concerns regarding this disease, and our ability to respond to a reintroduction of FMD into the United States.

FMD is an extremely contagious viral disease of cloven hoofed animals and some wildlife species. FMD is present in approximately $\frac{2}{3}$ of the world and endemic in parts of Africa, Asia, Eastern Europe, the Middle East, and South America. North America and Central America are free of FMD, as is Western Europe, Australia, and New Zealand. The United States has not experienced an FMD outbreak since 1929, yet FMD is still a significant threat to American cattle producers. International travel and trade pose a substantial risk for FMD by providing pathways to enter the United States. FMD can be transmitted over long distances by animal products, people and other vectors. FMD is also considered as a potential agent for agricultural terrorism. The size, structure, efficiency, and extensive movement inherent in the United States livestock industry will present unprecedented challenges in the event of an FMD outbreak. No country with a livestock industry comparable to the U.S. has had to deal with an outbreak of FMD.

FMD presents a great economic threat to U.S. livestock producers and is viewed as the most concerning transboundary disease in the world. An FMD outbreak in the United States would result in the immediate closure of most, if not all, of our foreign export markets. To put this into perspective, we need to only look at the economic impact of a single case of bovine spongiform encephalopathy (BSE) found in a Canadian-born cow located in Washington State on December 23, 2003. As a result of a single case of BSE, we saw U.S. beef exports decline by 2 billion pounds from 2003 to 2004. It took 8 years for U.S. beef exports to get back to pre-December 2003 levels. Over a decade later we still do not have access to several critical markets, such as China, nor do we have full access to every country we were trading with prior to December 2003. It's not just the international trade impact which concerns us. In addition, we expect to see significant economic impact to U.S. beef producers due to depopulation, restrictions on cattle movements, and a potential shutdown of overall cattle trade in the affected regions. There are many variables which affect how we may see introduction of the disease and its spread. These variables include the region of the country, the type of operation, the timely reporting of the disease, and the response time. In the "Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment" conducted for the National Bio and Agro-Defense Facility, models are used to estimate the economic impact of an outbreak of FMD. In scenarios that model the economic impact of FMD on cow/calf operations, feedlots, and livestock markets, the total economic impact of a case of FMD can reach over \$50 billion in losses to the U.S. beef industry. Again, we must note that this report was based on 2010 cattle prices where the average fed cattle price was \$95 per hundredweight. Currently, Live Cattle futures are in the \$135 per hundredweight range. Regardless of the model or scenario used, it is obvious from the information above that the reintroduction of FMD would cost our industry billions of dollars.

The goals of USDA's Animal and Plant Health Inspection Service (APHIS) in managing an FMD outbreak in the United States are to detect, control, and contain the outbreak in order to eradicate FMD from the country as quickly as possible. As a result of changes in livestock demographics and larger herd sizes, the FMD control paradigm at USDA-APHIS has shifted from "stamping out" or total depopulation, to the use of vaccination to achieve control for type 3 outbreaks or larger. In September 2014, NCBA joined other animal agricultural stakeholders attending a meeting called by USDA-APHIS to develop concrete strategies to improve alignment between USDA's response strategies for FMD and our current vaccine capabilities. The stakeholders in attendance were informed that gaps existed in vaccine preparedness for a type 3, (large regional), or greater FMD outbreak. An immediate

need was identified at this meeting to begin modernization of the current U.S. FMD vaccine response capabilities. Budgetary shortfalls at USDA for acquiring sufficient supplies of FMD vaccine present a major hurdle to achieving modernization of the FMD vaccine capabilities in response to an FMD outbreak.

There are critical reasons for considering vaccination strategies in an FMD outbreak. In anything beyond a small, focal FMD outbreak, stamping out or rapid depopulation is not viable or sustainable. There is a lack of capability and capacity to rapidly depopulate and dispose of the large number of carcasses which would be found in feedyards that can easily feed 50,000 to 100,000 head of cattle. Even the smaller feedyards would pose a challenge for “stamping out,” both logistically and economically. During the 2007 Palo Duro FMD exercise in the Texas Panhandle, rapidly depopulating 50,000 to 75,000 head of cattle was deemed a logistical challenge that would not be possible within 72 hours for depopulation and within 96 hours for disposal. Since the Texas Panhandle is a livestock dense region, 75,000 animals constitute only a small portion of the region’s total susceptible livestock population (over 3.5 million animals in a 100 mile radius). If FMD spread rapidly prior to detection, it is clear that a stamping-out strategy would not be feasible or appropriate.

Key objectives have been identified by APHIS Veterinary Services in regard to FMD vaccine and vaccination policy, and there is definite recognition that additional response capabilities will be required. There is an immediate need to increase the guaranteed access to FMD vaccine. The requirements to achieve response goals include: identifying the type of vaccine needed (topotypes and strains); establishing multiple sources or manufacturers; establishing which vaccines will be used in specified livestock populations; establishing a desired quantity of vaccine and determining the necessary time to deliver the vaccine.

Vaccination of cattle against FMD has been practiced with relatively positive immunity results. Cattle are considered to be the highest priority for emergency FMD vaccine use. If the disease is under control in cattle, it should not persist in other species. For example, in the 2001 FMD outbreak in Uruguay, the outbreak was brought under control by the rapid vaccination of all the cattle in the country. To effectively induce immunity in the cattle population, all cattle in the affected region should receive two doses of normal potency FMD vaccine 1 month apart, or a single dose of high potency FMD vaccine as soon as possible. Certain limitations of vaccination, however, do exist. Vaccines provide only serotype specific protection. There are seven immunologically distinct serotypes of the FMD virus and more than 65 strains. There is a substantial amount of genetic variability in FMD viruses, and new strains can occasionally develop spontaneously. Also, vaccination against one serotype may fail to protect fully or at all against other strains within the serotype. Immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle as early as 4 days with protection improving over the next 2 to 3 weeks. No currently available vaccine provides “sterilizing immunity” which will prevent subsequent infection. It is possible that individual vaccinated cattle which are infected with FMD virus could become asymptomatic virus carriers. Differentiating field infected animals from vaccinated animals, known as DIVA strategy, is critical to emergency vaccination in an FMD outbreak. DIVA diagnostic techniques typically use tests for antibodies against viral non-structural proteins (NSPs) to differentiate animals that are infected with FMD naturally from those animals vaccinated with FMD vaccine. The diagnostic DIVA capability of a vaccine is important for an effective vaccine campaign, business continuity processes, and FMD surveillance. All FMD vaccines should be DIVA compatible unless the animals are intended for slaughter.

Currently, FMD virus is listed by USDA as a “select agent” on the Select Agent Program registration list. This means that it is currently illegal to have FMD virus on the U.S. mainland, even for FMD vaccine production purposes. As such, there is no conventional, killed virus FMD production (which requires live FMD virus) in the United States. The U.S. must rely on the overseas production of FMD vaccine in the event of an FMD outbreak.

Novel FMD vaccine technologies are currently under development using subunit and recombinant DNA. These vaccines do not utilize live FMD virus and can be safely produced in the U.S. mainland. USDA’s Agricultural Research Service (ARS) scientists at Plum Island, New York, have developed a leaderless FMD vaccine (FMD-LL3B3D) that will allow safe production of FMD vaccine on the U.S. mainland and protect livestock against clinical disease as well as prevent virus shedding and virus transmission. Although work has started for commercialization of the leaderless FMD vaccine, the cost and timeline for vaccine production remains highly uncertain. NCBA actively supports the development of novel FMD vaccine technologies, such as the USDA-ARS leaderless FMD vaccine technology, for use in

meeting future FMD vaccine needs. In addition, NCBA requests immediate steps be taken to update the current FMD vaccine supply made up of conventional vaccine technology in order to meet surge capacity for emergency use and to safeguard the health of the U.S. cattle herd.

