FTS-USDA OFFICE OF COMMUNICATION

Moderator: RJ Cabrera November 2, 2011 8:00 am CT

Verizon Coordinator: This meeting is being recorded. If you do have any objections, you may disconnect at this time. Ms. Cabrera, please go ahead.

RJ Cabrera: Thank you.

Donald Hoenig: Are we ready to go? Do you want to do that? Okay. No, go.

Kim Ogle: Good morning, everyone, and welcome to Day 2 of the Secretary Advisory Committee on Animal Health. I'd like to take a role call and check in and see who we have with us this morning. I'll just call off the names of the committee members and you can say here, okay, or not? (Max)? Okay.

Dr. (Fisher)?

Dr. (John Fischer): Here.

Kim Ogle: Dr. (Goodwin)?

Dr. (Goodwin): Here.

- Kim Ogle: Ms. (Hebb)? Dr. (Hill)?
- Dr. (Hill): Here.
- Kim Ogle: Dr. (Hoenig)?
- Dr. (Hoenig): Here.
- Kim Ogle: Mr. (Johnson)?
- Mr. (Johnson): Here.
- Kim Ogle: (Mr. Johnson)? Mr. (Kalmey) is absent, okay. Dr. (Massingill)?
- Dr. (Massingill): Here.
- Kim Ogle: Dr. (Meeker)?
- Dr. (Meeker): Here.
- Kim Ogle: Ms. (McGary)?
- (McGary): Here.
- Kim Ogle: Dr. (Parr)?
- Dr. (Parr): Here.
- Kim Ogle: Ms. (Pridgin)? She's not here. Dr. (Reed) is absent. Dr. (Rogers)?

Dr. (Rogers):	Here.
Kim Ogle:	Dr. (Stayer)?
Dr. (Stayer):	Here.
Kim Ogle:	Mr. (Stockton)? Mr. (Stockton)? And Mr. (Thomas) is absent. Let's see. Dr. (Wagstrom)?
Dr. (Wagstrom):	Here.
Kim Ogle:	Dr. (Wolf)? Okay. So I think we're missing (Vickie Hebb) and (Genell Pridgen) this morning and they are expected to join us. (Brian) will not be with us today. We do have a quorum, so we will begin the meeting.
Donald Hoenig:	Very good.
Kim Ogle:	Go ahead. First, I would like to introduce to you Dr. Clifford. He is the Deputy Administrator for Veterinary Services and he has some opening remarks for you this morning or just to say hi.
John Clifford:	Is that on?
Kim Ogle:	There you go, yes.
John Clifford:	I just wanted to welcome everybody and thank you all for your, again, for your service. I know that this has been a good group and I hear that you all had a nice, productive, long day yesterday and I appreciate that very much. So we look I look forward to seeing your comments from yesterday's meeting.

So I won't keep up or take up too much of your time. I'll be sitting in the back here for a couple of hours this morning and so, again, thank you all. Bye-bye.

Kim Ogle: Thank you, Dr. Clifford. I'd like to turn the meeting over now to Dr. Hoenig, the Chair of the committee.

Donald Hoenig: Good morning. Thanks, Kim. Yes, great work yesterday, everybody. I know it was a long day. I hope everybody had a good night. We're going to have a little bit of change of pace this morning with some presentations by Dr. Styles, who is a friend of the committee.

He has talked to us before by phone. I don't know whether everybody has met him. I think I met you in St. Paul last month. So I look forward to that and then Dr. (Rodriguez) who is here, was here yesterday too from (Plum Island) and then Tom DeLiberto from Wildlife Services, so we've got a pretty full morning.

A couple administrative things before we get started; I don't know whether we mentioned or not yesterday but I wanted to say it that the Aquatic Animal Health Subcommittee, as you know, it's been appointed in the meeting. It's going to be January 25th and 26th I believe and here in D.C.

So our committee, the full committee will have to meet after that subcommittee in order to consider their recommendations because all of their recommendations will come through this committee.

(Andy Goodwin) and I are members of that committee representing the larger committee. So that's one thing that we wanted to bring up. And (Judith McGeary) and I were just talking about at some point and probably it will be later on in the day we want to discuss how the committee can be I guess more effective in conference calls and whether those are -- how productive those are.

And I always get the impression that, at least for me, conference calls, if I'm not leading the conference call, I'm usually multitasking and I get the impression that a lot of people might be doing that, too.

And so at the same time, I think it is an opportunity for the committee to stay engaged through the year and I'm not suggesting that we not do them. I'm just looking for suggestions on how we might be more engaged or more productive. I'm not, so we're going to have some discussion of that.

So, without further adieu, unless there's any other items that come forward, I'll introduce Dr. Darrel Styles, who is with Emergency Response and Preparedness in Veterinary Services and he's going to talk to us about foot and mouth disease and the North American foot and mouth disease vaccine bank. Darrel?

Darrel Styles: Can you hear me now? Okay, great. What I'm going to discuss today is our gaps and challenges in terms of emergency response to foreign animals diseases with a special emphasis on foot and mouth disease because that one can be so economically devastating.

Veterinary Services Emergency Response capacity involves disease monitoring and surveillance, disease control and eradication, emergency response management and adequate vaccine stores for all types of foreign animal diseases. We have an expanding threat of a number of foreign animal diseases, more so than we ever have had before and this is due in large part to the increased amount of global trade in animal commodities as well as increased human traffic to and from indigenous (homes) for these diseases.

And just some -- at the top of the list here, there is a persistent threat of classical swine fever, which seems to linger throughout the world and is very close to our borders.

There is an emerging threat of African swine fever, which is diseased swine, of course, which is now spreading throughout Russia and is affecting also satellite countries of Eastern Europe. So it's virtually on Europe's doorstep at this point.

It's one of those diseases which we don't understand the dynamics. The paradigm was that it required a soft body (unintelligible) but clearly that's not the case now. It's moving on its own laterally from animal to animal, either through uncooked swill or by direct contact.

And it's believed at this time that the feral pigs and the wild European boars may play a role in the spread.

As you well know, there is an expanding threat of foot and mouth disease. you've heard Dr. (Lou Broth) of FAO say in the past that it may be the worst in 50 years in Asia at this point in time simply because of the number of countries that have been infected.

We have a highly unpredictable threat of highly pathogenic AV influenza. As you all well know, we've been battling H5N1 since about 2003 when the new

(clays) emerged that spread throughout the world and there is the insidious threat of Newcastle disease, which is always present.

The consequences of foreign animal disease outbreaks are certainly disruptions to commerce. And that can occur not only on an international scale but also a domestic scale if we don't have continuity of business programs and animal commodity movement control methods to ensure interstate commerce moves uninterrupted.

Collateral markets can be impacted. For example, if we had a foot and mouth disease outbreak, poultry and even grain may be impacted. Stakeholder impacts from emotional and economic loss, public fears, certainly we've seen where foreign animal disease strike other countries, that commodity -- those commodity prices drop in the short term and then that may actually lead to over supply and then a rebound undersupply.

There's (string) state and federal resources as regulators try to respond to contain the disease and certainly the length of recovery depends on the extent of the outbreak. So foreign animal diseases are not only infectious diseases, they're also economic diseases.

I wanted to give you some kind of an idea of some of the distributions of some of these foreign animal diseases and I picked three. This is classical swine fever. These are from the OIE and this is the cumulative map from January to June of this year. We don't have the latter part of the year data yet.

But as you can see, it's quite extensively spread throughout the old Soviet Union, China and it's on Europe's doorstep at this point. You may not know this, but many of our own U.S. companies have diversified to have extensive holdings in Poland, Hungary and the old Eastern European block. African swine fever has a similar distribution and over there on the right you can see that again it's very close to Europe and has actually almost breeched the borders.

This is a presumptive prevalence of FMD at this time. It's not going away and even where vaccination efforts are quite active without common biosecurity control, it persists.

There is an expanding threat of FMD. The last U.S. FMD case was 1929. We enjoy geographic isolation as well as a good control program monitoring products and commodities as they come into the U.S. but that's becoming an increasing burden because that number has expanded greatly over the last several decades.

So livestock numbers are great increased and they're also concentrated which tends to increase the risk of any kind of disease spread. We have high mobile animal products and humans. Just to give you an example, per day there is about 625,000 swine that move throughout the United States, so it's a tremendously mobile population.

We have increased global trade and, unfortunately, that also includes contraband. As resources are strained, our border and security controls may be challenged simply because they can't inspect all the shipments that they need to.

And there certainly has been a worldwide increase in FMD and there's an ever persistent bioterrorism threat.

So classically, what we have done for FMD response is to stamp out federally -- on a federal level -- infected animals maybe killed and disposed of promptly. That's the directive.

Certainly we have latitude on how quickly that can happen. But the numbers of animals that we would be tasked with and the timelines are quite insurmountable depending on the size of the outbreak. If it's a small outbreak, we could probably contain it quickly depending on the animals. But if it's an extensive one, that would certainly be quite a challenge to contain quickly.

States, some of the states mandate that the animals must be buried within 24 hours. That may or may not be practical and it may or may not be advisable depending on the state and the situation.

And it's very difficult for us to meet these types of schedules today although we do have certainly some latitude in doing that. But just the sheer number of the challenge of the animals certainly presses our resources and our personnel.

So our traditional response goals were to detect, control and contain FMD quickly, stamp out FMD while stabilizing agriculture, the food supply, the economy and protecting public health and then provide science, risk-based approaches and systems that allow commerce to continue.

However, these modern challenges require a new approach. This is because of the mobility of animals and I mentioned the movement of swine and, again, the confined animal feeding operations offer special challenges to controlling disease spread simply because of the proximity and the number of animals concentrated there. We have challenges when we come to depopulation and disposal. So if we did try to remove these animals from the population, it's very, very difficult. Just to give you some examples, if we're looking at cattle or swine, (captive bolting) is one of the options we have available to us but that's very labor intensive and it tends to be very slow.

There are some new swine mobile electrocution units that we are examining but these are expensive and few are available and we have not yet acquired those.

Rendering is our preferred method of disposal but, unfortunately, our rendering capacity is severely reduced nationwide for dead stock and there is logistics issues. The rendering plant may not be close to an outbreak or it may be in a state that is neighboring that may be uninfected and reluctant to take contaminated carcasses.

And then something that we've lessons learned from recent outbreaks, especially in Korea, underlined burial. Even though you are using maybe a small liner is not sufficient in order to contain the leachate. And that leachate will spill out beyond that.

You have to build something on the scale of a managed landfill which takes some time, years of planning and development in order to ensure that you contain that. So burial is not necessarily the most viable option and, in fact, unlined burial is the least desirable option and it has long-term environmental impacts.

To give you an example from the U.K. outbreaks, they are still pumping out leachate in some of those burial pits even though they are lined and,

unfortunately, some of that material has spilled out and contaminated the water supply.

So what are the implications for the U.S? Stamping out a loan just generates more mortalities than we can handle, so vaccination has to be considered, especially for FMD. We need to minimize depopulation and disposal and protect the environment and ensure that the food supply is uninterrupted.

What vaccination may do for us is buy sufficient time so that we can slowly feed the animals in through a depopulation and disposal system at a managed capacity rather than trying to do something that is overwhelming us.

So our best options for disposal would be rendering controlled incineration. Unfortunately, controlled incineration is not really a viable option because the throughput is so small and the facilities are so few.

Intermediate options for disposal: permitted landfill is one that we would certainly focus on but we have to remember that they have a limited capacity and they may or may not be able to take dead stock. Composting is another option but that's only really applicable where we can get sufficient carbon source and there's sufficient land mass in time to do it.

And then the worst option certainly would be unlined burial and opened pyro burning. Any of you have seen pictures of the U.K. experience know that that was highly objectionable to the public.

So we need to look at a more green response, if you will. And I don't like using buzz words, so we'll call it a sustainable response. So we need to reduce or minimize stamping out where we can, reuse and vaccinate for the food chain and then recycle those materials through a biodegradable means, such as rendering, landfilling or composting.

When we're looking at these responses now -- we're now factoring in vaccination. In the past that has not been a viable option. It's been an option of last resort and now we're moving that up to consider that as a part of the total tool package depending on the size of the outbreak and how we need to move forward with containing it.

So there are four possible strategies to an FMD response: stamping out with no vaccination, stamping out with vaccination to slaughter or kill, stamping out with vaccination to live and then vaccination to live with no stamping out and each of those would tend to imply that there is a different level of spread of disease and size of the outbreak and each of them has advantages or disadvantages.

And we will move fluidly from one of these options to the other depending on the response and how we tailor our plan because we can't anticipate at the beginning of the outbreak just how big it is, so we may have to move from a stamping out with a no vaccination to a stamping out with a vaccination, kill slaughter.

And in the worst possible scenarios, we would have to move to three but hopefully never to four. And even in option three there may be certain zones or even regions where we'll have to consider that approach.

For example, we can't destroy an industry for the sake of eradicating a disease. Dairy farms have a long ramping period in order to get back into production, so there may have to be an option for certain areas where we would vaccinate to live and then stamp out as those animals no longer become productive. However, all of that has to be considered as a total comprehensive control strategy. So vaccination is a tool to augment eradication and as a long-term control strategy.

And, of course, each strategy has a different impact on our foreign export markets. So, for example, the time for FMD free status to apply for that to OIE, is three months, whether we stamp out with no vaccination or stamp out with vaccination to kill or slaughter.

So at least options one and two are less equivalent in terms of the time to reapply for FMD free status to the OIE.

So when we're looking at these, we have to look at a balanced response strategy where we control the outbreak, protect the environment and minimize waste while we try to limit economic loss, maintain a food supply and sustain commerce at least domestically until we can reopen our foreign markets.

Stakeholder engagement is crucial in meetings like this and the one that will be held the 3rd and 4th here in Washington on continuity of business and movement control.

On our May 2nd meeting, some of you may have participated in our FMD vaccination meeting. We are moving forward on that one in order to develop a rational strategy to look at trigger points and methods that we can vaccinate and how we would do that, even on a regional basis.

November 3rd and 4th, we're going to focus on continuity of business. What are continuity of business plans? They are things like a secure milk supply, secure egg supply and, the now-in-development, secure pork supply. So when we have foreign animal disease outbreak, we can continue to move these commodities interstate with some assurance that there is low risk to moving these commodities.

But that has to be combined with movement control at a state level where we ensure that compliance is being followed. And here I just elaborate a bit more on the continuity of business supply plans.