The structure of modern agriculture in the United States, including large herd sizes and extensive intra- and interstate movement of cattle and cattle products will make it nearly impossible to control an FMD outbreak in livestock dense areas without the rapid use of tens of millions of doses of FMD vaccine. It is estimated that over 400,000 head of cattle are in transit daily in the United States. Established in 1982, the North American FMD Vaccine Bank currently holds vaccine antigen concentrate for use by Mexico, Canada, and/or the United States. The amount of antigen in the North American FMD Vaccine Bank is far below what would be needed to provide vaccine for a single livestock dense state in the United States. The funding that USDA has for the supply of FMD vaccine in the National Veterinary Stockpile is insufficient to provide adequate FMD vaccine supplies. An outbreak of FMD occurring in a livestock dense area, such as Iowa, and which was not contained rapidly with “stamping out”, could easily exhaust the world’s supply of emergency FMD vaccine. A FMD outbreak in South Korea depleted the banks of FMD vaccines from around the world in order to vaccinate a population roughly half the size of the livestock population in Iowa. For an outbreak in Iowa with over 20 million hogs and approximately four million cattle, the amount of vaccine needed could easily exceed 50 million doses in a very short time. Insufficient vaccination capacity limits the ability of a strategic response to FMD by USDA. The need for additional supplies of FMD vaccine, as well as new vaccine approaches and technologies, to help meet this need has been recognized by USDA and Department of Homeland Security (DHS) officials. USDA has funded the development of the Secure Food Supply Plans that incorporate the use of FMD vaccines as an important tool. Currently, the beef industry is involved in a collaborative effort with USDA, state animal health officials, and academic partners to develop a Secure Beef Supply Plan to manage movements of non-infected cattle in the event of an FMD outbreak; provide business continuity for producers, transporters, and processors; and to maintain a continuous supply of safe and wholesome beef for consumers.

NCBA supported the preparation of a white paper by Dr. James Roth, distinguished professor and veterinary specialist at the Center for Food Security and Public Health at Iowa State University’s College of Veterinary Medicine entitled: “FMD Vaccine Surge Capacity for Emergency Use in the United States.”* The objectives of the white paper involved securing and providing information concerning FMD vaccine that could be used to seek consensus among the stakeholders, Federal officials, and state officials on the best mechanisms to ensure vaccine availability to minimize the economic, environmental, animal welfare, and food security impacts of a large FMD outbreak in the United States. In the white paper, Dr. Roth concluded that the funds necessary to enable the surge capacity need for FMD vaccine for emergency use in the United States would be estimated at \$150 million per year for 5 years to help to protect a \$100 billion a year (cash receipts) animal industry. In September of 2013, the World Reference Laboratory for FMD at the Pirbright Institute in Pirbright, United Kingdom, recommended that national antigen banks for FMD maintain 23 strains of FMD virus as live master seeds and inactivated antigen concentrates.

Subsequent to the agriculture stakeholder meeting held in September 2014 with USDA–APHIS to discuss the U.S. FMD vaccination policy for response to an outbreak and existing gaps, USDA–APHIS agreed to develop a Request for Information or “RFI” to companies regularly engaged in FMD vaccine production so that an estimated cost to update the current FMD vaccine bank for the United States could be determined.

Homeland Security Presidential Directive 9 (HSPD 9, January 30, 2004) provides for the “Defense of United States Agriculture and Food.” This directive establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. HSPD 9 directs the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, and in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, to work with state and local governments and the private sector to develop a National Veterinary Stockpile (NVS) containing sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy and that will be capable of deployment within 24 hours of an outbreak. It is

***Editor’s note:** the referenced white paper is available at: <http://www.cfsph.iastate.edu/pdf/fmd-vaccine-surge-capacity-for-emergency-use-in-the-US>.

urgent to develop a plan to ensure that adequate supplies of multiple strains of FMD vaccine are readily available in the event of an accidental or intentional introduction of FMD virus into the United States. This action is mandated in Homeland Security Presidential Directive 9.

We encourage USDA to consider convening a stakeholder community working group of experts capable of evaluating existing and new technology FMD vaccines under development to determine the technologies which can best meet future as well as immediate needs for emergency response FMD vaccination in the United States. Furthermore, the Federal Government must conduct research into alternative delivery methods for FMD vaccines which have been shown in cattle and in swine to significantly reduce the antigenic mass required for each dose of vaccine, thus enabling existing and future vaccine antigen concentrate to be formulated into significantly more doses of vaccine.

The current FMD vaccine bank has several problems. Currently, the United States does not have access to enough FMD vaccine to handle an outbreak beyond a very small, localized disease event. APHIS manages the vaccine bank at Plum Island, New York, where vaccine antigen concentrate for a limited number of FMD strains is stored. In the event of an FMD outbreak, the antigen would need to be shipped to Pirbright, United Kingdom, or Lyon, France, to be turned into finished vaccine and then shipped back to the United States for use. This bank is currently funded at \$1.9 million annually. The turnaround time from the onset of an outbreak until finished vaccine product can be delivered to the field would be weeks for a small FMD event and months for a larger FMD outbreak. Of equal concern is the limited number of FMD vaccine antigen strains currently maintained at Plum Island and the limited shelf life of the vaccine antigen concentrate that would affect the potency of the finished vaccine, should the expiring vaccine antigen stock not be rotated out of storage. Additionally, worldwide FMD vaccine production is limited and there is no surge capacity currently available to produce the millions of doses needed in the event of a large-scale FMD outbreak in the United States. Manufacturers with contracts in place are producing at maximum capacity for their contracted customers and will not abandon these established customers to produce vaccine for the United States. Furthermore, the FMD vaccine bank is scheduled to move in the future to the NBAF facility in Kansas and the storage capacity may be limited for FMD vaccine. For these reasons, we recommend consideration for establishing a contract for a vendor-managed, offshore FMD bank that has the capability to produce vaccine antigen concentrate for all FMD strains currently circulating in the world. A contracted offshore FMD bank would provide a vendor-managed-inventory of vaccine with replacement of outdated product, facilitated vaccine finishing, and ultimately increased efficiency in FMD vaccine delivery for use in an FMD outbreak.

Finally, we request that the Committee work with USDA and encourage them to budget the funds needed for the update and modernization of the National Veterinary Stockpile of FMD vaccine.

Thank you for the opportunity to be here today, and we look forward to working with you to ensure that the United States is prepared for an outbreak of FMD.

Mrs. HARTZLER. Thank you, Doctor, and for all of you for your testimony. As a former pork producer and someone who continues to raise cattle on our farm, this is something that is very, very important to me and to Missouri's 4th District, and it is important that we get this right. And I am also a Member of the Armed Services Committee, and after we go through the first round, I might want to come back to agro-terrorism and some questions with that.

But I would like to start off with this question. In a recent briefing with USDA, they mention public private partnerships as a possible way to address the funding of a vaccine stockpile. So has your industry thought about what that would look like, and what you could support?

So I will just open it up to anyone who might want to answer that. A public-private partnership to help with the funding.

So the pork producers, the cattle, sheep, you don't want to say hey, we will help pay for it? Let's do a show of hands.

Dr. HILL. I mentioned that in my oral testimony a little bit. I guess it is not that our industry and probably the livestock indus-

try is opposed to some kind of partnership, but we would have to have some kind of a plan and know what the cost is before we would want to commit to it. No matter how you slice it, this is going to be an expensive program. It is going to be, and Dr. Roth can probably give you some idea of what he estimates the cost of developing an effective vaccine bank would be.

I don't think the industry is totally opposed to some kind of participation, though.

Mrs. HARTZLER. Yes, so let's go to Dr. Roth. You mentioned that you need 23 different vaccines, and so can you talk about that a little bit, and then what do you anticipate the cost would be?

Dr. ROTH. So the World Reference Laboratory for FMD in Pirbright, England, puts out a list of the strains that every country should maintain in their bank, and there are 23 strains that aren't cross protected, and that is based on active strains of virus around the world.

In this white paper that I developed for the commodity groups, we estimated that it would cost about \$150 million a year, and it would take 5 years to build a robust supply for all 23 strains, so you would have immediate availability, short-term availability, and long-term availability.

Now I think that can probably be reduced with more people engaged in planning and working more with the vaccine industry, and looking at some of these new technologies. So I think that is a very large number, but if we look at the potential impact of FMD, it is not such a big number to protect U.S. agriculture.

Mrs. HARTZLER. How long does a vaccine last? What's the lifespan of the vaccine, and how often do we have to replenish that?

Dr. ROTH. If you have finished vaccine in a bottle ready to go, that lasts for 18 to 24 months. The vaccine bank is frozen antigen concentrate, and that can last 5, maybe 10 years. But in the white paper, we proposed that work with the manufacturers to use vendor managed inventory, so they keep finished vaccine in their inventory, and when they make a new batch, they replace that. So they always might keep 20 million doses on hand, and then they sell from that inventory to their current customers. And you would have to pay them for that.

Similarly, with the antigen concentrate, they could maintain a rotating stock of antigen concentrate. After it begins to age, then they formulate it to vaccine, sell it, and replace it with more antigen concentrate. So there would be uses for most of these strains. You don't have to destroy it.

Mrs. HARTZLER. So now that we have at least a figure, \$150 million a year, 5 years, so back to the funding thing. One idea was a check-off. I'm a big supporter of check-offs for promotion and education. So the idea of a check-off for all cloven hoofed animals or perhaps a processing fee. So are either of these something that your industry would support? I will start with the cattle.

Dr. SJEKLOCHA. I would say that there are concerns about earmarking. If the beef industry would put more money into this check-off to develop this vaccine pool, and we had an outbreak and there would be some concerns, like if the pork industry needed X amount of vaccine, the beef industry needed so much, would there

be in-fighting or fighting between those two groups as to who would get the most vaccine to deal with their problems.

I think overall some industry involvement would be acceptable, but that is one of the problems that I think we would have to face.

Mrs. HARTZLER. Yes. Dr. Wolf?

Dr. WOLF. Challenging question, and my thought process is a little different in that the sheep producers would be cooperating on a scale they have never before cooperated. We would be talking about every sheep producer in a large area doing something that was not scheduled and time consuming, and complying 100 percent.

And so I look at it as that this isn't just a livestock industry problem. This is an all of agriculture problem. If we had FMD in our area today, there would be no grain moving to all the livestock producers in the area, and think of the ripple effect, or hay, or maybe there wouldn't even be fuel coming to your farm because of trucks not being allowed to move.

And so I think that the public stands to lose so much that the industry groups would step forward, but that they would have a difficult time shouldering a majority of the costs, because their losses are already going to be huge.

Mrs. HARTZLER. Good point. Quickly, Dr. Hill, do you have anything to add for the pork producers?

Dr. HILL. Yes, and I think when you are referring to a check-off, you are referring to mandatory check-off, and under the current law, that would not be legal for us to use the money for that. Our check-off is for research promotion and education, but again, I would agree with Dr. Wolf. I think the industry would be willing to participate, but not to the extent if the \$150 million is right, not to that level.

Mrs. HARTZLER. All right, thank you very much.

Ranking Member Costa?

Mr. COSTA. Thank you very much.

Dr. Sjeklocha, to the last question, doesn't that point out if there were such an outbreak, that there would need to be some sort of a protocol that would be established, and hasn't that been thought out in some fashion between the USDA and the various industries represented here?

Dr. SJEKLOCHA. As far as a check-off?

Mr. COSTA. No, not a check-off. In terms of how the vaccine that is in supply that would be readily available and that that would have to be developed. What is our supply of vaccine today? Dr. Roth, you talked about 23 vaccines. I would like some clarification, you are talking about a vaccine or 23 various vaccines needed to—

Dr. ROTH. To cover all of the potential strains around the world, it would take 23 vaccines.

Mr. COSTA. But, if we had a strain that would break out here, do we have a particular vaccine for any of those 23 strains?

Dr. ROTH. My understanding is that the North American Vaccine Bank has about 14 strains, perhaps.

Mr. COSTA. Fourteen of the 23?

Dr. ROTH. Yes, and they are the most common strains. They have banked the most common strains.

Mr. COSTA. And what is our understanding of the level of the supply in the event of it?

Dr. ROTH. My understanding is for most of those strains, it is about 2½ million doses.

Mr. COSTA. I see. The issue of animal husbandry of the stakeholders that are involved, I understand there was a meeting that began with USDA and APHIS to develop and improve the current strategies for an effective response. To what extent is industry involved in this preliminary planning and implementing for a defense and response program? I mean, it is too bad we don't have USDA here to respond, are any of you aware of those efforts?

Dr. HILL. Well, there are ongoing, what do you call them, practices or—

Dr. WOLF. Exercises.

Dr. HILL. What?

Dr. WOLF. Exercises.

Dr. HILL. Yes, exercises. Thank you, Cindy. There are exercises, ongoing exercises that the industry cooperates with USDA looking at everything from movements to slaughter and that sort of thing. Those plans are in place, but—

Mr. COSTA. Do they need to be updated?

Dr. HILL. Pardon?

Mr. COSTA. Do they need to be updated?

Dr. HILL. Well, I think they are continually updated.

Mr. COSTA. All right. Do they meet on a regular basis with industry?

Dr. HILL. Pardon?

Mr. COSTA. Does USDA and APHIS meet on a regular basis with—

Dr. HILL. Absolutely.

Mr. COSTA. Okay, so maybe it is a better question that we address to the Department.

In terms of the economic and market concerns, we again know about the outbreak with sheep in the UK in 2001. Any estimations in terms of the market aspects and export impacts to America's livestock industry in the event of an outbreak? What sort of constraints and confinements might be put in place?

Dr. ROTH. Well, the pork board funded a study using economists at Iowa State University in 2011, and they estimated that over a 10 year period—because without vaccine, this could go on a very long time before we get our FMD free status back, that it could cost the pork industry about \$57 billion, beef, \$71 billion, corn, \$44 billion, and soybeans, \$25 billion, because it will impact green markets also.

Mr. COSTA. Well, Madam Chair, I think for the record we ought to get an estimate in terms of the economic impacts, so we would have a better knowledge of that.

And it was mentioned here again in terms that a couple of you noted in the event of an outbreak, the ability to deal with containment. When I chaired the Senate Agriculture and Water Committee in California, we had in my district a dairy that had an unfortunate circumstance with poison in the feed, and out of what is considered a smaller size herd, 500 milking cows, 300 were lost. Just trying to deal within a 24, 48 hour basis with 300 carcasses

and the disposal and the complications. Dairies in California are anywhere from 1,000 to 5,000 head operations where you have cattle, 100,000, 50,000, 100,000 head of cattle are not unusual. What is the preparation to deal with that amount of cattle in the event that you have to deal with the eradication and the disposal and all the health and safety requirements that come with it?

Dr. ROTH. The new response indicates that when the outbreak gets that large, if it gets in a large feedlot or large dairy—

Mr. COSTA. Yes, feedlot, large dairy.

Dr. ROTH.—you just can't kill them. It would take too long. And if you could kill them, you can't dispose of them. So the recommendation is not to kill them, and to let them live and we go from stamping out to other strategies hopefully involving vaccine to control it. Because most adult cattle will recover from FMD, most adult pigs, too. It can be fairly lethal in calves and baby pigs.

Mr. COSTA. But at that point, and my time has expired, you would have to do some sort of isolation, I would think, from those, whether it be pork or livestock of any kind, so that they would not contaminate the other herds.

Dr. ROTH. So there would be major efforts made in biocontainment, and that is difficult, especially in animals outdoors like beef and dairy animals.

Mr. COSTA. Well yes, most of these are outdoors.

Dr. ROTH. Yes, so it would be very, very difficult if it gets into those big units to contain it without vaccine.

Dr. HILL. I might just add, though, in an outbreak situation, what you always try to do is you create circles, and the circles would be controlling movement but also if we had vaccine available, it would be vaccinating those animals in that circle, and the vaccine would help with the shedding of the virus. It drastically reduces the amount of virus that is shed by animals that are exposed or infected. That is part of this plan.

Mr. COSTA. So when the animals recover, are they useful?

Dr. HILL. Yes, many of them do recover.

Mr. COSTA. My time has expired. Do you want to say something?

Dr. SJEKLOCHA. Yes. I work for Cattle Empire feedyards. Our largest feedyard is 87,000 head, and the other end of that is that we have to keep in mind that when we are trying to contain that area, that 87,000 head feedyard uses about 35 truckloads of corn every day. So that is going to be a logistical nightmare on top of getting animal health supplies in, and that sort of thing. So it is a big issue.

Mr. COSTA. Protocols and preparedness are absolutely essential.

Mrs. HARTZLER. Thank you. The gentleman from Iowa, Mr. King.

Mr. KING. Thank you, Madam Chair, and I thank the witnesses. I would pick up where Mr. Costa was on this, that you envision, directly to Dr. Hill first, you turn first to the concept of containing this virus in as localized an area as possible with concentric circles growing out from that as you begin to see how broad it might be growing. What I don't know is how quickly the vaccine is effective, and if it is effective at all against an infected animal.

Dr. HILL. Well, the whole thing is based on developing immunity, and so immunity takes time. This is a kill vaccine, so for maximum production of immunity, you are going to have to give two doses.

So there is a time delay, but still, I think developing that circle and getting out far enough, a lot of times an outbreak situation has happened in England, the circle was too small. Then all of a sudden you have an outbreak here so you make a circle around that, making the circle bigger at first if we had enough vaccine to really encompass a large population in a bigger circle, we would have a better chance of controlling the spread of the disease.

But you are right, it does take time to develop immunity.