So our modified FMD response goals would be, again, the same things we saw before in our traditional but we're going to add a vaccine as a viable option here. Flexible response strategies, again, detect, control and contain FMD, eradicate, stabilize animal agriculture, food supply and economy and protect public health.

And if eradication is impractical completely then we would look to vaccine and then perhaps subsequent eradication using vaccine as a containment mechanism. But we'd also need to ensure that we have continuity of business plans, animal commodity movement controls in place and those systems have been at least tested well before we have any type of outbreak.

We would hope we could move to a regional or zoning type of system so that if we do have regions of the country that are free that they could potentially reopen to foreign export. That can be very challenging. However, we do hold out hope that that can be done.

Just so that you know what kind of vaccine needs we are going to require, we can't give you a solid answer and I know that's very frustrating but we're in the process of trying to determine that and you're going to ask me, well, why can't you give us an answer now?

It's a balance between what resources we have, what the challenge is and then the scenario of each type of outbreak that we may have. So we've looked at lots of modeling and some of those modeling scenarios have predicted a minimum of 2.5 million up to a maximum of about 50 million doses to have on hand.

And so that you understand clearly, the vaccine industry simply can't turn on production. It depends on the (sera) type. It depends on if it's a new (syra) type or not and it depends on whether or not they have the seed in stock, in other words, the concentrated antigen ordered to modify that into a useable vaccine quickly.

So there's lots of questions but one thing is clear. We need to up the number of doses that we have available to us or at least get access to those doses quickly. So if we can't store what we have on hand, we need to be able to make sure that there's rabid capacity to ramp up quickly for those strings that we do need access to.

To give you kind of a comparison level here, let's look at the recent experience in South Korea. South Korea is about the size of one mediumsized U.S. state. It's been compared to the land mass of Kentucky.

However, the animal densities there are much more -- are much greater, so it would be more online with Iowa in terms of the number of animals.

So South Korea needed about 20 million doses just to contain. That's not to carry out a long-term vaccination program but just to contain the outbreak. The numbers that we have from the 2007 U.S. census -- and I picked a number of select states here and these are vaccine-eligible hoof stock which

would be swine, cattle, sheep and goats -- and I picked out a number of states and I'll read those, some of those over the phone.

California, 6.4 million; Colorado, 4.1 million; Iowa, 23 million; Kansas, 8.7 million; Minnesota, 10 million; Nebraska, 10 million; N.C., 11 million; Missouri, 7.5 million; Oklahoma, 8 million; Texas 17 million; Wisconsin, 4 million.

So a total of all U.S. states is 173 million eligible animals. And depending on the size of the outbreak, we need to be able to at least have an initial capacity contained or to expand that very quickly. And Dr. (Rodriguez) is going to talk to you about the challenges in trying to do these types of vaccination and what it's going to require in order for us to be better prepared.

But this gives you an idea on a basic comparison that just a couple of our states combined or even one state alone is equivalent to what happened in Korea.

So our modified response details is that we should be flexible (unintelligible) and tailored to the region and to the production sector. States should have their own plan in place, [and] that are well coordinated with any kind of federal strategy.

The response process is complex and we cannot anticipate all contingencies. So we have to do the best we can.

Response is a complex process and stamping out may or may not be cost effective in all options. At what level does it no longer become cost effective to stamp out because we're damaging the industry or even the food supply too much? So we have to consider these alternatives. And depopulation, unfortunately, will still be required to remove infected livestock, both for humane and disease reasons. So we'll still have those challenges ahead of us.

So in terms of the national response, what would (AVS) do? Well, (AVS) would notify our state animal health and tribal official immediately if we have a detection. And (AVS) then would also notify our closest trading partners, Canada and Mexico.

Then we would immediately activate our North American foot and mouth disease vaccine bank to make sure that it's on standby and that production will at least be initiated soon as we have a sufficient identification on the type of virus we're being challenged with. A lot of you would be notified.

Interagency notification, coordination, would also occur at the level of DHS, Department of Homeland Security and Health and Human Services. Our trading partners would be probably notified through OIE announcements.

We would establish a multi agency coordination group under the national response framework. We're working to try to make that happen more effectively and then publish the unified public health messages.

We want to ensure the public for these diseases like foot and mouth disease that the food supply is still safe and that this virus poses no threat to them. We do not want panic and that has to come from all levels of government and state and industry.

At the regional and field level, we would establish a unified incident command post, so working closely with our state allies, we would work with them to establish this unified command and deploy state and federal (in step) management teams to being to effect a response.

We would also begin to deploy the National Veterinary Stockpile countermeasures for depopulation and containment as well as perhaps vaccine in the future.

Institute movement control plans, initially movement would probably need to be halted but then it would need to be reopened very quickly. That's why we're trying to develop these continuity of business plans and animal commodity movement control systems so that we can quickly -- we don't want the food supply to be uninterrupted -- I mean, to be interrupted.

So we want to ensure that our commodities can move. We need to then initiate trace out investigations quickly to see what the extent of the outbreak may be. And then we have to establish local, state, federal communication plans so that everything is transparent from the field level all the way up so that we can ensure effective coordination.

This is the classical approach for control zones. These may or may not be modified by future studies in the future. We would hope that we do not have to draw these extensive level zones but hopefully on science-based approaches, rather than doing these concentric circular approaches, we can tailor it in terms of movement, wind flow and other epidemiological factors in the future so that less animals would have to be impacted.

But that's going to take a lot more science to determine. So we're left with this somewhat classical approach of concentric circle control at this time.

What have we done in order to help prepare for this? Well, certainly we have strategic plans and concept of operations. We have our National Animal Health Emergency Management guideline, which gives us a general idea of how to approach these management of diseases.

We do individual industry manuals, dairy, swine, poultry. We have individual disease response plans. Both the FMD and the (HPAI) plans have been competed and are available for your evaluation.

We have also done critical activities, standard operating procedures, for example, for depopulation and disposal and disinfection. We are working on the continuity of business plans as we speak. As you know, the November 3rd and 4th meeting will focus on those.

And we are working on outbreak response tools. One of the things that (AVS) has done is invest resources in trying to identify new methods of 3D, depopulation, disposal and disinfection.

We're working with state and tribal planning through our stakeholder outreach and we work actively with our academic and industry partners through our stakeholder meetings.

One of the things that we've done is bad prep materials or foreign animal disease preparation and response plans. These are -- have been extensive developed. Dr. (John Zack) has led that effort and these plans are available online for you to examine.

The FMD response plan, the Red Book, is available now and you can look at those SOPs and provide critical feedback for us if there are issues.

We also have additional prep materials through the National Animal Health Emergency Management guidelines, depopulation, disposal and disinfection, biosecurity, personal protective equipment and so on.

And the secure milk supply plan is under development. We already have a secure egg supply plan, which is being adopted in some states. And we're working on a secure pork supply plan. We hope to have other commodity groups work with us in the future as well as funding becomes available.

And with that, I will redress any questions that you may have.

Woman: (Unintelligible). I guess for lack of better word, maybe the term I will use is zealous or over zealous. What would a farmer-rancher do in case whoever was in charge in that state -- maybe if they were -- we deem them to be zealous in the fact that maybe there would be the potential to vaccinate those animals versus, you know, eradicate or slash and burn type thing?

> As a farmer, what would be our ability to ask for a second opinion so to speak? And I know there's probably not going to be much of a chance for that. I'm just wondering, you know, because of the urgency of it and because everybody's going to kind of freak out, you know, if FMD happens, what is our ability as a farmer to say, hey, can I get a second opinion higher up?

Is there a possibility to vaccinate those animals versus, you know, immediately slash and burn, so to speak?

Darrel Styles: Well, I think that's going to depend on the outbreak and that's why we're trying to engage our stakeholders now in order to prepare each industry sector for what may or may not be an eventuality. And so we come together as both regulator and stakeholder in a consensus capacity to ensure that we've made the right decision for the food supply and the nation as a whole.

Now, certainly, we do not want to overlook the needs of the individual stakeholder and we're going to work to address those. But we have to look at, in terms of what is our -- what are our challenges and how quickly can we contain this and how can we effectively contain this?

And the use of vaccine will be made on a case-by-case basis and I can't give you an answer because that would simply depend on the kind of outbreak, the extent of the outbreak and what animals were affected and perhaps even where they were affected.

Woman: Okay, I guess one of my biggest concerns is, you know, for the genetic breeding stock, it's one thing to have a commercial pig like a pig line or something like that but it's another thing if you have a breed that is -- like I imported genetics from South Africa through Canada and also from Australia for my (Duliper) sheep.

Well, you know, the state veterinarian in North Carolina, you know, he may say, oh, that's not all that big a deal. Sheep industry in the United States and we can just import lamb from Australia. But for me and for my customers, it is a big deal and the fact that I just can't go out there once this is all over with and, you know, and fulfill my genetic base.

Now, grant it, FMD has to be put under control. I'm just wondering kind of how that's going to go down.

Darrel Styles: Well, I don't think we're going to be looking at a slash and burn approach. If you look at our response, (AVS)' response to the 2003 exotic Newcastle disease outbreak, one of the things that we did was certainly look at the biosecurity of each individual facility and if we could ensure that the biosecurity of that facility was sufficient and testing confirmed that that we had negative premises, that premises was held in abeyance and so it may or may not be depopulated.

> Whether or not we can move to that kind of a system in an urgent situation in an FMD outbreak would depend, again, on the circumstances that are very difficult for someone like me to predict.

> So certainly I think, you know, we would consider the needs of the individual stakeholder. But, again, we have to look at the broader picture of the industry and the food supply. But we would definitely consider that.

Woman: And then -- hey. And then my other comment would be that I would see it to be most important that there was a secure feed supply for those farms that weren't infected so that we're not having to run and go get feed somewhere and picking up FMD in the process and bringing it back to...

Darrel Styles: That's something that we're certainly considering now. I skipped over it very quickly but we do need a secure food stock supply plan because, remember that if we have an outbreak in the grain centers of the U.S. where are we going to get our corn and soybean for the meal?

So it's important that we do have a secure food supply plan as well for forage and cereal and grain.

Donald Hoenig: Dr. Clifford?

Donald Hoenig: Dr. Styles? Oh, John, did you want to respond to that before we take another?

John Clifford: I just wanted to add one thing to what Darrel says. And I think it's kind of understood here or I would think it would be with the group but I want to make sure that we say that.

> I think, you know, with this new approach, we definitely don't want to do slash and burn. We realize that there's a lot of genetics out there that it would be important to try to protect.

But we also have to look at this from a standpoint of the whole. So we're looking at it from a standpoint of what's best for the U.S. as a whole and, of course, the states are going to be looking at it from the standpoint of the states and you from the local level.

So we just have to take all of that into account when we make these decisions and I just...

- Donald Hoenig: (Howard), do you want to go next? I've got like four people, so (Howard), (Judith), (Gilles).
- (Howard): First of all, I want to compliment (AVS) for what I would call a modernization of your thinking. You know, it wasn't that many years ago that the only thing we talked about what how we're going to kill them, how we're going to bury them. And so, you know, you guys have -- hats off to the new thinking here.

And the other thing I'd like to say is that from our industry and I think I could speak for dairy, this working with the commodity groups, how you're

interacting with the commodity groups on the safe food supply, safe feed supply and all that, is really appreciated by the industry.

And so, you know, I think we've kind of come out of the dark ages on how to control a foreign animal disease. My hat's off to you. Thank you.

- Darrel Styles: Thank you.
- Donald Hoenig: (Judith)?

(Judith): A couple of different questions. The first one is I remember reading quite a while back in a (GAO) report a recommendation about rapid field testing and I was wondering where you all were on developing the ability to do diagnostics in the field on FMD to determine what's infected and what's not.

Darrel Styles: Many of our National Animal Health network labs, which would be at the state level and some at the university level, are gaining the capacity to do FMD testing in the field.

We think that this is excellent because this gives us the capacity on a local level to respond quickly to any kind of an outbreak and get a presumptive diagnosis, which then would be confirmed by either NVSL or (FATL), depending -- or (unintelligible) facility depending on the disease.

So we are deploying that type of testing to a local level. If you're referring to pin side testing, that's somewhat different. We don't have a reliable FMD pin side test yet. Those are in development in a number of different countries but none of them have actually met the need for addressing all the different strings of FMD that we may be challenged with.

And also you remember that pin side tests should not be used in a nonoutbreak environment. It would only be used perhaps in an outbreak environment for a presumptive confirmation because it could damage our trade irreparably if we had a false positive.

So we are ensuring at least at our non-lab level, out state lab levels that those types of tests are being deployed. In the future, we hope to deploy other (FAD) tests out as well but that remains to be seen.

(Judith): Okay, thank you. And as a follow-up to (Genell)'s question -- I'm very sorry but I missed the May meeting on vaccination and she was saying, you know, a lot of our industry -- you know, when we talk about industry, you talk about the industry of the local foods movement, the genetics is a recurring question and the issue of movement, which I know we address in the November meeting.

What would be the process by which we could have input, you know, on the rare breed or the genetics issue from that May 2nd meeting? I mean, what's sort of the continuing process coming out of that where we could get involved?

Darrel Styles: (AVS) is looking at deploying an instrument called (decision lens). It's an online tool that provides stakeholder input. And I'm not sure exactly how these venues will be couched or for what they will be but they will definitely be access for stakeholder input on developing a larger vaccination schema. And in terms of where we should place emphasis and I think that certainly there will be opportunities for stakeholders to provide input through that mechanism in the future either through their industry trade groups -- perhaps not individually but certainly through your industry trade groups as your representatives to provide an underpinning for how we would move forward with a vaccination program.

- (Judith): Is there -- and I know tomorrow's meeting is focused mostly on the movement issue. But is there an opportunity for us to grapple a little bit with some of these issues, you know, from the May 2nd meeting as well?
- Darrel Styles: Vaccination is a very complicated subject.
- (Judith): We'll stay focused on movement tomorrow.
- Darrel Styles: Yes, we want to make sure that we -- these -- the animal movement and commodity -- animal commodity movement and movement control programs are going to be in some ways much more complex than the vaccination because we're looking at multiple levels of authority, state, local and federal trying to coordinate our states and having states in agreement that they will allow this kind of commodity movement across their borders in an emergency situation.

It's fine to agree to it in peace time, but when we're in an emergency, people sometimes have a knee jerk reaction of closing state borders quickly. We want to ensure that that doesn't happen because that could destroy an industry.