Mr. KING. And just taking that in the picture, let's just suggest that we drew the circle big enough to contain the virus and I guess it doesn't matter for our discussion purposes how broad, but I am just going to say a 10 mile radius. And if we are working within that circle and we have contained the livestock within that circle, then if you are not going to euthanize the animals, but vaccinate them, there will be an infectious spreading period of time until the vaccine might begin to contain it. What happens to the animals that are infected? Can you ever get them cleaned up where they can go to market? Do you allow the infected animals to go to market?

Dr. HILL. Yes, the adult animals will recover. With pigs, your suckling pigs, small pigs are probably more severely affected and mortality is going to be higher in those pigs. But the adult animals, any finishing pigs, for example, most of those would recover and being as it is not a food safety issue, could go to market.

Mr. KING. I know that we have done that in the past, like pseudo-rabies, for example, can go to market safely. What about livestock identification traceability? How much of a factor is that in addressing this?

Dr. HILL. Well, I can speak for the pork industry. We now have identification of sows, mandatory identification of sows going to slaughter, and we can identify our slaughter pigs by batching systems that are very effective. So we do have a good identification program in the swine industry, and I will let my friends in the cattle and sheep industry speak for themselves.

Mr. KING. I am about to ask him, but first I want to follow up on this. From the moment that you might recognize a disease and issue an order to quarantine that radius we talked about, let's say a 10 mile radius, how long does it take before that quarantine order could be effective? And then I am going to ask you how far has some of that livestock been hauled in that period of time?

Dr. HILL. Well, I will answer your last part of your question first. That is whole rub on this thing. We import a lot of pigs into Iowa, as you well know. If we had a shipment of pigs that came from North Carolina, for example, or out of Canada, they can be in transit for 24 hours. They could spread virus all the way across the United States. The first part of your question again?

Mr. KING. Was how long does it take to implement a quarantine order? How long does it take for the information to get out? If you say we are going to stop the transport of pigs as quickly as we can, how long would it be before we can expect that can happen?

Dr. HILL. Well, every situation is going to be different, and that is probably a question we need to ask APHIS.

Mr. KING. Yes.

Dr. HILL. But with the state health officers and the Federal people, it would be fairly quick, as we had with high path AI. And I will just mention, Dr. Roth talked about how to get rid of these animals. That was one of the biggest problems in Iowa and Minnesota that we had was how to dispose of these birds.

Mr. KING. Indeed, and that is a bigger question, of course, with livestock, and I wanted to get to that. But I would like to direct a question over to Dr. Sjeklocha.

The question to traceability that I asked Dr. Hill, what about traceability of cattle, and what is our capability, and how much does that help us address a disease outbreak?

Dr. SJEKLOCHA. At this point, I would say traceability of cattle: first, traceability of cattle would be helpful. It is not widely followed. There is not a real good system ever since the eradication program went away. There are some people that do have source and age verified cattle in their feedyards. Those are usually producers, cow/calf producers that want to, for instance, track their carcass data all the way to the slaughter plant, that sort of thing.

There isn't a good traceability system in place right now. I would say at our place, we probably receive cattle from ten different states just last week, so yes, it would be a big issue.

Mr. KING. Let me just submit that when the industry is ready, I have a good framework to look at for a traceability bill that a lot of the industries looked at and agreed with. I don't intend to move it until the industry is ready, but when you are, let's talk.

I appreciate the testimony of all the witnesses, and I yield back the balance of my time.

Mrs. HARTZLER. Very good. Now we go to someone who certainly knows this, a veterinarian from Florida, Mr. Yoho.

Mr. YOHO. Thank you, Madam Chair. I appreciate you all being here, and I can relate real well with what you are talking about. I just want to express how thankful I am that you are here bringing this up as the importance of it, how it would affect this market. The billions of dollars that it would cost production here, the food supply here, plus our export markets. It would be hard to really comprehend or tabulate that. It would be in the hundreds of billions of dollars from what I have seen, just on the beef side. Again, I want to thank you for this. The thing I do feel good about in asking fellow veterinarians is knowing how rapidly we respond with the diagnostics, getting that word out, reporting that, and that is imperative that we let all of our associations know that, and then on the other side is to make sure that countries that have active cases, they don't come in here. Because as you brought up, Dr. Hill, did you bring up about the BSE, how that one case that happened—or you did over there, Dr. Sjeklocha, how you brought up that one case from 2003 and how it cut down \$2 billion worth of exports, which that was one case. And so we can imagine the detrimental effect this would have. And so I feel good that we would jump on the quarantine. The circle would be there. We would vaccinate on the perimeter of that first, I would think, and then follow up.

Mr. Parker, you are with Merial, correct? What is the turnaround time if you had the specific serotype diagnosed, what is the

turnaround time from diagnosis, starting production, and getting it out in the vaccine form? Did you say 4 days for 2½ million doses?

Mr. PARKER. I am sorry?

Mr. YOHO. Did you say 4 days for 2½ million doses?

Mr. PARKER. Yes, sir. Once we receive official notification of a confirmation of diagnosis from the USDA, that starts the process. We are prepared to begin the gearing up to make our production facilities available to receive, as in today's situation, they would need to take that antigen that is in Plum Island, send it over to us in England or in France, and while that is in transit, we are preparing our abilities to convert that antigen into—

Mr. YOHO. Are there any restrictions on that new serovar or one you haven't used? Is it already FDA approved? Does it have to go through all the regulatory hoops and that, or is it ready to go in 4 days?

Mr. PARKER. Not at this time. Anything that is in the North America Bank is up to the point of registration, so that there is the willingness of the USDA to accept that, because we have demonstrated with our outline of production, as with approved vaccines here in the United States—

Mr. YOHO. Okay.

Mr. PARKER. We have gone up just short of the point of approval.

We can convert. Once we receive it in our facility, we can convert that antigen within 4 days to finished vaccine.

Mr. YOHO. And so we have those banks and we have 14 serovars here that we can—or the antigens stored that we could go into and find out pretty quick as soon as diagnostics are done, start producing that, and if it is a serovar that is in another country, we can bring that over here? There are no restrictions as far as you know?

Mr. PARKER. Well if it is not in the bank and we do not have the strain, then we have to adapt to that strain to a vaccine master seed. So that is a little bit longer process, but anything in the bank, we have the ability to turn that around within that 4 day time period, once we receive it.

Mr. YOHO. All right, and then on the new technology with the DNA recombinant vaccines, and I know we are looking at the leaderless ones, which in my understanding, that would be almost like a multivalent type of vaccine, is that correct?

Mr. PARKER. Jim, do you know?

Dr. ROTH. You have to make multiple monovalent vaccines, and then combine them with that leaderless. There is also a human adenovirus 5 vectored vaccine, too, and those are one strain at a time also.

Mr. YOHO. I was over at the NSF and we were talking to the researchers over there, and they are developing a monovalent influenza vaccine that they are taking a glycoprotein out for the cell wall, and it was for all strains of influenza and that is cutting edge. And if that is where we need to go or if that is possible with this type of infection, this type of viral infection, if that is possible, that is something we need to put the R&D in and make sure that is readily available.

Mr. PARKER. Yes, sir, Congressman, as far as I am aware right now, there is not that universal vector platform for new vaccines;

however, that does not mean that there is not work being done in that area. There is plenty of effort within many company's R&D effort to look at the most optimal solution.

Mr. YOHO. All right, and then just one last question. I know FMD is the one we are most concerned about right now, but we have African swine fever and all the ones we haven't thought about coming here. I hope the research and development is being done on that, and I would like to see a private-public partnership done in that so that we are ready, that we are never set with a national food security crisis in this county.

So I appreciate your time here, and I appreciate your efforts in bringing this to our attention. Thank you.

Mrs. HARTZLER. I thank the gentleman.

Now we have the gentleman from Mississippi, Representative Kelly.

Mr. KELLY. And this first question, Mr. Parker, is directed to you, and you probably have answered this. I am just trying to get it clear in my mind. If you have the antigen, 4 days until you can get the vaccine, is that correct?

Mr. PARKER. I am sorry, repeat that?

Mr. KELLY. If you have the antigen available, it is 4 days until you have an effective vaccine that is available to start?

Mr. PARKER. Once we receive it back from USDA, then we can turn it around for delivery back to the U.S. within 4 days.

Mr. KELLY. Okay, and if you don't have an adequate supply of antigen, then how long does it take to go, I guess, from scratch to a vaccine, if you know the strain?

Mr. PARKER. To characterize the strain and develop a new master seed, I would have to check with my industrial ops folks. I can't answer that specifically, but it is an extended period of time.

Mr. KELLY. You are not talking days, you are talking at least weeks?

Mr. PARKER. Yes, sir. Yes.

Mr. KELLY. Okay, and then the other question, and this is for anybody on the panel, but probably Mr. Parker again, you are probably going to be in a better position to answer this. When you are counting the number of doses that you have on hand or the antigen that you have on hand, is that for the initial dose or is that for both doses that an animal will have to have?

Mr. PARKER. What is in the bank now, that would be up to USDA and the industry to determine what the dose regimen is, and in general, swine typically require two doses. There are some situations for ruminants where you can get away with a single dose, but then again, that is going to be up to APHIS and working with the industry to make that determination.

Mr. KELLY. And again, this is to anyone on the panel. One of the things that concerns me most is kind of like with the avian flu. It is not so much the trucks that go across this country carrying animals, okay, domesticated animals, but the actual wildlife, the feral swine and the deer. There are more deer in Mississippi than there are people, and there are a lot of other states that are like that. What is our plan to deal with those which; first, aren't as easy to depopulate. If they were, there wouldn't be any deer or wild swine in Mississippi, because the feral swine are very destructive in our

state. So what is the plan to keep those from spreading and to keep them in those concentric circles?

Dr. ROTH. That would be very difficult to do, as you can imagine. The deer and feral swine, especially the feral swine, move pretty freely, and they can be infected with the virus and they can also transmit it just as fomites on their feet and so forth. So movement of wild animals between herds of livestock would be a real risk, and pretty hard to stop.

Mr. KELLY. And then again, this is probably something I should understand, in what way is it passed from one animal to another? Is it airborne, is it through mites or mosquitoes or ticks? In what ways can it be transmitted from one animal to another?

Dr. ROTH. So it's not vector-borne through ticks and mosquitoes and that kind of thing. It is mostly direct contact, and animals that are infected shed high concentration of virus in their saliva and feces, so anything they contaminate that another animal touches, they can pick it up.

Mr. KELLY. And then this is my final question, and it is to anyone on the panel. The avian flu hit Minnesota and some other states pretty hard. There was a lot of cross talk between the spring and the fall when we thought it would come to Mississippi or to other southern states with the migratory fowl and those things. So I guess my question is have you studied the outbreak of the avian flu, and what are the lessons learned from the way they handled either well or poorly that we can use for this similar foot-and-mouth disease, or for any other disease that can be transmitted through our livestock?

Dr. ROTH. We have also worked on the secure egg and turkey supply plans, and what we learned is that the biosecurity that was adequate for the normal diseases in poultry was not adequate for high-path avian influenza. Biosecurity is expensive and inconvenient, and we would pretty quickly find that the biosecurity we have in the cattle industry isn't adequate for foot-and-mouth disease. And to implement enough biosecurity in the cattle industry would be pretty difficult for animals like yours.

Dr. SJEKLOCHA. It would be a monumental task to tackle biosecurity in the beef industry.

Dr. HILL. If you still have some time, I would like to go back to your question about vaccines.

Mr. KELLY. Absolutely.

Dr. HILL. Okay. So what Mr. Parker was talking about was developing this vaccine in 4 days, but he's talking about developing 2.5 million doses. We need 40 million doses, okay. And the other thing is in regards to the question about different DNA types of vaccines, yes, we are working on those. The industry is working on them. Do we need more money and research to do that? Yes, but those are down the road type things. Those are not vaccines that are going to be available next year or the next year, or maybe within 5 years. So when we are talking about this vaccine bank, we are talking about doing something now, rather than waiting for one of these newer vaccines. Thank you.

Mr. KELLY. I thank all you gentlemen and lady for your expertise and you coming here to help us with this, and your preparation, and Madam Chair, I yield back.

Mrs. HARTZLER. You have good questions. I want to build on some of your questions there.

So how long does the virus last, if it is transmitted through saliva and feces?

Dr. ROTH. So an infected animal will shed virus for up to a week or so, and if that virus is frozen in the winter, it will last a very long time. In the middle of summer with a sunny day, it doesn't last very long at all. So it depends on the climatic conditions.

Mrs. HARTZLER. Okay, and we have talked about the problem with disposal. So how would that typically—if you did do that—I know you said we are not going to try to do that anymore, but would it be burying them or incinerating them, or what types of things?

Dr. HILL. Well, we wish we had the answer to that question, because we did not have the answer to that question with high-path AI. I mean, there were all kinds of problems. Some people didn't want to bury them on the farms. Some of them were taken in closed trucks down the interstate to a landfill. I mean, there was all kinds of different problems. And that is one of the issues that APHIS has addressed is that even if we could kill all these animals, how do we dispose of them? It is a monumental problem. That is one of the reasons they decided that vaccinating and living for another day is the plan of choice.

Mrs. HARTZLER. Okay. I wanted to build on what you said earlier, Dr. Wolf. I thought that was very insightful about the need for in addition to the vaccines, to have a vaccine preparedness plan that includes making sure you have enough needles and ear tags, and those type of things. So first of all, do we have a vaccine preparedness plan? Is there one?

Dr. WOLF. There is a plan in place that Dr. Roth has with him. It is extremely well-written and I encourage all of you to go to the Iowa State site and read that, and then APHIS also has a published plan. But the challenge is, from my experience, for instance, when we had bovine TB in northwest Minnesota, when we were ready to enact the TB control plan, we found producers didn't have handling facilities, for example, and so going back to where we are in today's economy, if all of a sudden we order, whether it is 2½, 10, or 40 million needles, I don't think that our suppliers would have that on hand.

Mrs. HARTZLER. So is that part of the plan to have those in place, in addition to the need for the vaccine itself? Is that what Congress potentially—and industry, because you all are going to support chipping in—but anyway, is that all something that we would fund? Have enough vaccine have enough needles, have enough ear tags, all of that, or not? That is just a side issue, and by the way, we need these other things.

Dr. ROTH. The National Veterinary Stockpile is stockpiling needles and syringes and personal protective equipment, and those sorts of things. Their funding has not been adequate to have a really robust stockpile, but they are stockpiling a lot of equipment that might be needed. They haven't had the funding to stockpile the vaccine yet.

Mrs. HARTZLER. Okay, and my last question, and I know Mr. Yoho has a question, so back to my statement earlier that I am on

the Armed Services Committee as well. I am very concerned about terrorism and agro-terrorism is certainly involved in that. That is why I was trying to get to how is it spread. I know this has been talked about. Some are local meetings that have been held, don't want to talk too much to give people ideas, but how concerned are you of this virus being used potentially as a terrorism threat to hurt our economy, just like terrorists hijacked airplanes and impacted Wall Street, our whole economy with that type of attack. If they were to attack our livestock industry in this way, it would have a huge detrimental impact on our country. And so how concerned, let's say from a scale of 1 to 10, 10 being this is extreme threat to 0, probably not. How concerned are you of this potentially as a terrorism threat?

Dr. HILL. Twelve.

Mrs. HARTZLER. Wow. Wow.

Dr. WOLF. I would agree.

Mr. PARKER. I think most terrorists are interested in killing people, but yes, it is a huge concern. I would put it up there maybe not at 12, but definitely at 10.

Mrs. HARTZLER. Okay. I think that adds impetus to the importance of this, not just from important to agriculture, but then to our entire economy as well.

All right, Mr. Yoho?

Mr. YOHIO. Thank you, Madam Chair, and again, I appreciate you guys being here.

That is something I would like to talk to you more about, but I would rather not talk about it on the record. You were talking about the cost of this, and I want to bring up a couple things. The RFID identification tags, I have been kind of reluctant with my clients, because you just hate to have a mandate or force them into something. But on something like this, when we see the potential and the potential damage that it could do, it is something as you go back to your industries, talk about that and the hog industry just seems to have a lot better tracking system, it seems like the way you manage. I have complete confidence that we can contain, get our circles in there with modern husbandry practices and get the vaccines out there. We would have a little lag in there. The thing we can't control is the wild movement of animals, and I know in Florida there is a feral hog behind every pine tree or oak tree, and it is hard to contain all of those. And so when we are talking about the cost, and the 2008 Farm Bill established a program of plant, pest, and disease management and disaster prevention. Mandatory funding has been used very effectively through the program for the benefit of the specialty crops. To what extent has each of your organizations discussed the possibility of creating a similar program within the Animal Health Protection Act, and should it be mandatory or would it be voluntarily through your associations, and put into a trust fund for R&D and let it grow, at some point the best case scenario is we don't have to use it for a long, long time, and have it becoming self-perpetuating possibly. What are your thoughts on that?