(Judith): Okay, you'll keep us posted on how we can be involved in the vaccination input process. I think you said (Gilles) was next.

Donald Hoenig: Yes.

- (Gilles): This program is sort of akin to emergency program to declaring martial law.Do you -- and if you go into it, I mean, there's going to be huge legal implications. Is the authority there to do so? And if not, is there some way that this committee can help?
- Darrel Styles: I think Dr. Clifford better address that one.
- Donald Hoenig: I saw him shaking his head.
- John Clifford: The secretary has the authority to declare an extraordinary emergency and under such conditions then we would -- the federal has the authority to go into a state and take action based upon that.

Any takings of private property require 100% compensation to the producer for -- so basically fair market value for the takings of those animals if we do a taking.

- (Gilles): Well, that's a taking but, for instance, if you stop movement, that impacts (Charlie)'s business of a livestock market. There is a lot of levels of taking and...
- John Clifford: So during a quarantine, as far as whether -- basically compensation is not typically paid for quarantines. So we wouldn't be looking to pay people for a loss of business during the period of quarantine or stock movement.

But that's the reason we are working with a lot of these plans and it's important to work with the industry on these plans and the states ahead of time so that we can allow safe movement and trade as soon as possible.

- (Gilles): So I imagine the state governors they're going to either be helpful or not helpful. There is going to be a lot, a lot of confusion, I'm sure. But the secretary's authority is clear enough to move ahead in this.
- John Clifford: The secretary's authority's very clear on this issue, very clear. Our state counterparts are very well aware of that authority. The state themselves, oftentimes -- if you look at exotic Newcastle disease outbreak in California that was in, what, early 2000.
- Darrel Styles: 2003.
- John Clifford: 2003, initially California did not call in federal authorities for assistance but it didn't take very long and then California requested us to step in, declare the extraordinary emergency and to apply proper quarantines over parts of California that ended up expanding into Nevada and Texas, I believe.

And so we were involved with that. We also, though, during that period if time, developed permitting system to allow the movement of certain types of poultry products and certain types of birds that we could allow for safe movement in and out of that area.

So we recognize we can't, you know, there's no way everybody's going to be able to shut down all commerce across all of the U.S. for a week. It just isn't going to happen.

So our intent is to hopefully contain the -- identify the area that's affected, contain that, quarantine that area in order to get it controlled and then as quickly as possible, start allowing movement based upon the knowledge of the presence of the disease and the safe movement of product in and out of that area.

Donald Hoenig: (Liz)?

(Liz): Yes, I think some of the discussion that has just happened is kind of addressing my question. And, Darrel, I'll fill you in. But I spent last week in Russia looking at their response to African swine fever.

And the thing that they identified as probably the biggest gap in their ability to respond to it is a lack of a strong federal veterinary structure and that the fact that the federal veterinarians have no control over what happens at a regional level to the point where they have to write a letter to the regional authorities to be allowed to go onto the farm and receive a letter -- like a physical letter, not an email, but letters, handwritten, stamped, signed, the whole thing.

So they're delaying response to some of these outbreaks by two to three weeks because of just the (rigermaroll) between getting federal versus state in there. So I think that that just in many ways underlies the importance of having that strong federal veterinary structure that is cooperating and coordinating with the states.

The other thing we learned is that they're trying to make a compartment, their commercial swine herds, to be able to continue to move product out of those herds. And as a suggestion, I think we could perhaps learn if they go through the OIE process of trying to call some of those herds a compartment.

But having been over there, I mean, I was a believer in foreign animal disease response. When I got back on Sunday I think I probably became a disciple. So I just encourage you to keep up the work and help us safeguard our herds.

Donald Hoenig: (Boyd)?

(Boyd): Yes, Dr. Styles, I certainly appreciate the presentation this morning. I echo a lot of the comments that Dr. (Hill) made about how far we have come. Just an aside, you may not know, as you began your presentation, I saw a news release, since we talked a lot about vaccine, about Paraguay saying they had an error in vaccine manufacture that caused their latest foot and mouth outbreak.

Have you had a chance to see that news release and can you make any comments?

Darrel Styles: No, I haven't.

John Clifford: I've seen the release but we don't know, (Boyd), the -- yes, you know, we just don't know about the vaccine. He's good. He's just going to talk about that. So you have some information on that, (Luis)? Okay.

Donald Hoenig: (John)?

(John): Thanks. One of the issues that we discussed yesterday and are concerned about is projected funding for National Animal Health Laboratory Network. And obviously it's a huge component in a situation like this with a surge capacity for diagnostics.

Who is expected to pick up the tab for that I guess is the main question? Are the states being looked to to continue the support for the (non) funding?

Darrel Styles: There is still some (non) funding there and -- well, it's been reduced some. (NITHA) still has some money there and we still have some resources that we're putting into (non) activities for -- it's a fee for service approach. Sorry.

Donald Hoenig: (Genell)?

(Genell): Yes, okay. So if there is an FMD outbreak, I know in Britain there were some of the farmers that took their animals and put them in barns and shut them up. What would be your suggestion to my stakeholders for me to tell them? What is the best way for them to try to make sure that their animals don't get the disease?

> I mean, I know that they can't, you know, secure that they absolutely won't, but what's the best thing for them to do if they hear that there's an outbreak in the county or in the area?

Darrel Styles: One of the things I think you should do is avail yourself of an (AVS) resource for the Center for Epidemiology and Animal Health and (CEA) can help you define what a good biosecurity control program could be. And in fact, they would sort of codify this that if you meet these requirements and you stick to them and you're compliant that you would be at low risk -- I don't want to use the word premises but facility.

So certainly I would avail myself of that resource and approach them to discuss that as a breed association as to what you could do to meet some biosecurity guidelines.

We did that with (E&D). It was quite successful. We had some facilities within the control zone that remained clean throughout and were able to even continue business with testing and carefully regulated movement.

Donald Hoenig: (Chuck).

(Charlie): Thank you. The beef industry really appreciates, Dr. Styles, the work you all have done to develop this vaccination option or at least this -- the potential for using this.

As an epidemiologist, I don't (unintelligible) in the weeds. I live in the weeds, so I'm down on details. When we talk about vaccinate to live, how -- these three questions are really related. How long are we talking about those animals living?

For instance, would a cow live through her productive life as a breeding cow or would she live until the next cycle? Second, management and identification of vaccinates certainly is tied into that vaccinate to live program.

And third, probably one of the most important points, is the public health message ready because I'm not sure we're going to hear about this on the way home from here and I'd like to know that my calves are still going to be consumable and that the public is going to be aware that that is a safe and wholesome food source?

So those are the three questions I have: public health messages, is it ready, management and idea of vaccinates and how long are those animals going to live on a vaccinate to live program?

Darrel Styles: Let me start with the last question first. (AVS) has developed message maps already for safety, the food supply in terms of the foot and mouth disease outbreak. What I would encourage -- and I know Dr. (Parker) has worked with (NCBA) has worked on message maps and messaging within the beef industry in order to provide public assurance that the product is safe.

But this is something that I think we need to coordinate better with our stakeholders individually is looking at each industry sector, whether that's a swine, beef, dairy or poultry. We need to ensure that we have a unified message coming from an industry source, a federal source such as (AVS) or even a federal source such as Health and Human Services.

There was tremendous coordination, for example, around the 2009 H1N1 messaging from -- (AVS) kind of led that effort and brought in Health and Human Services to assure the public that the swine, that the pork supply was safe and that there was no threat to public health at this point.

And I think a similar effort is ongoing but we just -- we need to step up our efforts in order to ensure that those messages are developed well ahead of time and the industry itself needs to formulate that kind of plan so that we can coordinate our messages now rather than waiting until there's an outbreak.

In terms of how long your animals would live, it depends on whether we're at that three or four. If it's vaccination to live with no stamping out, that's where we've made the decision, well, it's just too extensive. We can't contain it and we're going to have to just vaccinate to ensure that we have a safe, domestic food supply.

So at that point, you know, we may eventually work back towards vaccination but it could take decades. Look at some of the countries that have actually tried this. We don't anticipate that happening but certainly it's a possible scenario. More likely it would be, you know, vaccination to live with eradication where in certain sectors we would -- and this is why we need to work with our industries now.

In the dairy sector it would probably be until that cow has gone through her productive cycle and then she is removed from the population. With the beef, the beef industry needs to help engage with us on what they think a rational plan for that would be and looking at it as a national strategy.

We can't make these decisions on a sector-by-sector basis in a vacuum. What happens in the beef industry will affect the pork industry. And sometimes these are two contravening purposes because on industry may rely more upon a foreign export than another.

This is why reasonalization and zoning is critical. These are very complex questions and I can't provide you with sound byte answers as to what they may be, so they have to even develop on perhaps even a regional basis on how we would approach this depending on what the lead industry would be in that particular region.

I'm sorry I couldn't be more satisfying but it's a very complex question.

Donald Hoenig: Go ahead, John.

John Clifford: I'd just like to add to that, too. On the international level, you know, one of the things that we're doing with some of our other counterparts from other countries is getting greater acceptance.

When we have a diva type vaccine approach and we can definitely have good indicators of the, you know, between virus, actual field virus versus vaccine that we get greater international acceptance for this.

Now, we're probably a long way from that as far as having that kind of acceptance internationally. But if we could move more and more in that way and then we get more tools as technology advances to where we could have that type of vaccine available, you know, at some point in time we might be able to use vaccine prophylactically in certain high-risk areas in the country, you know, to prevent from that first introduction so that we have some protection in our national herd in certain locations.

But the other issue too, as we talk about from a food standpoint, it's critical that we work with packers and slaughter facilities now. We've had issues where a product has been very safe but because of a brand name they've refused to take certain animals for slaughter because of that brand name. So we need to address that.

Donald Hoenig: Just to kind of get us where we are as far as time goes, I'd like everybody to kind of have their say, but also we need to leave some time for discussion of whether we want to make any recommendations on this issue and I'd like to try to do that now and then move on to the next presentation and then look at recommendations.

So we have almost 10 minutes left. And I haven't said anything so far, so I will.

Number one, there are many people who have been working on this response plan for a long time now, particularly since the U.K. outbreak because a lot of U.S. veterinarians went over there -- over 400 went over to see what happened there.

This is a major nightmare for animal health and industry and for the country. This would be economically devastating for this country and that's why many people are trying to get answers for producers in the agriculture industry.

And the answers are not all there. And so it's a very, very slow, deliberative process that we're going through to try to figure out what we're going to do in an emergency and it all depends upon so many factors, as Dr. Styles says and others have said.

So there are no easy answers but we're going through it in a step-wise fashion and I agree with Dr. (Hill) who said that it's a huge step forward that USDA has, you know, officially acknowledged over the past few years a vaccination's going to be part of the plan.

Dr. Clifford is going to Argentina on Monday. That's a country that has had split status for many years. They vaccinate everything north of the 42nd parallel, I think, twice a year. 58 million cattle are vaccinated twice a year. It's just like vaccinating for BVD or (Triangle Mind).

You know, you add foot and mouth in there and they're shipping into the E.U. meat. They would like to ship in to here but they're not right now. But south of the 42nd parallel it's free without vaccination. So that's a (two) status and I think that's what (Chuck) is getting at.

You know, well, what can we expect if we go to vaccination across the country? And countries have done it. One more comment from (David) and then let's talk about...
(David): Thanks, Don. I'd also like to comment (AVS) for some excellent work on preparedness. And what I have to say might or might not have to do with any recommendations but I'd like to relate some of our discussion here subsequent to Dr. Styles' presentation to some of the discussion yesterday.

And when we discussed the impacts of an outbreak, consumer concerns, commerce stoppages, trade implications, you know, the cost on rare and valuable genetics, innocent bystanders, whatever you want to call it, to me these things indicate why every single stakeholder group should be trying to make traceability work and not trying to find ways to make it not work.

Donald Hoenig: Thanks, so let's take the next 10 minutes if we can to talk about any recommendations that we might want to make out of this or not. I guess I would -- my sentiment would be that I have -- I support what the USDA, (AVS) Veterinary Services has been doing to upgrade the Red Book, get it out.

They got it out for comment. I actually got a letter back from (John Zach) saying thanks for your comments and they listen. They made a couple changes in response to comments, so I'm sure it's not just because it's me but others probably made comments too. So they've been very transparent and cooperative on those lines. (Judith)?

(Judith): Both a comment that had come up online before but I think it also relates to possible recommendation, an issue of sort of consumer confidence and messaging. My experience, when I'm talking to consumers, and I do -- you know, we're at farmer's markets. I deal with the consumer population directly on a regular basis.

When the subject of foot and mouth disease comes up, they are shocked to hear -- I mean, it baffles them to hear that there isn't a Human Health issue because the picture of killing millions of animals in England, well, if there wasn't a human health threat, why did that happen?

You know, it's a method that doesn't make sense to them. And I think that, you know, if we're going to, you know, if USDA and industry wants to ensure that consumers feel safe as human beings and consumers and their food, if there's foot and mouth disease outbreak, you know, this move away from slash and burn and towards looking at things like vaccination, looking at how do we protect premises that aren't infected, looking at, you know, possibly vaccinating to live as an option.

These are relevant to the messaging as well as to the substance. You can't expect consumers to buy into a line that says don't worry you're safe. Don't mind the big piles of burning animals. You know, it's not going to -- it doesn't make sense to people.

So, you know, for myself, I'd like to see if we do any kind of recommendation or comment to USDA certainly support for this focus and investigation into options for vaccination. I know around the table there are differences of opinion as to how far that goes but hopefully maybe we could at least support just generally the consideration of vaccination and multiple options.

Donald Hoenig: (Charlie).

(Charlie): You know, something that might be pretty important here in an outbreak is to already have the stakeholders, producers educated. You will reduce the panic if producers are already educated as to what this means.

I don't know how we go about that but there has to be a way and maybe that's a recommendation we need to make.

Donald Hoenig: I agree. And in our state, we've been trying to sound the bell for 10 years now telling people, you know, this -- we've been fairly lucky that this hasn't happened. We've also been -- upgraded our safeguarding efforts. So we're trying to prevent it from happening through introduction and those types of things at border ports.

But still, there's a little bit of luck involved in there. But we've been trying to get that message out that biosecurity is important. This is going to be a major disaster if it happens and this is what we're doing and planning. So is there anybody who would want to offer language for drafting a recommendation? (Liz)?