Dr. HILL. Are you referring to the Commodity Credit Corporation? Is that what you are talking about?

Mr. YOHO. The Animal Health Protection Act from the 2008 Farm Bill.

Dr. HILL. Yes.

Mr. YOHO. With plant, pest, and disease management and disaster prevention, there was a mandatory funding used in that to benefit the specialty crops for research and development.

Dr. HILL. We would support that, at least in the swine industry, and it needs to be mandatory, not just advisory.

Mr. YOHO. That is right.

Dr. HILL. And so that money possibly could come from the Commodity Credit Corporation.

Mr. YOHO. Well, that is something. If you take it back because nobody wants to put more money into a program like that, but the penny a day doubled theory every day, in a months' time or 31 days, a penny if you double it every day becomes \$10.3 million. And if you can come up with some minute formula and just put a little bit in there, but we're doing it on every head that gets sold on all livestock, not that I am mandating or recommending a mandate from the Federal Government, because we need less of those in my opinion, but to be prepared for that day when it comes, and hopefully we don't ever see it. But it is better to be prepared for that, because it is hard to play catch up, especially in the situation this country is in now economically. And so if we can have that lead-in from industry and say, "You know what, we would like to do this, and it could be cross species or animal disciplines." Just more food for thought, than even an answer, but if you have any other different thoughts, let us know.

Dr. SJEKLOCHA. I think we would be interested in any and all options. We are certainly open to discuss any of that.

Mr. YOHO. Yes. Worst thing is when you go to a farm and you pull out, you see an animal and you don't have the right antibiotic or the right vaccine there, and it is like well, didn't do much good here. So we don't want to be caught short like that. I appreciate your time. Go ahead.

Mr. PARKER. Congressman, just one follow up on some of the premise behind your question. It is not just a question of the money to do this. There is a time element.

Mr. YOHO. Yes.

Mr. PARKER. As I stated in my testimony, it is not only my company, but any other conventional manufacturer of FMD vaccine today. We have no excess capacity. We have to build to meet a demand that is the size of the United States. That would be larger than anything that we consider, so as of today, there is no excess industrial capacity for FMD vaccine manufacturing. If we have an outbreak today, it may be 2 to 3 years before we can get you the vaccine that you need to address this.

Mr. YOHO. See, I didn't know that. I mean, that is just coming out now. Is it almost like something the Federal Government maybe ought to have on hand, ready to go, ready to produce something?

Mr. PARKER. That is the vaccine bank. That is in a coordinated effort in partnership with the government, we can work towards something like this, but we need to know what we need to shoot at. Right now, we have not been asked the official question, so we

don't know what to shoot at, but if we are asked the question, we can work with the government to achieve some notion of optimization.

Mr. YOHO. I can't speak for the Chairman, but I would recommend you send those recommendations up here to this Committee, and I am sure he would be happy to look at those.

And with that, I yield back, and thank you for your time.

Mr. PARKER. Thank you.

The CHAIRMAN [presiding.] Well, I want to thank everybody for attending the hearing. I am sorry that I missed a good portion of it. We had a Transportation and Infrastructure FAA markup, and had about six amendments to vote on that took a little while. But I want to thank all the Members that came, and their participation. I want to thank all the witnesses for your time and your expertise. I understand that a lot of the questions that I had have already been asked, so I am not going to go into all of that. I will catch up with it in the record myself.

But I want to thank each of you again for your time and your interest in this. I think this is a very, very, very important issue to stay out in front of, to stay ahead of the curve on, and I really appreciate your time and attention and working with the Committee to do everything we can to make sure that we don't have an issue in this country.

Under the rules of the Committee, the record of today's hearing will remain open for 10 calendar days to receive additional material and supplementary written responses from the witnesses to any questions posed by a Member. This hearing of the Subcommittee on Livestock and Foreign Agriculture of the Committee on Agriculture is now adjourned.

[Whereupon, at 3:21 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUPPLEMENTARY MATERIAL SUBMITTED BY DAVID B. SJEKLOCHA, D.V.M.,
OPERATIONS MANAGER OF ANIMAL HEALTH & WELFARE, CATTLE EMPIRE LLC,
SATANTA, KS; ON BEHALF OF NATIONAL CATTLEMAN'S BEEF ASSOCIATION

Responses to Questions Raised During the Hearing

Question 1. In a recent briefing with USDA, they mentioned public-private partnerships as a possible way to address the funding of a vaccine stockpile. Has your industry thought about what that would look like and what you could support?

Answer. The beef industry remains committed to identifying solutions to strengthen and improve our country's Foot-and-Mouth disease (FMD) preparedness plans. Together with the National Pork Board and the National Milk Producers Federation, the National Cattlemen's Beef Association financed a white paper, written by Dr. Jim Roth at Iowa State University, to explore the FMD vaccine supply for emergency use and surge capacity in the United States. The current FMD vaccine supply for the United States was found to be inadequate for control of a type 3 or larger FMD outbreak. The white paper estimated a financial need of \$150 million/year for 5 years to acquire the necessary vaccine antigen concentrates (VAC) for the most common FMD serotypes viewed as potential threats to the United States. In a stakeholder meeting with representatives from USDA-APHIS, held in September 2014, discussions for financing the needed FMD vaccine included proposals for developing funds through the commodity check-off programs or through user fee systems. Unfortunately, the Beef Promotion and Research Order (1986) does not authorize for Beef Check-off funds to be used to directly finance a national FMD vaccine program. Furthermore, the user fee vehicle, upon further discussion at the meeting, was believed by many in attendance to be inadequate for producing the necessary funding in a timely manner. It is our understanding that in order to secure the necessary FMD vaccine, working within the current market supplies, a significant financial commitment would need to be made by the United States Government to a vaccine manufacturer to produce the FMD vaccine product and most likely, a new facility for vaccine production would be required from the vaccine sponsor to meet the production demands. With the knowledge that significant and readily available funding would be needed, the animal agriculture industry seeks to increase Congressional awareness for FMD vaccine supply problems and requests consideration for ways to increase funding at USDA-APHIS to meet the agency mission to protect animal health.

Question 2. What are some of the activities that the livestock industry has been involved with to prepare for the event of an FMD outbreak? Any focus on consumers or business continuity?

Answer. The beef cattle industry has been involved in a variety of FMD preparedness activities. The beef industry quality assurance program, Beef Quality Assurance (BQA), contains biosecurity components that are focused at the individual farm level with discussions for prevention and control of possible disease agents, biocontainment, and managed movements. Individual farms are encouraged to develop biosecurity plans. The beef industry is currently working with governmental and academic partners to develop a secure food supply plan for the beef cattle industry in the event of an FMD outbreak. The Secure Beef Supply plan would provide managed movements for non-infected animals and products in an FMD outbreak situation and would function to maintain continuity of business for producers and to ensure a safe food supply for consumers. Collaboratively, the beef industry works with other commodity groups and state and Federal animal health officials to develop FMD preparedness action and communication plans. The industry has been involved in a variety of FMD preparedness drills which occur in the various states. Additionally, the beef industry is actively involved with the Cross Species FMD Communications group, whose goals are to create a unified FMD crisis response plan; share FMD messaging; and form government partnerships for a coordinated FMD response. The group works to prevent supply disruptions to consumers and to ensure consumer confidence in meat and milk products during an FMD outbreak. Finally, the Cross Species FMD Communications group maintains an informational website, www.FootandMouthDiseaseInfo.org.

Question 3. FMD presents a great economic threat to U.S. livestock producers and is viewed as the most concerning transboundary disease in the world. If an FMD outbreak were to occur in the United States, what would be the result with regards to our export markets?

Answer. FMD presents a great economic threat to U.S. livestock producers and is viewed as the most concerning transboundary disease in the world. An FMD outbreak in the United States would result in the immediate closure of most, if not all, of our foreign export markets. Commodity group exports for 2014 for beef were

at \$7.1 billion, for pork at \$6.7 billion, and for dairy at \$7.1 billion. To put this into perspective, we need to only look at the economic impact of a single case of bovine spongiform encephalopathy (BSE) found in a Canadian-born cow located in Washington state on December 23, 2003. As a result of a single case of BSE, we saw U.S. beef exports decline by 2 billion pounds from 2003 to 2004. It took 8 years for U.S. beef exports to get back to pre-December 2003 levels. Over a decade later, we still do not have access to several critical markets, such as China, nor do we have full access to every country we were trading with prior to December 2003. It's not just the international trade impact which concerns us. In addition, we expect to see significant economic impact to U.S. beef producers due to depopulation, restrictions on cattle movements, and a potential shutdown of overall cattle trade in the affected regions.

Question 4. USDA has worked with some industries to ensure the flow of products and animals in the event of an animal disease outbreak. Can you discuss those efforts and at what stage your preparedness plan is with USDA?

Answer. The Secure Beef Supply Plan is intended to identify and address issues to better prepare government and industry to enable business continuity for the beef industry in the event of a Foot-and-Mouth Disease outbreak in the United States. A component of the Secure Food Supply Plans, the Secure Beef Supply Plan is currently under development by a number of partners who are being led by the Center for Food Security and Public Health at Iowa State University. Initial work on the Secure Beef Supply plan is focused on the feedyard sector of the beef industry as well as the transporters and processors. Later, work will take place to include planning for the cow/calf sector, dairy beef and the stockers/backgrounders. The current work in the feedyard sector is being divided among six working groups: biosecurity, surveillance, communications, data management, managed movements, and continuity of business for infected feedyards. It is important to remember that during an FMD outbreak in the United States, it will not be business as usual for cattle producers. In addition to meeting specific biosecurity performance standards, beef cattle operations within a FMD Control Area will need to conduct daily surveillance of cattle and keep records of all observations. Since FMD has not occurred in the United States since 1929, it will be important to train cattlemen to know what clinical signs to look for in examining their animals. Early recognition of FMD will be critical to preventing disease spread and limiting the negative impact on cattle health and performance. One goal of the Secure Beef Supply Plan for the feeding and packer/processing sectors is to allow feedlots with cattle with no signs of clinical FMD to be able to receive a permit to move finished cattle to processing.

Question 5. On a scale of 1 to 10 with 10 being the greatest risk, what does the industry feel is the risk for the use of FMD virus as a weapon of bioterrorism?

Answer. The beef industry believes that FMD virus could easily be used by terrorists against this country and would rank the bioterrorism risk as being the greatest at 10. Although FMD has no real public health consequences, the virus does carry an extreme potential to create monumental economic and animal health consequences that could be devastating to the United States. FMD virus is viewed by USDA as a Select Agent and it is restricted from being present on the U.S. mainland. FMD virus is highly contagious among cloven-hoofed livestock and some wild-life species and able to persist in the environment for significant periods of time as well as being able to be disseminated for long distances by wind.

Question 6. Where is the industry with regard to animal identification and traceability in the event of an FMD outbreak?

Answer. In the feedyard sector of the beef cattle industry, where the highest concentration and greatest numbers of animals exist in a single location, there is a good system of animal identification in place. Cattle 18 months of age and older are moving interstate under the guidance and movement regulations for animal disease traceability as outlined in phase 1 of the USDA-APHIS ADT rule. Cattle under 18 months of age will come under phase 2 of the ADT rule when it is developed and finalized by APHIS.

SUBMITTED LETTER BY EXECUTIVE COMMITTEE, AMERICAN ASSOCIATION OF
VETERINARY LABORATORY DIAGNOSTICIANS

February 19, 2016

Hon. DAVID ROUZER,
Chairman,
Subcommittee on Livestock and Foreign Agriculture,
House Committee on Agriculture,

Washington, D.C.

Dear Congressman Rouzer,

We would like to comment on testimony before your Committee on Thursday February 11, 2016 regarding Foot-and-Mouth Disease (FMD). We fully agree with comments on the importance of the National Veterinary Stockpile and the urgent need to increase the amount of vaccine for FMD. Unfortunately, none of the witnesses commented on the importance of early detection of FMD in minimizing the dissemination and impact of FMD. Early detection means less spread and less need for vaccine. The most important and effective tool we have in the United States for the early detection of FMD and other foreign animal diseases is the National Animal Health Laboratory Network (NAHLN). The NAHLN, composed of Federal, university, and state veterinary diagnostic laboratories, is an established surveillance and emergency response system that provides critical and ongoing resources for laboratory testing, surveillance, information management including data analysis and sharing, quality assurance and the development and validation of new tests. Member labs of the NAHLN receive thousands of samples on a daily basis and perform early analysis and testing for a variety of animal diseases and therefore are the most likely point of early identification if FMD entered the U.S.

In addition to vaccination, another important aspect of FMD control and recovery will be the need to differentiate animals infected with natural virus *versus* those that have been vaccinated. Current serum based tests cannot make this differentiation. However, there has been early testing within the NAHLN of methods that will help in Differentiating Infected *versus* Vaccinated Animals (DIVA methods). The full development and validation of these methods will be vital in recovering from an FMD incursion.

The NAHLN played a critical role during the 2015 Highly Pathogenic Avian Influenza (HPAI) outbreak that devastated the U.S. poultry industry. NAHLN laboratories operated 24/7 to test poultry samples which provided results needed to allow for rapid depopulation of infected flocks, surveillance testing of samples from surrounding areas to halt [the] spread of the virus and testing to establish freedom from disease to allow continuity of business during the outbreak and repopulation of farms and resumption of trade after the outbreak. However, in some states the NAHLN was stretched to its maximum and with HPAI the labs were only testing poultry. With FMD we will be dealing with an agent that is easily transmitted through the air and which infects all cloven hoofed livestock—some of which can serve as silent amplifiers of the virus.

When the NAHLN concept was first developed (2004) it was calculated that annual Federal funding of \$30M would be required to maintain this surveillance network. The network has never been funded at this level. The American Association of Veterinary Laboratory Diagnosticians (AAVLD) has been advocating for full funding of this network for several years. Authorization for funding of the NAHLN was included in the 2014 Farm Bill but appropriation of the full amount has not been forthcoming. More funding for a stronger NAHLN will be critical to the success of an effective detection and response to introduction of FMD. Current funding for NAHLN is simply not adequate to assure FMD will be caught early before it spreads broadly in U.S. livestock and wildlife. We respectfully request that the Members of your Committee help secure full funding (\$30M) of the NAHLN.

Respectfully,

Executive Committee of the AAVLD

SUBMITTED STATEMENT BY KANSAS DEPARTMENT OF AGRICULTURE

The Kansas Department of Agriculture submits the following statement to the U.S. House Subcommittee on Livestock and Foreign Agriculture for its February 11, 2016, hearing on foot-and-mouth disease (FMD) preparedness. This statement, submitted on behalf of Secretary Jackie McClaskey on February 10, 2016, is for consideration by the Subcommittee and for inclusion in the printed record of the hearing.

Introduction

The Kansas Department of Agriculture, the nation's oldest department of agriculture, is committed to a balanced approach of serving the entire agricultural industry and providing an environment that enhances and encourages economic growth, advocating for and promoting agriculture, while helping ensure a safe food supply and protecting natural resources, and human and animal health. This is a charge we take seriously, as agriculture is the largest industry, employer and eco-

conomic driver in Kansas, accounting for 43 percent of the state's total economy and employing 12 percent of the entire workforce.

Within agriculture, the beef cattle industry is the largest sector, with 6.25 million head of cattle and calves on ranches and in feedyards as of January 1, 2016, an increase of six percent from a year ago. In 2014, cattle generated \$7.77 billion in cash receipts. Further, our state's dairy industry has been one of the fastest growing regions in the nation, and we are ranked tenth in the nation in hog production. Kansas is also among the nation's top states for red meat production, processing more than 5 billion pounds of red meat in 2014 for an estimated value of \$9.15 billion. Finally, in addition to being a leader in raising livestock and processing meat, Kansas, along with our neighbors in Missouri, is located within the Kansas City Animal Health Corridor, the single largest concentration of animal health and nutrition companies in the world. In fact, companies within the Animal Health Corridor represent 75 percent, or \$19 billion, in worldwide animal health sales.

FAD Preparedness

It is no stretch to say that the health of the Kansas economy is dependent upon a healthy and thriving livestock industry. As such, the Kansas Department of Agriculture is committed to working alongside our partners in the livestock industry and within the Federal Government, other state agencies and local entities to be as prepared as possible to respond to animal health emergencies, including foreign animal diseases like foot-and-mouth disease (FMD). Over the course of the past 15 years, the department has put an increased focus on FAD preparedness and strives to be the best prepared state in the nation when it comes to an FAD response.

This is not a goal arrived at overnight. In the aftermath of the September 11, 2001, terrorist attacks and the FMD outbreak in the United Kingdom, the department, in cooperation with the Kansas Division of Emergency Management and other state agencies, developed the first state level food and agriculture response plan, which recognized the uniqueness of food and agriculture incidents as compared to other "traditional Emergency Support Function 11 Agriculture and Natural Resource" (ESF 11) emergencies.