(Liz): How about something along the lines that the committee urges the secretary to continue foreign animal disease preparedness as a priority for the agency and that preparedness should include not only response plans but communication plans for stakeholders throughout the food chain, all the way from producers to consumers?

Donald Hoenig: Sounds good. Yes? I'm sorry, (Genell).

(Genell): I agree with (Liz) and including the consumer component. And I know we kind of walk a fine line between educating the consumers ahead of time and making them nervous when there isn't a problem. But also if they're educated to what FMD actually means to their food supply, not the production of the animal, but to their food supply, maybe they won't be, you know, so freaked out if it happens. Do you understand what I'm saying?

- Donald Hoenig: Yes, absolutely. I mean, I don't think there's a -- I think 90% of the consumers in this country think foot and mouth disease is mad cow disease.
- (Genell): Right.

Donald Hoenig: And that's a huge educational piece.

- (Genell): I think the lack of the consumer education component ahead of time, when it actually -- if it actually does happen is just going to be, they're going to be so nervous I think they're going to want to turn vegetarian, you know. So I think maybe that's a very important component.
- (Judith):
 (Liz), would you be comfortable if we included something in there not just about -- to me response plan and communication plans implies coming out from USDA but also include a provision, perhaps language continue, you know, continue involvement of all stakeholders.
- (Liz): (Unintelligible).
- Donald Hoenig: Good. Somebody can probably put that into -- that's good. Maybe we can probably tweak it a little bit, yes. Everybody good with that? (Liz)?
- (Liz): (Unintelligible) wondering about continuing FMD preparedness as a priority for the agency because right now it just says do it. And just in terms of like, you know, turning this into complete sentences. Stay about where you are. So it's a priority for the agency comma including involvement of all stakeholders in the planning process period, preparedness plans should include response -preparedness should include response plans and communications, yes. And then you can delete that last bit.

Donald Hoenig: Better, yes.

Man: (Unintelligible).

Donald Hoenig: (Four)? (Four). Getting better, all right. What do you think? I like it.

- (Judith): I'll second.
- Donald Hoenig: All right, (Liz) moved, (Judith) seconded, further discussion? (Max), you good? All those in favor signify by saying aye.

((Crosstalk))

Donald Hoenig: Opposed, same sign. Abstentions, none. It's unanimous. All right, thank you.Wow. All right, well, keeping right on schedule, we'd like to welcome Dr.(Luis Rodriguez), who is a (Plum Island) worker, veterinarian, research leader at (Plum Island) Animal Disease Center.

I've known (Luis) for a number of years now and he came down today to talk to us about the agricultural research service work on FMD classical swine fever and African swine fever. And, (Luis), welcome.

(Luis Rodriguez): Thank you. So thank you very much for the invitation. This is the first time I attend this committee meeting and I'm very pleased to learn about the process and how this might result in a stronger animal health safety and security for our country.

So what I wanted to do -- this is a big task. Foot and mouth disease CSF and ASF, each of those I could talk to you for several hours on a number of

subjects. But I picked actually countermeasures vaccines and our research program and current capabilities and potential future capabilities as well.

So I will focus on those areas but I would be happy to answer questions. We do have also research on diagnostics and other areas that if you want to learn more about I can share that with you as well.

So as I said, our (ARS) -- so I'm here as an (ARS) researcher. And our mission is very clearly defined, which is to provide research solutions to agricultural problems of high national priority.

I think the diseases that we're dealing with qualify as high national priority. And we're a very small team of researchers. It's only eight of us, what we call senior researchers at (Plum Island). I list them. I include myself as one of them. I do get to do some research once in a while still.

And we have expertise in molecular biology, pathology, immunology and we have added also bioinformatics and we do have some epidemiology expertise but we do that through collaboration with other institutions and we have a lot of that collaboration outside of (Plum Island).

We are focusing our research in three areas. As you can see, these mimic -list the diseases that I will talk to you this morning about. The first one is the innovation strategies for the global control and eradication of foot and mouth disease. This is a much broader mission that we were given by our national program staff in the last cycle of research programs that were just approved about a month ago.

And as you can see, the global control is now one of our main objectives in addition to keeping the U.S. free of these diseases, of foot and mouth disease.

The second addition to our program, we had a classical swine fever research program and African swine fever was added. Unfortunately, no money was added but the mission was added to that. But we have some good news on that and I will talk to you about African swine fever.

And finally we have a small, very tiny program on (VSV), which is a foot and mouth disease look alike. I will not talk to you about that today but it basically focuses an understanding how does it come to the U.S. and every time it does it causes disruption in our trading and quarantines and unwanted results. So we want to learn more about how we -- how this happens and how we can prevent it.

So another issue I want to bring to your attention is that (ARS) and specifically our foreign animal disease research unit at (Plum Island), when we're given a mission and resources, we deliver.

For example, we have delivered in 2004 we were given the mission of providing rapid diagnostic tests for all foreign animal diseases, all major foreign animal diseases.

We have delivered each and all of those rapid diagnostic tests to (AVS) over the years. We delivered the first ones actually in 2004 and the latest ones in 2009 and 2010 and (AVS) has now deployed those tests to the National Animal Health Laboratory Network. So we have provided these tests for foot and mouth disease, African swine fever, classical swine fever, (render pests), (sheep pocks).

There is a total of 14 tests were developed by (ARS) and provided to (AVS) for deployment, validation and deployment. The other thing that we have done

is we have -- we were given the mission, as well, to provide effective molecular vaccines for foot and mouth disease. I will talk to you more about that. We have delivered that.

And in fact, this vaccine, there are -- I think within the next week or two, there will be a number of animals in the U.S. mainland in three states will be vaccinated with t his molecular vaccine. This is the first in U.S. history where we actually will safely be able to vaccinate animals using this kind of vaccine.

This is the first in the world and I will give you a little more detail in a few minutes.

We also have delivered the first classical swine fever vaccine candidate. This is not a vaccine yet. It's a candidate that has molecular markers so you can distinguish easily between vaccinated and infected animals.

This doesn't exist in the world today. This is the first, again, and we're about to transfer this to private industry for development.

And we also have generated a lot of information. For example, how foot and mouth disease replicates, where does it start the infection. For example, we're looking at a new generation of foot and mouth disease vaccines that I will share with you today that will allow production without the use of (veraline) virus, which is a very important step in global foot and mouth disease production.

I also want to share with you some of our achievements in the biotherapeutics, which is a way that we can actually prevent foot and mouth disease infection with 24 hours of vaccination.

So, again, I just wanted to bring to you some of the recent deliverables that we have produces. A lot of these publications have come up in the last year in terms of -- and these have had an impact globally in terms of understanding how the foot and mouth disease infection begins.

And foot and mouth -- and I will show you a little bit of data on this -- it's actually more a respiratory infection than it is a foot and mouth disease. It really behaves as a respiratory virus.

I'll show you some information on that. But there is a lot of this information has been recently published. If you look under foot and mouth disease early replication or pathogenesis, you will see some articles including the cover of the Journal of Veterinary Pathology back I believe it was earlier this summer.

Okay, so foot and mouth disease is -- again, I don't want to boar you with some -- too much technical information but it's very important that this is a family tree of all these viruses called (pichorno) viruses where foot and mouth disease actually belongs.

And that little purple bubble there has three viruses in a genus called (afto) viruses. And of course, the main virus there is foot and mouth disease but the other companions that are very closely related to foot and mouth disease are rhino viruses.

One of them is bovine rhino virus and the other one is equine rhino virus. Those are the closest relatives to foot and mouth diseases virus. And we've determined this several years ago at (Plum Island). We've done the full genomic sequence of many of the foot and mouth disease viruses around the world and also these other viruses and we are comparing them and see how they relate to each other. One of the things that this is important that was mentioned by Darrel earlier on is the confusion of diagnostics. The reason that many times foot and mouth disease diagnostics can be confused and, for example, we had animals in the U.S. that turn out positive for some of these tests for foot and mouth disease is because they're very -- a lot of our animal population is infected with these rhino viruses that are very closely related to foot and mouth disease.

So we're trying to understand how to tell them apart and so that we can provide that information to (AVS) so that they can develop better diagnostic tests we can use in the future.

The other feature of respiratory infections is that they're highly transmittable. This is the most transmittable virus we know of. And the other issue is it's highly variable and there are seven serotypes. I'll show you a little bit about the distribution of them around the world.

This is basically a map of outbreaks between 2005, 20011. And it really matches very well what is called these endemic pools. So foot and mouth disease is not equally distributed around the world and there are different serotypes that exist in these endemic pools.

And these are what we have, you know, to understand foot and mouth disease -- we don't talk about foot and mouth disease in China or in Russia. We talk about foot and mouth disease in these seven pools that comprise, you know, East Asia and South Asia and EurAsia and East Africa and West Africa and so on.

And as you can see, the composition of serotypes is different for each of them and the vaccines that are recommended for each of these sites is also different. So it's a very complex situation where in order to have vaccines for every single one of those seven pools you need to have several dozen vaccines in any vaccine bank.

And then for each of those, you need to have probably several dozen million doses for each one of them if not more. So it is a very complex issue and we need to have a better understanding of how these viruses move around, hence our interest in this global control.

The more control at the global level we have, the lesser risk that we have of introduction into the U.S.

Now, this is how vaccines are made today. And basically the way is very simple process where you actually grow virus, which is a fully virulent virus that comes out of outbreaks and then you adapt them to grow in cell culture and then you grow thousands of gallons of these things and then you kill it once and then you kill it twice because killing it once is not enough. You have to make sure it's completely inactivated.

And then what you do is you purify these antigens. You have to remove this waste material for the cells. But also, very importantly, the proteins that the virus uses for replication and that are not packaged in the virus you want to remove those and the reason for that is the high quality vaccine where you remove these proteins and it allows you to test the animals that you vaccinate against those proteins and differentiate animals that are infected from animals that are vaccinated.

So that's a very simplistic view of why it is that we want high quality vaccines that are highly purified antigens.

Usually these antigens are not made into vaccines right away. They're put away into these banks where you freeze them. And this is research, by the way, that was done at (Plum Island) several decades ago where they found that if you freeze these antigens under liquid nitrogen they last for decades.

And we have tested antigens from the 1980s and still it's perfectly viable. And this is how we keep our vaccine antigen banks today is under using this technology of freezing.

And hopefully, when you have an outbreak, hopefully you will have a vaccine in your bank that will match the outbreak strain and then you go back to that bank, you formulate that vaccine. It usually takes -- they say a week. I don't know if -- I think I takes probably about a couple of weeks to get it out of the vaccine and get it shipped elsewhere around the world to be formulated and then shipped back to the U.S. for use.

So that is something that we have concerns about and we're trying to cut the time to have antigen vaccine ready for use.

Now, there are concerns about the current vaccine, particularly in FMD free countries. And one is that when you have a new strain of foot and mouth disease -- and there is one example that is worrisome. There is a vaccine that just emerged in Ecuador that it doesn't -- is not covered by the current serotype O vaccine.

So in South America there is a vaccine called (O Campos). It is a strain that has been used for the last 20, 30 years as a vaccine. Well, this virus emerged in Ecuador about 1.5 years ago that is not covered by that vaccine.

So now we have a new strain of foot and mouth disease and we don't have a vaccine for it. And so what do we need to do to make a vaccine out of it? First thing you need to do is you need to adapt the virus to grow in cells and then you have to make large volumes of these and you have to go through all the processes of regulatory process to get this vaccine approved.

But in addition to that, there is a problem that some of these viruses do not grow well in tissue culture and sometimes when they do grow they change and then they're not good vaccines anymore.

So there is a lot of problems with current vaccine production. Another problem is that the virus can escape from the manufacturing facility which has occurred recently. In 2007 U.K. is an example of an outbreak that actually began from a vaccine production facility.

I already mentioned you have to have multiple antigen concentrates. Some of these antigens are not so good in stability and they fall apart for the -- so the shelf life of the vaccine, once you formulate it, it's not very long.

It takes about two weeks to induce protection. Another big problem, particularly if you're going to go into the scenario that you described about vaccinating long term like many countries do like Argentina, is the fact that immunity doesn't last that long.

So once you vaccinate, say that you spend -- you figure, I'm going to spend an extra \$1.50 to \$2 per animal. In the U.S. it's probably going to be more like \$2.50 to maybe \$5 to \$10. I don't know what the cost of vaccination would be here.

But in countries like India or Argentina, you know, it's probably about \$1 to \$2 to vaccinate an animal. Well, that's every six months for life. And what they've come up with -- so it's not just once.

And then you have to pick which of the 30 antigens that are circulating around the world are we going to vaccinate preventively, the U.S. population against. So those are not very simple questions. Like vaccination -- preventive vaccination in the absence of outbreaks or a clear threat is very difficult to predict.

And the other issue is the difficulty to differentiate vaccinated and infected animals. However, that is improving as quality of vaccines improve. And finally, there is an issue that is a problem. We don't have a solution yet. That is that vaccinated animals, if they get exposed to the virus, they do become carriers.

So they don't show clinical disease, so the vaccine is good at prevention of clinical disease, but the vaccines today -- none of the existing vaccines prevents infection.

So the virus actually infects the primary side of replication that is in the pharynx in the animals and these animals can then shed virus for a while. Whether this virus plays a role or not in the epidemiology and further transmission, nobody knows and we are trying to do research in some endemic countries like Pakistan, Vietnam, Coumarone with very little resources but trying to go to those countries and understand the role of those carrier animals in the transmission of foot and mouth disease. We don't know that yet. So an ideal vaccine for foot and mouth disease is something that is effective, that is rapid induction of protection, that induces long lasting protection, that only requires one inoculation, so you don't need to be catching animals over and over again.

You want a vaccine that prevents viral transmission that is easy to differentiate vaccinated and infected animals, ideally something that we can make in the U.S. so we don't need the virulent (unintelligible) to make it, something that will prevent the carrier state, something that will protect against serotypes. That will be wonderful and something that, you know, will have a long shelf life, we can keep stocks of ready-to-go vaccines for years.

Of course, this is pie in the sky. We can all dream. We actually have, you know, some of these things we are making progress and, again, the answer to that is not to give another, you know, \$100 million to set up emergency, you know, these things are in addition to that that you need, the emergency response.

You also need that pipeline, that basic research that will bring the tools to the table so when you do have an emergency you actually have better tools that you can deploy and that's what I'm here for is to bring that research component back to the table.

We always get -- we forget where all these current vaccines came from and they came from some of that research. So I want to remind you of that.

So one of these vaccines that I want to share with you is a vaccine that provides answers to some of the issues of current vaccines and that's a vaccine that was created at (Plum Island) by (Marvin Grobman), a man that you can see in that little picture there. And he years ago started using this vector called, it's a human defective antivirus (unintelligible), which is basically a cold virus that is pretty much dead. It doesn't do anything to people. It's not -- it's defective. It doesn't grow anymore.

But you can use it to put genetic information from foot and mouth disease or other viruses into it and then use it to deliver that information into animals. So it's a kind of an interesting way of making -- you don't make vaccine.

What you do is the animal makes the vaccine itself. You give it the information, the antigens that -- and then the antigens, the vaccine, the foot and mouth disease structure of proteins are actually made by the animal.

This is a very noble approach and people didn't believe it would work but it actually did. And this (routine) is effective. It's as effective as the current (kill) vaccine. It's not more effective but it's as effective.

It lacks all of the non-structure proteins of the virus, so it has the advantage and you can very cleanly distinguish infected and vaccinated animals using a variety of diagnostic tests and, more importantly, it can be safely produced in the United States and it's been produced a few miles from here, actually, a very small company that has produced this vaccine and it's being produced in the Midwest and it's about, as I said, to go into the -- in a field test in about, I believe it's 300 or 400 animals in the U.S. in the next couple of weeks in three states.

And this effort is led by the Department of Homeland Security Advanced Development Group in cooperation with private industry. So we provide the technical support but they are in charge of doing the field studies and bringing this -- ideally this product will be licensed by the Centers for Veterinary Biologics and ideally it will become part of the National Veterinary stockpile as one more tool.

Now, there are several advantages that this technology has and one of them is that you don't need to grow the virus to get a vaccine. So this Ecuador virus, for example, you don't need to adapt the tissue culture. You just need the genetic information from that virus and then you just take that genetic information and put it into this (adeno virus lecture) and now you have a vaccine against this new Ecuador virus.

So your turnaround time for making new vaccines could be greatly improved. And, again, it does not require an adaptation to tissue culture and does not require the growth of infectious virus to make the vaccine.

This is just one slide to show this is as effective as the current vaccine out there. Of course, it requires a high dose of vaccine. It's not a perfect product but it prevents transmission, so if you're having infected -- I'm sorry, vaccinated animals and non-vaccinated animals in the same room and then you challenge the vaccinated animals, these animals do not transmit virus to indirect contact animals in the same room.

So what I mean direct contact, so they're in the same room in direct contact and they do not get infected. So it is an effective vaccine that prevents transmission and, of course, prevents clinical disease. However, we don't know yet if it prevents carrier state. So we're working on that and it seems that it doesn't. It seems that these animals also become carriers just like they do with the normal current vaccine. So this vaccine addresses some of the issues that the current inactivated vaccine on the left column does not address and one of those is that it has very strong (viva) components, so you can have a number of diagnostic tests to distinguish vaccinated and infected animals.

For the first time, we can now produce a vaccine for foot and mouth disease in the U.S. This is historic. This is first time and this vaccine made, if possible. The vaccine is -- once you formulate it, it's actually very stable, unlike the current antigen vaccine.

This thing actually can last even in the refrigerator for a long time and under normal -- you can take the formulated product and freeze it and use it right away. You don't need to take it out of the antigen bank and send it somewhere else to be formulated.

This product actually has the potential to be used directly. And, of course, it would be compatible with the vaccinate to live strategy that I'm very happy to see (AVS) clearly stating now that that is one of the options because we have been advocating for the last decade as (ARS) researches come up with these solutions to these vaccination problems.

Now, there are issues. For example, the cross serotype protection, no. We don't -- this vaccine doesn't do any better than the current vaccine. You have to have one vaccine for each serotype and subtype that you want to protect.

So it solved a number of issues but not, obviously not all of them. There is an issue with potency, so it's an expensive vaccine to make. The duration of immunity we don't know yet. We haven't -- we will know after these 400 animals of vaccinated and they will be kept, by the way, through their natural cycle of production.

Some of them will be dairy cattle and they will be tracked and kept for years to come and we will determine and some of those -- we will bring a number of those animals back to (Plum Island) and we will challenge them six months, eight months, a year to see if we do better than the current vaccine in duration of immunity. We don't know that.

And we also will test them -- when we challenge them we will also test them for carrier state and, you know, we don't think that cross serotype protection is going to be better than we currently have.

Now, there are some improvement that we are doing to this vaccine. For example, we found that interdermal delivery increases potency. I don't know what (AVS)' plans are for delivery of vaccine, if there's going to be needle and syringes but we have very strong data that needle-free technology has actually induced much better protection with the current foot and mouth vaccine than needle do.

And we have transferred this information to (AVS) and we have published this data. Interdermal delivery increases the potency both of the current vaccine and also the antivirus vaccine.

The other thing that helps is if you do multiple sites. So instead of one spot in the neck, for example, you do four spots in the neck, you get more potent and we don't know what that does to duration of immunity yet.

We have also some (aguments). And I mentioned interferon as an (agument) and that's something I would mention. This is very exciting. And, again, it's cutting edge research in terms of preventing foot and mouth disease within 24 hours of vaccination, which is very -- would be a very nice thing to have.

Particularly, we're going to use these in the middle of an outbreak. So if you want to buy yourself some time while the judge signs the order to go shoot the animals, you might want to vaccinate them with interferon, for example. That will provide this very early immune response. So that's something that, again, is at the research level.

And finally, we're trying to improve the vaccine so it targets specific tissues. And the reason I mention this is because if we know that the primary set of replication is in the pharynx, can we target those tissues so that we can actually stop the virus right on its track at the primary site?

And if we can do that, we could prevent carrier state. Again, those are research question. They're not -- we don't have a product that will do that yet but we're aiming to improve our products toward that.

Okay, now I want to -- this is kind of a complex slide and has a lot of information but I just want to point to you that we can do better than just the way that vaccines have traditionally been developed.

The more we understand how -- and that cartoon that you see there with all those letters and numbers is the foot and mouth disease genetic information and that is how -- that's what makes the virus work.

And they have structural proteins and non-structural proteins. How each other interact and how they interact with the host cell and so on is very important. And one of the things that we are learning about and we're investing on is understanding which of these proteins make the virus do what it does, which of these proteins are determinants of virulence. And we found one several years ago. And we have found others, by the way but this is the first one we found called (liver) protein. And we know that viruses, if you take out these proteins, the virus can still grow in tissue culture, in cell culture but it cannot grow in animals anymore.

This is very important because it gives the opportunity to produce a rationally designed vaccine that now is accentuated. It doesn't make animals sick but it might be able to prevent infection.

So we're trying to identify these areas of the virus and try to engineer this into accentuated viruses that could be used potentially as vaccines. This is very promising research and we really need to invest into this.

For example, these (liver) proteins that I told you about, when you take that out of the virus and you make this virus -- and we make this virus in the laboratory several years ago and we infect animals, what we see is the virus remains only where that red area is in the pharynx. It doesn't go anywhere.

It doesn't cause disease. It doesn't go in the blood. It only goes to the primary site of replication and stops.

Unfortunately, this virus is so accentuated that when we actually go and challenge these animals, these animals are not protected. So it's a little too accentuated and we're trying to work with that. Can we make it a little less accentuated and make a vaccine out of this?

But I just wanted to share with you this because what we have done is to explore this technology as a way to make inactivated vaccine. So today vaccine is produced with this virulent virus that if it escapes or it's used (on inactivated) completely, which this is something that was brought up by one of you a few minutes ago about what's happening in Paraguay.

And in Paraguay it's not clear what's happening, so there are contradictory news releases where the veterinary authority says that it was a human error in vaccine production but then in the next sentence they say it was a human error in vaccine application, in vaccination, not vaccine.

So we really don't know. Is it possible? What they're talking about is the vaccine was poorly made and it was not fully inactivated and that is what caused the outbreak. It is possible.

And the current vaccine, that is a possibility. Of course, the good manufacturers around the world, they make sure their vaccines are killed before they sell them. But not all of these companies around the world -- I mean, you realize that foot and mouth disease vaccine is the best seller for the pharmaceutical industry around the world.

Billions of dollars of vaccines, billions of dollars in sales. It's number one. There is no other animal vaccine that makes as much money as foot and mouth disease does.

So there is a lot of companies out there. Some of them are not so good. And they can make vaccines that is not completely inactivated. So it is possible.

But most likely what's happening in Paraguay is that they did not vaccinate the animals they were supposed to and that's how the disease started. We really don't know. We need basically to see when the dust settles what the scientific information was behind the press release that was -- that came out yesterday. So but we did. So going back to can we do better for vaccine production? So we came up with this idea where basically we took this virus that doesn't grow in cattle because it lacks this one protein called (liver) and we took this (liver less) virus and we engineer it so that we could easily swap (capture) sequences.

So we can put any foot and mouth disease antigen into this virus with a very simple step in the laboratory and then we can derive virus out of that that we can grow in the subculture and make vaccine.

The other thing that we engineered into this platform is that we deleted some markers so that we can use that (unintelligible). So now we have companion tests, at least two of them companion diagnostic tests that we have transferred to (AVS) now and they are currently in the FADDL, the Foreign Animal Disease Diagnostic Lab (Plub Island). They are working on developing this companion test.

But the idea with this is that you can make vaccine very safely now. This vaccine, of course, is the same technology that we have today around the world. You basically grow this virus in subculture and then you kill it and you do all these other processes that I showed you before.

So it's no different than that. The advantage is that this virus for some reason escapes out of your facility, nothing will happen because it's not transmittable. The other advantage is that it has built in negative markers, so you don't have to spend a lot of money purifying the antigen. You can actually just concentrate it and use it. So it could improve and decrease the cost of production of vaccine. And it, of course, has this easy swap of (captive) sequence. So if you have a new virus like Ecuador, you can -- the same as the antivirus, you can make that sequence and put it into this vector and grow your virus vaccine a lot quicker.

Oops, sorry. Let me see how I (unintelligible). Okay, no (unintelligible). So we tested this and we actually made an activated vaccine using this technology and we vaccinated cows and long story short it's as effective as the current vaccine, no different.

You can protect 100% of the animals with one shot and, by the way, these animals are very easy to distinguish from infected animals because of these markers that we included that are lacking in the vaccine so you can test with very good diagnostics these viruses.

Now there are challenges out there for foot and mouth disease vaccine. So what I presented to you are some of the answers of the research answers that will require more work. But some of them are pretty close to a product like the (adeno), for example, is very close to a real product that is going to be license and hopefully used.

The other technologies are coming right behind it. But we need to, for example, to understand how come that you need specific serotype and subtype to protect against foot and mouth disease? Why can't we have broader vaccines?

And these are very big questions that have been tackled by very smart people around the world for many years. So we need to really put some man power -we have some good tools now. We have a lot of computer power, modeling. We can do a lot with three dimensional structure of proteins. So there is some promising research that we're doing right now on (Plum Island) in collaboration with other partners around the world like in the U.K. and also in India and we hope to bring some new knowledge to the table that may allow this broader reactive vaccine.

We also need to get over the six-month duration of immunity in the next generation of FMD vaccines. This is something we need to tackle particularly if we want to provide the world with vaccines so that they can use it for eradication.

I don't think every six months vaccination is going to be possible for many countries that have other priorities in human health, for example. And we also need vaccines that prevent persistence because that is one of the main problems with trade and you vaccinate.

Your trade partners want to know are you free of the virus or do you have carrier animals around the country that could pose a risk to me? And so they impose very strict.

So it's not just OIE guidelines in terms of so many months for after you vaccinate and control your disease. It's what your trading partners are going to say when you try to sell them animal or animal products.

So persistence is a big issue and we have some research ongoing right now both -- it's very difficult as you can imagine. We cannot keep animals at (Plum Island) for very long. Our animal rooms are in very -- you know, all the time. We need to turn them around quickly for the next trial and so on. So we're doing some of this work in collaboration with countries overseas, Vietnam, Pakistan at the moment.

Now, what other things are we doing? We have some very nice new technologies on understanding immune responses and we're using -- this is state of the art what is being used for human infections, detecting, for example, what is called the T-cell responses.

Again, I don't have a specific product to give you today but the information we're gaining from this research might help us understand the long-term immunity, for example. So that is something that's ongoing.

We also have these noble control strategies that I mentioned to you before that has to do with the use of interferon. This is work that we pioneered at (Plum Island), again, in the laboratory of (Marvin Grobman) and where he actually showed that if you administer interferon antivirus containing the genetic information of (person) interferon alpha to pigs you can protect them in 24 hours against any FMD serotype.

The beauty of interferon is they're not specific for a virus serotype or subtype or even for FMD. They can protect against other viral infections. But we do know that they protect against foot and mouth disease of different serotypes. It doesn't make a difference.

Now, the animals are not protected very long. They only last for three to five days. But guess what? If you combine the interferon with an antigen vaccine, then you get protection in 24 hours and after five, six days, the vaccine immunology -- I'm sorry, the vaccine immune response actually kicks in and now you have long-term protection.

So this is something that we want to do in cattle and we haven't been able to so far to do that because in cattle, well, they say they're bigger. Okay, maybe that is the right -- we don't know what the reason is.

We gave a lot of interferon to a cow and we have never achieved full protection. However, until very recently -- we recently found through bioinformatics -- and what that means is people sitting in front of a computer screen looking at the cow genome and finding new proteins and finding new information.

And what we found is that cattle have these interferon called interferon (landa), which is different than the other interferons that we knew about before, which were alpha, beta and gamma. Now we know this (landa) interferon.

Well, with that information, what we did is we put this interferon (landa) into the antivirus vector and then we vaccinated cattle with this and then we did, you know, different doses and so on and we combined it with interferon alpha, you know, what researchers do, trying to understand how this works.

And what we found was that actually -- and this is just, it's a complex graph but I will explain to you. It's very simple. The green bars mean clinical disease. So those are the days after challenge. Each one of those squares is a cow and the green bars mean the animal is sick. So you can see the top three animals in the top row, they all got sick very quickly after 24 hours after challenge.

The second group of animals where we actually had interferon alpha and interferon gamma -- I'm sorry, interferon alpha alone, we had this information

before, they also get sick. Some of them they have a little bit lower green bars, so they might have a little bit less infection but eventually they get very sick.