While an ESF 11 Function incident focuses on response to natural disasters, the root cause of the emergency in a food and agriculture incident is food contamination, plant pests and diseases, and livestock diseases.

At that time, the department also joined with other states to form the Multi-State Partnership for Security and Agriculture. Between 2001 and 2008, the department added a Homeland Security Specialist to the Office of the Secretary and worked to provide Incident Command System (ICS) training for key staff at both the Department of Animal Health and the Department of Agriculture. The department's plan recognizes that food and agricultural emergency situations are highly complex, with jurisdictional issues affecting private industry as well as local, state and Federal entities, and that most food and agricultural incidents are interstate issues.

Through our state's work on FAD preparedness, especially in our efforts working with neighboring states, we know that, from the state's perspective, we will be on the front lines carrying out the response plan and that each state's plan must fit their respective industry needs. There is no doubt that there will be policy challenges, with regard to specific authorities and actions taken to stop the spread of FMD or other animal diseases, that will have to be addressed state by state. However, it is also incumbent upon states to take their FAD preparedness responsibilities seriously and to do their part.

FAD Exercises

In Kansas, we recognize even the best and most comprehensive response plan is without use unless that plan is regularly exercised and practiced. While the words on paper may sound good, if we are not able to stop the spread of the disease and return to normal business operations as quickly as possible, we have not accomplished our goal of providing total support to the industry and protecting animal health. Further, we also recognize that a response to an FMD outbreak would be the most challenging, given the highly contagious nature of the disease, its ability to spread rapidly through susceptible species, and the complex challenges that could arise with feed and food scenarios as well as international trade implications. This is why each time the department exercises our plan, we focus on an FMD response, and we include as many of our partners outside the department as possible, including farmers and ranchers, other state agencies, local partners and the Federal Government.

Beyond the highly complex nature of an FMD response, we also know that an introduction of FMD in the United States would be economically devastating to the livestock industry. According to a recent study published in the *Journal of Agricul-*

tural and Applied Economics about the economic impact of FMD vaccination strategies, without an emergency vaccination strategy, producer and consumer losses of an FMD outbreak in the Midwestern United States would likely approach \$188 billion, and government costs would likely exceed \$11 billion. Even with a high-capacity emergency vaccination strategy together with a large vaccination zone, producer and consumer losses are projected to reach \$56 billion, and government costs could reach more than \$1 billion.

According to Kansas policy, the Animal Health Commissioner has access to any department staff necessary to response to an animal disease incident. The Commissioner can assign personnel to the Division of Animal Health until demobilized by the Commissioner. This is a policy that has been instrumental in our ability to expand our response team. Today, more than 70 department staff have attended ICS training and volunteered to serve on the response team. This is a policy model that could be replicated in other states to help build a larger response team that is prepared and trained to implement each state's plan.

Since 2009, the department has hosted three major, multi-day FMD response exercises and more than 20 smaller, tabletop-setting or regional response exercises. The first major exercise was in October 2009, and was focused on movement control at state borders as we know that this will be one of the most challenging aspects in an FMD response. This exercise included local government, four Kansas counties and three Oklahoma counties, seven state-level agencies in both Kansas and Oklahoma, the U.S. Department of Agriculture, the FBI, and industry association partners and representatives from academia. The goal was to evaluate each state's plan for a stop movement order and the communication and coordination issues related to the order, to determine resource needs, and to achieve consensus from border states on the most practical and effective method for routing livestock-related transports during an FMD outbreak. As a direct result of this exercise, Kansas has worked with our neighboring states to establish clear plans for which state has authority over checkpoints at each state and Federal highway that crosses the state line in order to maximize the use of limited resources.

Between 2009 and the next major exercise in 2013, not only did Kansas elect a new governor, but the Department of Animal Health merged with the Kansas Department of Agriculture, and the Kansas Department of Agriculture moved its headquarters from Topeka to its current location in Manhattan. During this time, we also developed a 5 year strategic plan to improve our ability to respond to animal disease emergencies, with specific goals related to stakeholder engagement, business continuity, information management, response readiness, traceability and communications. We also made changes to the response plan based on learnings in the 2009 exercise regarding the permit management system, and the delivery and sharing of data information from the border checkpoints to the Incident Command Post, from the Incident Command Post to the surveillance branch in a timely fashion, and sharing information with border states.

The 2013 exercise, also based on an outbreak of FMD where the index case was in the southeastern United States, was a 2 day exercise with more than 250 participants and focused on practicing the new permit management system with specific objectives related to the resource needs, the development and communication of movement control orders, the use of phone banks to respond to public inquiries, and more. This exercise also fell during the 2013 Federal Government shutdown. Rather than postpone the exercise until that situation was resolved, we implemented our plan without immediate Federal assistance. While we learned there will be specific information requests and declaration requests states will need during an FMD response, we realized we were able to implement our plan without a lot of Federal personnel assisting.

In 2014, two regional exercises were held with groups of Kansas counties and focused in the local response. In December 2015, the department hosted its largest exercises to date, a 4 day functional FMD response exercise. Similar to previous exercises, participants included industry, local emergency responders, multiple state agencies and the Federal Government. From that exercise, we know that challenges remain regarding the stop movement of susceptible species. We are currently in the process of finalizing the after action response plan and identifying key learnings, including challenges and successes, that will drive changes and updates to the Kansas response plan. We will have an opportunity to exercise those changes in December 2016 at our next scheduled FMD exercises.

Exercises like those we've undertaken in Kansas require time, financial resources and cooperation among many different stakeholders. But the lessons we have learned in Kansas from regularly exercising our plan has resulted in a better plan and has made us better prepared to implement our response. It has also helped us

identify resource, logistic and policy issues, both intrastate and interstate, that need resolved.

Resource Challenges

Whether it was during an exercise setting or during the state's actual response to highly pathogenic avian influenza in spring 2015, a key challenge we have continually identified is human resources. We know that there will simply not be enough local, state and Federal personnel to adequately carry out the response plan. This is a challenge Kansas is currently working to address.

Multiple states throughout the country and even USDA have veterinary volunteer response corps, which can be activated to assist with an animal disease outbreak. It is without doubt that there will be a need for additional veterinary support, but we also know there will be a need for case specialists, appraisers, manual laborers, information technology specialists, communications professionals and more. We will need assistance with data entry and record management, behavioral health specialists, and other trained volunteers to adequately carry out a response. That is why Kansas is working to develop a Kansas Agricultural Emergency Response Corps, which will recruit volunteers with key skills and training necessary in a response. We will provide them with ICS training and education regarding the Kansas plan. Then, in the event of an animal disease outbreak, we will activate the volunteer corps to work alongside our response team to carry out the plan.

Our goal is to begin recruitment and training of Response Corps volunteers later this year and include them in the December 2016 exercises.

One factor contributing to our ability to continually improve our FAD preparedness is our effort to secure resources in the form of grants and cooperative agreements to implement our strategy. Preparedness itself takes resources and many states have not been as fortunate as Kansas to find the necessary funding to implement their own strategies. If the nation is to be prepared for FMD and other animal diseases, all states must also be prepared. FMD will not stop at the state line, and if Kansas is prepared but our border states are not, we will ultimately fail in stopping the spread of FMD and protecting our states' livestock industries.

FAD Preparedness in Kansas Feeding Sector

Kansas has a robust cattle feeding sector, with more than 2.2 million head of cattle on feed as of January 1, 2016. With the transient nature of the cattle feeding sector, with multiple loads arriving and leaving individual yards each day, FMD preparedness at the feedyard level is critical. The department, in direct collaboration with our partners in the industry, met with more than 20 individual feedyards in summer 2015 to identify strengths and challenges related to FMD preparedness at that level in the industry. Based on those meetings, we are working not only with our feedyards, but also with veterinarians who work with feedyards, to provide FMD response planning resources they can implement.

Additionally, it is our goal to base the December 2016 exercise on the cattle feeding and dairy sectors.

Conclusion

While the state-level response plan is just one element of FMD preparedness in the United States, it is and will continue to be a critical component of an overall response and recovery effort. We recognize the critical need for a viable FMD vaccination strategy in the United States and encourage all efforts in that regard. We also cannot stress enough how important our partners in the livestock industry have been and continue to be in our state's FAD preparedness efforts.

Finally, we commend the Livestock [and Foreign Agriculture] Subcommittee for holding this hearing and we will continue to work toward improving FAD preparedness efforts in Kansas.