And the combination of the interferon didn't do very much. It delayed disease by a couple of days but the animals broke through by 48, 72 hours. But look a the bottom row.

The bottom row is actually interferon (landa) alone. And look at that. This is the first time we have been able to protect cattle. So now we have one interferon that can protect cows for up to four -- three or four days after one dose of this -- containing this new interferon.

So this is brand new. This is data coming right out of the open and we're building upon this. Can we combine this with vaccines and provide (AVS) with products that are not only induce long-term protection but also very quick protection so you can actually put the fire out?

So one of the things that we find is that you can gain more, instead of shooting the animals in a herd, you could vaccinate the animals, even if they are already infected. And we have shown that by doing so you drop about 99.99% -- you can drop four logs in shedding from animals, even after they are infected within 24 hours from infection.

So vaccination really I think needs to be at the forefront in the first line of defense rather than as the last resource. And we're strong believers in that. And so we're very happy to see that we're talking the same language with (AVS) and we're very supportive of that.

And when we talk about our larger mission in USDA, which is around the world, how can we help the world from the burden? And I didn't share this

with you today but we -- I can share this. I have a paper that I recently wrote, a review paper, where we actually look at the impact of foot and mouth disease and human health and human wellbeing is huge.

It affects millions around the world every day. And what we need to solve this issue is better vaccines, better strategies. And in doing so, in helping these endemic countries to control for the masses is we will learn a lot about this disease and it will help us if we ever have to deal with it in our own country.

So we're very strong proponents of this global approach to help develop better countermeasures to control foot and mouth disease globally.

All right, so I'm going to change gears. And I don't know how late I am but...

Donald Hoenig: We're...

(Luis Rodriguez): My next topic is ASF.

Donald Hoenig: Yes, we're getting tight here, I think, right.

(Luis Rodriguez): ASF and CSF are a lot shorter because we don't have as much.

Donald Hoenig: We've got like five minutes.

(Luis Rodriguez): Yes.

Donald Hoenig: Okay, go for it.

(Luis Rodriguez): So ASF is very quick. It's already been mentioned, very major threat right now in Europe. There is no vaccine available. So there is nothing. We have nothing. The world has never been able to come up with anything that looks even remotely effective against ASF.

The other thing is 100% mortality. If you're a pig and you get African swine fever, virulent strain from Africa, you're dead. There's no cure. So this is a big deal.

It's endemic in Africa. You can see that for many years it was only endemic in Africa. There were some incursions into Europe. There were some incursions into the Caribbean and this has nothing to do with pigs. ASF moves around the world in meat, meat products, swill feeding. It's not a vector born in domestic animals as we know it.

The way it will come to the U.S., if it does, is going to be through, you know, direct transmission into (pigs). It's (not) going to probably be in pigs. Now, once it's here, can it be established in the pig population? We really don't know.

But what is very worrisome is that it began in 2007 with an introduction of an African virus that came from somewhere in southwestern Africa and it came into Europe, into Georgia, and it's been there. It has not gone away. And, in fact, it's been going into Russia and if you look at the recent headline, this is yesterday. Seven more cases of ASF in Russia.

When Russia tells you they are in trouble about a disease, you should look at that. I mean, this -- and I think this is probably the product of the invasion of Georgia and I think those Russian troops when they came home they brought some gifts with them, some of which were hams and pigs and things that actually, I think, might explain the reason they spread throughout Russia so quickly.

And there's another headline from yesterday. I mean, they want to do something. Unfortunately, there is no vaccine. We don't know much about this virus. For example, we don't know what make a virus virulent. We don't know about the ecology, transmission, immunology. There is no protective response and we don't know why. Epidemiology, we don't know how important transmission is direct versus vector, huge gaps in research.

Now, fortunately for us, up until 2004, (ARS) at (Plum Island) had a very strong research program on ASF. In 2004, our budget was cut in half and we had to decide between ASF and FMD and we picked FMD. So this work was discontinued in 2004.

And but up to that point, what we learned -- and this is a complex little graph there but basically I will summarize for you. We have the best way of making (recombinant) ASF viruses in the world. Actually the only system that I know of that works is at (Plum Island) today.

And fortunately, at least one of the researchers -- yes, well, maybe two of the researchers that were involved in this work are still at (Plum Island). They have not retired or left (Plum Island).

So with this technology, what they did -- and this is work that was done in 2004 -- they found one of the genes -- and it's a huge virus, by the way. It has 190,000 bases compared to foot and mouth disease is only 8000 and see how much trouble it gives us.

So imagine this is 190,000 nucleotide long genomes. It's very big. It has a lot of genes, a lot of proteins. But they found this one protein called (9GO) that if

you delete that from the virus through this (recombination) the virus actually becomes accentuated.

And they did this and this is -- you don't need to see this. But this is very important. What they did is then they made this for different viruses from (mallowed) (unintelligible). So these were diversity of some of the African swine fever viruses in Southern Africa and what they found is that you can achieve protection of pigs with this virus.

So you inject this mutant virus that lacks the (9GO) and then you challenge with the (wild type) virus of the same serotype or different -- they are not serotypes. They are called groups. But the same group or different group. And you see that there is homologous protection.

So the (mallowed) virus, defective (9GO) virus protected against the (wild type mallowed). The (tingani) protected against (tingani) and all the (RSA), which is South Africa viruses, they all protected against its own group.

So this is important because this is the only, again, this is the only paper published in the literature where we have been able to show anything that looks -- and I'm not saying this is a vaccine. This thing, you know, we don't know those pigs if you vaccinated with this mutant are going to grow two heads. I don't know that.

It's not a vaccine yet, okay. You need to all the process of developing a vaccine. But it's the best candidate vaccine in the world today.

And before I go into that, I want to -- CSF -- I want to say that we have obtained some funding from DHS, Department of Homeland Security, to actually look into this vaccine, pick up where we left in 2004 and we're investing into this trying to rebuild some of the research program that was discontinued in 2004.

So I don't have a vaccine but we have the best candidate in the world today is what we have.

Now, the other thing I want -- and just in closing is classical swine fever. I know it's a concern for (AVS). You can see, if you look at the outbreak reports, you can see there is a lot of outbreaks in Central America. There are some in the Caribbean. There is a lot of sausages and things that are being tried to smuggle from those areas into the U.S. Thankfully, (AVS) has been, I guess, now is border control, customs, has been very effective at stopping this.

But it could happen at any time. And what we have now is a vaccine actually that has, is a promise candidate -- promising vaccine candidate that has two features, has two (viva) markers, so it has a positive marker, so you can actually, when a pig is vaccinated with this vaccine, it's called flag. It will make antibodies to this flag.

And then when you test it with a number of (unintelligible) test or so and you can find which animals are vaccinated. This is important, for example, for wildlife. You're going to vaccinate feral swine and you want to know the effectiveness of your vaccination in pig population, you could use this test.

And then, more importantly, it has a negative marker which is (viva) test, so you can differentiate vaccinated from infected animals.

There are very effective vaccines around the world against classical swine fever. The problem is none of them has differentiating infected from vaccinated animal. This is going to be the first vaccine with such characteristics.

Now, we engaged in a transitional research with a private partnership. Actually, we're engaged with the largest animal vaccine production in the world today in developing this product. This is a long process. We started about a year ago.

But we're making progress and we hope to have effective vaccine with a marker that could be incorporated into the National Veterinary stockpile in the next few years.

And our strategy for countermeasure development is we leverage (our time) with the other agencies, (AVS), DHS, so we're not going at this alone. We work with international partners as well. We engage industry. We engage regulatory authorities early on, so to make sure what we're developing will make sense and will be useful.

And we also, of course, want to engage National Veterinary stockpile so that they know what is coming down the countermeasure pipeline. And I guess -funding, we don't know for FY12. FY11, this is what we had.

Most of our funding from USDA is spending in paying our people and we depend for our materials and supplies from (soft funds). And we've been very successful. We get about 50% of our funding now from external, non-USDA funds.

And I have to thank several agencies but DHS is the first contributor to our (soft funds) but also big time for (unintelligible) board is making big

contributions to some specific things that they want to know, both in ASF and foot and mouth disease and as well as Welcome Choice and others.

So with that, I'd like to end and take questions, thanks. Sorry for going too long.

Donald Hoenig: That's all right. That's great stuff. Thanks, (Luis). We can probably have a couple of questions. I mean, this research is, as you can tell, is the only place in the world where this kind of stuff is going on I think on (Plum Island) and I think it's also very expensive because doing research on large animals takes up space and it's not using mice, you know, or even chickens. You've got to use big animals.

So, yes, take a couple questions. (John).

(John): (Luis), thanks for that information. In view of the recent eradication worldwide of (render pest), is there room for optimism regarding a potential eradication of foot and mouth disease or are things just too different epidemiologically and also immunologically as far as the vaccine end of things goes?

(Luis Rodriguez): Yes, we've had some conversations with FAO and others on this subject and, unfortunately, no, it's very different. (Render pest) is very easy compared to foot and mouth disease.

> First of all, there was a live vaccine that protected against all (render pest). There is only one (render pest). And it was a live vaccine, which induced very strong life long protection. We don't have that for FMD.

So the complexity of foot and mouth -- I mean, I could elaborate but, no, it's -we're optimistic, as we always have to be, but it is a huge, huge task to control FMD globally and eradicate.

Donald Hoenig: (Howard).

(Howard): Hi, Dr. (Rodriguez). With the (adeno) vector virus vaccine, can you give a second dose or is the animal immunized against the (adeno) and it won't replicate? So how do you handle that?

(Luis Rodriguez): Our marching orders, when we developed this vaccine was a vaccine for emergency use. And the animals that will be vaccinated will be killed. That was the march in orders back in 2004 when we began this research.

> This vaccine is designed for that. The animals, when you vaccinate them once and then you vaccinate again, the antibodies against the (adeno) would prevent the response to the FMD.

> So it's not a vaccine that is going to be helpful to India or China. You know, it's a vaccine for emergency use. You vaccinate and that's it. The animals are -- they could be kept alive for their production cycle but if there is a second outbreak and they need to be protected against foot and mouth disease again. They will have to be used either in other serotype or antivirus, which there are, so there are others out there, (adeno two, adeno 32) and so on.

> Or they will have to be vaccinated with another vaccine. So it's an emergency use vaccine.

Donald Hoenig: Other questions? (Cindy).
- (Cindy): The interferon, how do you give that, aerosol or it could actually be sprayed on feed or what?
- (Luis Rodriguez): You know, we're not giving them interferon. We give them the genetic information and the animal makes its own interferon. So the (adeno) contains the sequence of the interferon and when you give that to the animal, the animal actually makes it.

So, unfortunately, we haven't tried any routes other than intermuscular so far. We kind of like this transdermal delivery and we have tried it and it looks really nice.

The cells that actually make interferon, a lot of them are right underneath the skin, so it would be very nice to have a delivery that would go right into that. Same goes -- is true for the antigen, for the FMD vaccine. So I don't know. John, is there a transdermal delivery plans on National Veterinary stockpile? I'm not familiar with that.

- John Clifford: (Unintelligible).
- (Luis Rodriguez): Yes, yes. And we have data for you if you want in cattle as well on FMD vaccine in cattle using that technology. So I believe it's either published or will be published soon. So I can provide that. I think that's very promising. Sorry, longer.
- Donald Hoenig: Okay, well, thanks very much, (Luis). That was fascinating. We're going to take a break. It's 10 after, so let's take 15 minutes, come back at 25 after. Okay, great.

If people could come back to their seats, we would want to get started here. We're ready for next presentation. So please take your seats. We're going to get started.

- Woman: I'm going to get the phones back on, okay. Operator, we're ready to begin recording again.
- Coordinator: Thank you, one moment.
- Woman: Thank you.
- Coordinator: You may go ahead.
- Woman: Thank you very much.
- Donald Hoenig: Okay, Tom, this is Don Hoenig. I apologize that I don't have a suitable introduction for you. But maybe I'll let you introduce yourself if it is Tom DeLiberto. I see (Tony).
- Tom DeLiberto: It is.

Donald Hoenig: Okay. Maybe you can introduce yourself to the group. We're here in D.C. This is the Secretary's Advisory Committee on Animal Health. And Tom DeLiberto is going to talk about wildlife disease surveillance and emergency response and I know he works for Wildlife Services. So why don't you go ahead, Tom?

Tom DeLiberto: Thanks very much, Don. I hope -- I think RJ has assisted us with my presentation through WebEx, so I hope this is a suitable forum given the situation of the fact that I'm in Ft. Collins. And I'm in Ft. Collins because I

serve for Wildlife Services as the National Wildlife Disease Coordinator for Wildlife Services National Wildlife Disease program. And our headquarters for that program is located here in Ft. Collins, Colorado.

I've served in this position now since 2003. Before that I was with the Wildlife Services Research Unit, the National Wildlife Research Center, which is also in Ft. Collins.

My background is I'm a wildlife biologist. I also have a range science degree and I'm also a veterinarian. So I think I've been very fortunate to get a variety of educational background and that's really, I think, provided me with the opportunity within (AVS) to really evaluate some of our wildlife disease surveillance activities as it relates directly to animal health.

And that's kind of what I am going to talk about today is give you a brief overview of the USDA (AVS) Wildlife Services National Wildlife Disease Program and how that program interacts with not only state agriculture and natural resource agencies but also universities and other federal agencies working in animal health.

Am I coming through okay?

Donald Hoenig: Yes.

Tom DeLiberto: Okay. All right, so with that, I think I'll just move right into the presentation. I have a relatively short presentation and hopefully there will be some time then for discussion and questions for me as we move through this.

Just a brief overview of disease surveillance as it relates to primarily livestock and wildlife, there's some major differences that sometimes are apparent and sometimes they're not apparent.

For example, some of the basic things that we require some knowledge of in disease management is often very difficult to get in -- or at least for wildlife populations.

In livestock situations, we generally, as you know, we have a captive animal population for the most part. That allows us to get a good estimate of denominator as opposed to the wild populations where it's very rare that we have a decent estimator of our denominator factor.

And so sometimes some of the simplest disease parameters such as prevalence can be much more difficult for us to obtain in wildlife disease management.

So the picture on your left, even under range conditions in the western United States, we're often able to round our animals up and get a pretty good idea of what the total population size or herd size that we're interested in as opposed to the picture of snow geese on the right where this particular case -- picture I took from a lake, probably a 1.5 acre lake in Nebraska, these birds (flushed).

And you can say even when you're looking at a very, very small area, size of a restricted geographic area -- in this case, 1.5 acre lake -- it can be almost impossible to know how many animals you have on that.

So just an example of how some of the simplest things can be very difficult in wildlife disease management.

Also, the question or the point of authority of management can also be much more confusing in wildlife. In the case of livestock, usually you're dealing with a resource that's individually owned and there is very good coordination -- relatively speaking, there's really good coordination between regional and federal and state agricultural authority and even to some degree international authorities.

However, with wildlife, we're talking about a public owned resource with mixed regulatory control, consisting of multiple state and federal agencies and even when you look at those state and federal agencies, that can be a combination of natural resource agencies, state agriculture agencies or federal agencies.

They've got military -- federal military properties and lands that have some authority over access and so forth, Native American lands as well as some of the public health agencies under certain circumstances have exerted authority over disease management and even wildlife management.

So even from a regulatory standpoint, wildlife disease management can be a very, very complicated matter compared to what we see on the agricultural side of the fence.

There's many validated diagnostic tests available and oftentimes, from an agricultural standpoint, we think that we still don't have for many disease very good and validated diagnostic tests. But actually from an agricultural side, we're very fortunate compared to a wildlife side.

There are very, very few diagnostics for wildlife. Usually what we end up doing is applying diagnostic tests that have been validated for certain livestock species and applying them to wildlife and often don't even really have a good idea of the simplest things like sensitivity and specificity for those tests in the species we're looking at.

And then sometimes we actually do do validated tests. We do do testing to see if we can validate diagnostics for wildlife. We'll do it on one species -- for instance, a mallard -- and then we'll assume it's the same for all wild ducks or even all wild birds. And we know that, you know, that is essentially like saying, you know, if we had a validated test on a (Hertford) cow that we could take that test and run it on any ruminant species and assume that it's validated.

Oftentimes if you're not in the field of wildlife, (even) wild birds or wild ducks is all the same and that couldn't be further from the truth, no more so than it would be for any of our domestic species.

And finally, there is many, many more vaccines available and they have much more practical use than what we see available for wildlife. So, again, on the left, clearly we have the vaccines and when we want to administer those vaccines to domestic animals.

The normal way we do that is through some type of injection, hand injection. In wildlife that's pretty impractical and we have very few vaccines that have been proven efficacious in wildlife and when we do, not only do we have to develop a vaccine that's efficacious in a particular wild species, but then we have to deliver -- have a mechanism for delivery because it's really impossible under most circumstances to actually capture and administer that vaccine to a large enough population to have an affect on the disease prevalence in that population.

And so on the right, one of the best examples we have is the rabies vaccine that we use for foxes, coyotes and, in this particular case, in raccoons where not only did we have to make sure that the -- develop the vaccine, conduct the efficacy trials on the species of interest.

But then we had to develop a delivery system that could deliver the vaccine in a way that would make it not only available to the animals but also efficacious once they ingest -- in this case, ingested the vaccine.

And so, in the case of rabies, we tend to sue aerial date drops where we fly large portions of the country and drop these bates out of aircraft and they're formulated such that the matrix that's around the vaccine is palatable and has a high preference for the target species of concern.

And then we've got to hope that either we know that the vaccine doesn't adversely affect non-target species or we've got to develop a bating system, then a matrix that targets only the target animals and not the non-target species.

So it's a very, very complicated and much more expensive endeavor than simply developing a vaccine than can be hand injected.

So wildlife services works in these realms as a partner primarily with our other sister agencies in (AVS), in particular Veterinary Services. And while we often view ourselves, Veterinary Services and Wildlife Services as (AVS), it can be confusing to many people that aren't familiar with our structure.

And so I thought I would just spend a couple of minutes just highlighting some of the differences and some of the similarities between the two agencies. What makes us very strong from an animal health perspective is that we have both wildlife and veterinary services in the same infrastructural unit, meaning (AVS), the same agency. And we also have research capacity on the wildlife side, at least within (AVS). And those can be very strong advantages in the sense that we have fewer difficulties moving funds, for instance, across our programs to address problems.

So in the past, this has been things like avian influenza and feral swine diseases and chronic waste and disease. And it's really been -- it's relatively simple to move those resources and even people back and forth between our agencies to manage a disease.

Now, we do have obviously some differences and, clearly, in Wildlife Services we focus on wild animals. And so our workforce is primarily wildlife biologists. We do have, I think, four -- I think there is three or four now veterinarians in Wildlife Services, however our main focus is wildlife biologists.

As opposed to Veterinary Services, which focuses on domestic animals and clearly the main workforce in Veterinary Services is veterinarians. In Wildlife Services, we have our primary cooperator are the state natural resource agencies, at least at the state level they are.

However, we have a fair amount of MOUs and cooperative agreements with agricultural agencies. Historically, Veterinary Services is focused on the state agricultural agencies. However, in recent years, they've done a tremendous job of expanding those focuses to also work directly with some state natural resources agencies.

Obviously, since our resource wildlife is publicly owned, our public tends to focus more on hunters whereas on the agricultural side, our cooperators are primarily farmers and ranchers.

And finally, although Veterinary Services does work with some public health agencies, we tend to focus -- in Wildlife Services, we tend to work more with (zoenotic) diseases and public health agencies, things such as (tuberinium) plague -- and we'll talk a little bit about these in a little bit.

Those have been big focuses for us, not only when they overlap with agricultural agencies but purely from a human health standpoint. And so we work very closely with many state public health agencies as well as the CDC and FDA, for instance.

So we're similar in, you know, a lot of ways. We have a common focus of managing and protecting the nation's animal health resource but we also have some differences that when we bring them to the table we can -- it makes us stronger and actually increases our ability to handle disease and really in a more comprehensive one-health standpoint.

Most recently, in (AVS), Veterinary Services, International Services, Animal Care and Wildlife Services just completed a draft, a business plan for how all four agencies then can move forward in the next five to 10 years with improving how we work together on managing diseases in wildlife.

So a little bit more on our program, in Wildlife Services, we focus primarily at the animal human wildlife -- domestic animal human wildlife interface. We've been doing that since the late 1800s. We actually were an agency that was created partly in response to protecting -- primarily in response to protecting

livestock from predators at that time and that actual mission has continued right through the 20th Century into the 21st Century.

But one of the other reasons we were created in the early 1900s, we had a big focus on plague. And so we tend to do a lot of plague surveillance and management way back in the 30s and 40s.

And it wasn't until the late 80s where we started to expand that focus into rabies management and created the National Rabies Management Program and then in 2003, that all culminated with the creation then of the National Wildlife Disease Program within Wildlife Services.

And the goal of that program is to facilitate development and implementation of a nationally coordinated wildlife disease surveillance and emergency response system specifically for the purpose of protecting wildlife population to agriculture (to) human health and safety.

So this is where we brought in all three of those resources that for the last, you know, 100 plus years we had already been working on from various aspects and have brought that mission in more -- and consolidated in this program into a disease mission to protect all those resources.

We do that primarily through an inverted pyramid kind of a structure, which is a little bit unusual in this day and age for at least a federal agency, if not many state agencies.

And what I mean by that is that the reason why I'm showing this as an inverted pyramid is because we really focus on our field folks and what we call our wildlife disease biologists that are located in our state offices and that's very traditional within Wildlife Services.

We have traditionally been a bottom-up agency rather than a top-down agency and, frankly, that's worked very well for us. It does create problems for us as well. That focus tends to be very different from other programs within (AVS) as well as the federal government.

And so oftentimes we find ourselves having a difficult time relating to policies and directives that come down from the top when we're trying to fit that round peg into a square hole, which is our bottom-up approach.

But I think we've done it pretty successfully to this point. That's -- those state wildlife disease biologists then are located in our state offices and then everything down below is what's here in Ft. Collins, so we have staff biologists and our administrative staff is here in Ft. Collins.

We have two assistant coordinators in this office now. We went from three to two more recently and then myself, who serves as the coordinator. So what we ask these state wildlife disease biologists to do is to primarily lay us on with the Veterinary Services offices in their states, also to lay us on with natural resource, agricultural and public health agencies, state agencies and also other state, tribal and federal agencies that maybe relevant.

And we ask them to assist these agencies in accomplishing disease surveillance and control and their particular disease surveillance and control objectives.

So one of the primary functions of our wildlife disease biologists is to go out and lay us on with you all, many of you, and try and help you accomplish your disease surveillance goals as they relate -- as they focus primarily on that public health and domestic wildlife interaction, that part of the disease equation.

At times, we can help out. For instance, with (BFC) in Washington, for instance, there was -- we -- these are wildlife biologists. They know very little about livestock health. They're not (unintelligible). However, many of them grew up in rural communities and have experience working with animals, including domestic animals.

And we were able to provide people to the state and to Veterinary Services in assisting and handling cattle in which -- and working those cattle to get them to the veterinary in a safe manner in which they could conduct their activities.

So while we focus on the wildlife and the public health aspect, we also can assist on purely livestock or agricultural interest well.

One of the other things we do is we conduct national level disease surveillance programs. And we try not to duplicate other programs that might be in existence and we'll talk about some of those.

Where we focus is in areas where we see that there hasn't been a lot of emphasis. So, for instance, we've got a national plague surveillance program, a national (turinius) surveillance program, national feral swine surveillance.

We don't go in and conduct, for instance, national or even regional or local surveillance programs for avian botulism and water fowl. That's clearly something that the state agencies and the Department of Interior have a long history and established programs in. So we look for areas that we might have expertise and could provide something to contribute to the overall wildlife disease surveillance activities in the U.S.

And the last thing we do is emergency response. And we have a fairly extensive background with responding to not only disease outbreaks and assisting state and federal agencies in agricultural or even wildlife disease outbreaks but we're all hazard responders. Our folks are all trained in, you know, hazard response and I'll talk a little bit more about that in a bit.

So where are our field people located? Well, in 2007 we had just about a wildlife disease biologist in about every state. Unfortunately, with recent federal budget constraints and cuts, we've really had to cut back on the number of folks that we have employed in the program.

And so, in 2007, we were at 44 people in 43 states. We're currently at 33 people in 33 states and likely we'll bring that number down significantly over the next 18 months as directed through Congress, the President and our Secretary.

But we still continue to have a very active program and in -- fiscal year 2011, which just ended, we conducted disease surveillance or management programs on over 75 diseases, syndromes or toxins. I've listed some of those here.

In red I have emerging or foreign animal diseases that we've conducted programs in this past year. In yellow are diseases that are agriculturally -- are of agricultural concern and really how many of these overlap categories. I've listed them as what was the driving factor that caused us to get into these types of surveillance. So while obviously the (unintelligible) can be a (zoenotic) disease, its main driver for us conducted with surveillance is not necessarily (zoenoses). It's agricultural health.

The (zoenotic) diseases, I've mentioned plague and (unintelligible) but also swine influenza virus and hepatitis E in (unintelligible) and in feral swine. We had food safety concerns. We've worked a lot in California dealing with the Ecoli 0157(H)7 as well as (triponela) toxoplasmosis in feral swine.

And then finally, we do work in some -- what would be traditionally characterized as wildlife diseases such as chronic wasting disease and (EHD). So a large number of diseases that, even though we decreased our workforce and our budgets are decreasing, we still try and provide some significant contribution into the overall agricultural and wildlife disease health surveillance and management programs in the U.S.

We do most of these activities primarily through collaboration and communication. There's very little and I'd be hard pressed to come up with any disease that we don't collaborate on with another agency or program.

I've listed a few up here. Clearly Veterinary Services, we've mentioned is a big collaborator but also the National Animal Laboratory Health Network. And we started really working with the (NOM) system with our (High Test AI) early detection system but have since expanded that into swine -- comprehension swine health programs as well and look forward to opportunities to work more closely with the (NOM) on other diseases.

On the wildlife side of the fence, we've got, you know, one of our big collaborators is the National Wildlife Health Center at the USGS in (Madison) but also (unintelligible) in Athens and I think (John Fisher) is there. You're probably all familiar with his program down there.

But we try not to overlap with the things I have listed here. Some of the things that they are clearly expertise -- have a lot of expertise in, we try not to overlap with those as best we can. And when we do overlap, we try and work with them.

So, for instance, in -- we just started a (unintelligible) national surveillance program in raccoons and some other species. And clearly some of the folks at (unintelligible) have had some very good background in that and so we try and identify those experts and work directly with them in collaborative approach rather than trying to work independently of them.

As a couple of examples to what we just -- what I just mentioned on collaboration, communication, clearly I mentioned (Hi Path AI). This was a huge endeavor that really required -- the first time that required many of our agencies that are in this meeting today to work together on a national scale.

And I think that this is a shining example and it was the largest wildlife disease surveillance program that was ever initiated. Not only did we do it within the U.S. but we coordinated those efforts with Canada and Mexico for a complete continental scale look at what -- whether (Hi Path AI) was entering the country and, if it was, where and, even if it wasn't, we learned and we continue to learn a lot about how what we know about low path AI viruses and how they might cause some risk to domestic poultry.

Another one that I've mentioned, the feral swine disease surveillance program, this is a comprehensive, really an example as the AI is a one-health kind of surveillance program. I've looked at the name diseases in that program that we conduct surveillance for in feral swine and we do that directly with Veterinary Services, primarily some state agriculture agencies but also some natural resource agencies at the state level.

We work with (unintelligible) on mapping those -- some of those diseases -the locations of those feral swine populations. We work with the CDC on swine influenza as well as Veterinary Services, hepatitis E.

We work with the NIH and also the FDA as well as E-coli, (tripinela) and toxoplasmosis with (ARS) and Veterinary Services. And so this is a really good example of how in this case a feral species really can have potentially large impacts on a broad diversity of interest groups and not only from an agricultural damage standpoint and a property damage standpoint but from a disease standpoint as well.

I think my computer just locked upon me. Oh, let me go back here. So I mentioned emergency response is another big function that we do and we recognized in 2003 that if we were going to have an emergency response capacity we needed to have dedicated personnel and equipment.

We had to have the right training. We had to have increased interagency communication and cooperation, that our agency had to be really flexible and we had to coordinate really well, not only amongst ourselves but across agencies.

And I think we've done pretty well. We've used our disease biologists as our first responders. And so those field disease biologists that I mentioned, they get -- they're our first responders, so they have annual PPE training,

respiratory fit test training. They have HAZ (unintelligible) training, which is required to go into oil spills and other chemical spills, for instance.

They have ICS training. They do that annually and we practice it. When we don't have emergencies to respond to, if a state -- for instance, like Michigan or Minnesota where we've had TB and they needed help conducting surveillance for TB in their wildlife, those state agency folks would call me and say, you know, we could use 10 people during this week in November.

I would kind of keep that pretty close to the belt here in the Ft. Collins office and then a couple of weeks before, even a week before they needed folks in those states, I would mobilize those folks -- I would mobilize some of our disease biologists from everywhere, even Hawaii and Alaska.

I would pull them in from and give them very short notice to actually get their arrangements made and get in the field and assist. And so that's one way we use to stay mobile.

We learned with (END) in 2004 that, you know, (AVS) hadn't had to respond to a major FAD introduction in over 20 or 30 years and one of the things we recognized and learned from was that when you don't respond over a long period of time, you can have a whole workforce that has never responded to an emergency and never realized that it was their responsibility to respond.

And so we keep our folks very mobile in that sense to try and keep it in their forebrains that we may need them to move. And, you know, if they've got cats at home, they need to find arrangements for someone to take care of their cats because that's not a reason why they cannot be mobilized.

These are some pictures and the top three are of our folks in the deep water horizon oil spill. We mobilized over 80 personnel over a four-month period to assist in identifying where birds were oiled or dead. And times we -- if they were alive, we rescued those animals and brought them to rehab facilities.

On the bottom right, we have our emergency response trailers. These are mobile labs with (necropsy) tables that can do some basic disease testing. But primarily they're (necropsy) facilities and we have three of those -- there are three of these spread out across the country that we put in the field during an emergency disease operations.

We also work in international capacity with our sister agencies at (AVS) and over the last four years we've worked in close to 40 countries around the world on various topics from AI to West Nile virus to just a variety of things.

Probably our newest activities are in the area of African swine fever and we work with Kenya and Uganda in Africa on that and are beginning a project in Ukraine on African swine fever.

But we tend to -- where the stars are located is where we actually have surveillance programs, those countries in which we collaboratively work with those countries to conduct surveillance or management.

The other areas where there's no stars -- and those countries are colored -- we don't have disease surveillance activities but what we provide is training and capacity building to those countries to help them develop their own surveillance activities in wildlife.

So that's a quick overview. I wanted to just identify some future challenges that we're all up against, in particular, Wildlife Services and our disease program and that's really one of those challenges being prepared for the next disease (dojoure) and whether that's a foreign animal disease or an emerging or reemerging domestic disease.

I've listed some up here. You can probably list others that you would be concerned -- particularly concerned about. The trick is how do you maintain a mobile integrated workforce during times of, you know, fiscal restrictions that, you know, are able to meet and maintain some type of (infrastructure) to meet those needs?

That's a huge challenge for all of us, not just with (AVS) but across all our agencies during these times. You know, I'll throw it out there. We rarely mention this but, you know, there's -- and publicly we rarely mention these things but probably one of the biggest challenges for us, not only across livestock or agriculture and wildlife but also within our fields, especially within wildlife.

You know, there's a lot of urgency in (unintelligible) turf, a lot of territory. And many times those kind of turf battles really interfere with our abilities to work together and get the job done. And oftentimes it takes us a huge emergency like (High Path AI) where Congress is concerned, the President is concerned, the public is concerned.

It takes something like that for us to break down some of these barriers and I think we all need to work harder at breaking those barriers down now before the next disease (*du jour*) comes.

Budgets, obviously we can go on on this. You all face the same thing in your programs. But in our case, some of our major funding line items, influenza,

tuberculosis and swine disease surveillance, all of those things have been decreasing rather rapidly.

In the last three years, we've experienced over a 75% reduction in our budget. We've reduced -- in our disease program, we've reduced our workforce by 52% just within the last two years and we will probably reduce it in half again in the next year or two.

So having maintained an infrastructure capable to meet these challenges of disease emergencies and in those kind of -- face of those kinds of things and what I means in my mind is that we just need to work harder then to collaborate and not let those turf battles interfere with that collaboration.

And of course, one health is where we're all going and I'll throw my two cents in here finally on one health and while this is a tremendous concept and one that we all would agree, I think, that is a place that we need to be as far as health management but for all of that and for all our needs and all the attention this has been receiving, I still do not see how we are moving fast enough in that direction.

We still view one health from our own world. You know, everything we do is viewed from our own perspective and we really need to start moving away from that and when we start talking about a disease program, we really need to be from the perspective of not worrying about how it affects us, our agency or our interest groups but look and start thinking about how it affects other agencies, other interest groups.

That should be the starting point and then coming back to how it affects us and how we integrate into that bigger picture. Until we do that, one health really won't be one health. We'll all view it from our own perspective. And when you view a problem from your own perspective, the solutions will be based from your own perspective and that's a big challenge for us I think in the future.

And so I'll leave it there and if anybody has any questions, I'd be happy to answer them.

- Donald Hoenig: Thanks a log, Tom. Any questions for Tom? Seeing none, okay. Well, thanks a lot for visiting with us today, Tom.
- Tom DeLiberto: Thank you all and if you have any questions, most of you probably know me, but if you don't, RJ can provide my email address and contact information.
- Donald Hoenig: Great. I think we're going to get copies of all the PowerPoints from the various speakers this morning, so thanks, again.
- Tom DeLiberto: Okay, Don. Thank you.
- Donald Hoenig: So long.
- Tom DeLiberto: Bye.
- Donald Hoenig: It's lunch time.
- Woman: Before you go, I just want to, for the record, reference the presentations. All the presentations will be on the (APHIS) Web site—through the Secretary Advisory Committee link and each committee member will receive them via email. Okay?

Donald Hoenig: Great. So let's try to be back here about 10 after 1:00? (Genell)?

(Genell): I have a quick question. The last speaker, when he was talking about (Plum Island) and the research being done, are we going to try to put forth any motions regarding that before the day is over with?

Donald Hoenig: That's great. I'm glad you brought that up because what I'd like to do is we have TB framework down for this afternoon but I'd like to revisit both of those presentation before we go into the TB framework this afternoon. So, (Luis), are you going to be with us for questions?

And maybe Darrel has left but so and, yes. So let's revisit both of those this afternoon when we get started, okay? Thanks.

- Woman: Operator, we're going to break for an hour for lunch and we're going to resume at 1:10. Hello? Operator?
- Coordinator: One moment.
- RJ Cabrera: Operator, we're ready to resume.
- Coordinator: Thank you. You may begin.
- RJ Cabrera: Thank you.
- Man: If people would take their seats, we can get started again. They never do. All right, we're going to start anyway. I think the order of business for this afternoon is there's a lot of time for the committee to have discussion and deliberation which is good.

We had some great presentations this morning and I wanted to start out the afternoon before we launch into the discussion of the TB framework to just revisit what we heard about this morning and find out if there're any recommendations that would come out of this morning's - other recommendations (to) come out of this morning's discussion.

So I'll open the floor.

(Judith): I decided to work through lunch again, along with (Jag) and a couple of others along with me and worked up just something I'd like to put for the committee, you know, for discussion and wherever it goes. This will be the committee recommends the secretary prioritize research on animal health, specifically the development of vaccines and other countermeasures for diagnosing and treating foot-mouth-disease and other foreign animal diseases rather than relying on animal depopulation as a first line of response.

And (Kay) I can give you this. Thank you having to...

Man: (Judith) could you put something in there along with the treatment because the vaccination's not going to be a treatment to prevention somehow you want to control prevent some other word in there maybe in addition.

(Judith): Diagnosis prevention and treatment because I think I had diagnosis and treatment. Okay add in prevention into that list or preventing whichever would be the appropriate.

Man: Comments.

Man: I certainly support the prioritizing of those things. I would prefer language as opposed to rather relying on to adding them to the tools at our disposal.

Man: Yes. I agree just as a state animal health official I'd realize that we may have to use the foot depopulation if we're the initial herd in the first state and that probably is going to be the first line of defense.

I don't think there's too much discussion of that. It's if we're the tenth state and the 1000th herd or the fifth state in the 20th herd then what happens?

Now that's not what we're all not really clear on it at this point I don't think, but.

So I would agree with (Boyd).

(Gilles).

(Gilles): I think, you know, I helped a little bit on the wording of this resolution or recommendation. And I think our intent is that, you know, we view it that there'd been a process.

Ten years ago depopulation was the only consideration, all right?

And now I see that, you know, there's been evolution in the thinking and also the capabilities of how you're going to respond to foot and mouth disease.

And, you know, hopefully if there's a priority and it's a, you know, the proper funding is made in the research and development, you know, a vaccination program would then become really the first line of defense, right? So it's not a question of, you know, recommending that a foot and mouth disease happened tomorrow have an outbreak that, you know, depopulation wouldn't be a consideration.

But if the research was getting the funding that it needed, maybe then depopulation comes off the table completely.

Man: I guess I wouldn't be comfortable with that position because the decision to depopulate or the speed with which we reduce the existence of a disease is driven in a good part by our excess international markets. And I think that is a consideration.

The Secretary certainly cannot through research or other prioritizations manage to get us access to markets that's going to take an OIE and a world move to do that.

So I think that we're merely a production disease or even a fatal disease of animals that would be different than diseases that are going to have such an significant impact on our access to international markets.

Man: Why don't we just take off that first line of response because depopulation will be the first line of response.

That's not needed. Vaccination and all that's a secondary step.

(Judith): And perhaps - I'm not sure what wording so I'm going to sort of think out loud for a moment if you don't mind about the reasoning.

To be honest - I mean personally I'd rather see vaccine than depopulation. My animal I will fight for that for my animals. Absolutely.

I also understood and anticipated (Jack), you know, this isn't there wasn't going to be agreements at on this Committee that geez we should vaccination instead of depopulating.

What I'm hoping for and what I'd like to if I can figure out the right words or you can help me figure it out is it's not just adding it as another tool.

I mean I'm very grateful what I've heard today is finally we seem to have gotten to some vaccination and treatment options as another tool in the tool chest. And I'd like to try to push the level of priority.

Not saying necessarily absolutely you vaccine rather than depopulate every time because it depends on the circumstances what that happened with the outbreak whereas what's going on.

But to create some sort of greater emphasis to continue the direction of looking into this more, emphasizing it more, that was the intent.

Man: We're talking about the...

((Crosstalk))

Man: ...foreign animal disease not just foot and mouth disease. And we've got foreign animal disease we don't have vaccines for.

So, you know, to I'm - if you heard what was going on they're putting a lot of emphasis on developing better vaccines, more effective vaccines, vaccines that don't allow the virus to shed and things like that.

But, you know, Plum Island's been there for a long time. I've been on Plum Island. They've done research on foot and mouth disease for years and years and years.

And it's not like next year they're going to have the magic bullet. We cannot take the tools that our regulatory officials have out of their hands not that this Committee has that power anyway.

But, you know, we just need to - I'm all for encouraging it but to say that that's going to be the first line of defense vaccine for foreign animal diseases, you can go ahead and make the recommendation but I'll tell you what, it's going to fall on deaf ears.

Because that's not going to be the case. If you have a single herd outbreak which could happen and it hasn't spread, I don't care how big the herd, where it is, or what, it's going to get depopulated because just like (Chuck) says we're going to - it's just as important to try to protect international markets.

Ad if it's a if it's in the middle of Texas and it's affected tons and tons of herds, a lot of cattle, that's a different situation.

But as he said today, as Dr. (Styles) said, you know, none of this can - you cannot plan all this ahead of time. You can make - you can do the planning, but every case has to be handled individually because we don't know where it's going to be, we don't know what disease it's going to be.

So I just would not be comfortable supporting something where we say, vaccines got to be the first line of defense.

(Judith): For (Genell) first. I think she went out sorry.

(Genell): I've got something I want to say in response to what (Howard) was saying.
And I understand that vaccines won't always be used even if they are
developed maybe not used completely at least not at this point because they're
not - it's not a perfect situation.

But what I will say in talking to Dr. (Rodriguez) is that up until a few years ago, the research that was done at Plum Island regarding FMD was just basic research and it went in to publishing papers.

And what his real push has been is to take it beyond that into the vaccine development and finding the vaccines that will work.

And so what we want to make sure is there's priority given to providing whatever tools are needed money or whatever it is so that they can take it beyond just the research is being done and publishing a nice little paper and making workable vaccines that will work to handle classical swine fever, African swine fever, and FMD.

Man: I would in response to that. First of all they've had foot and mouth disease vaccines for years. They've had stores of vaccine granted not the development that we have today.

If we want to give support to vaccines and vaccine development, what we need to do is we need to look at the funding of Plum Island. Did you see those numbers?

What \$3.8 million was their budget, I mean it's a - we would lose \$10 million a day for every foot and - that's what the estimate's been for every foot and mouth disease day that goes by. If we want to do something about this we need to get behind this support for Plum Island and for the new Plum Island in Kansas, you know, rather than worrying about arguing about whether it's the first line of defense or not.

(Genell): What I'd like to say on that is what Dr. (Rodriguez) shared with me is the manner of funding that China is spending and the staff that they have to deal with FMD.

And we are what they're like three billion and we're like 3.8 million that's kind of where we're at.

And that there's significant money being put into the new facility in Kansas and that facility can't study, can't do research on FAOs. So they're not I don't think they're doing - not the live animal studies with it. I don't think they are.

It's but what I'm saying is, is the research is actually going on at Plum Island but they're not getting enough money to do what they need to do.

Man: If you've ever been Plum Island it's an embarrassment. I mean they got water dripping through the ceiling onto the lab benches. It's an absolutely embarrassment.

It's an antiquated facility that's very, very high cost to run. We finally got, you know, funds to do the assessment. I don't know, (Liz), you know more about this than I do.

But the facility in Kansas will be able to do foreign animal disease research. That's what it's all about. (Genell): But we've got two more years at Plum Island. It...

Man: Unfortunately you're right and, you know, the question is how much money do you want to put into a facility that needs to be blown off the map, you know.

(Genell): I don't know but ten years can make a big different on whether we have FMD or not in the country, you know.

Man: Right.

(Genell): Ten years can make a big different into whether we have FMD in the country or not.

(Judith): I'm sorry I think (Gilles) has another comment I wanted to try to shift it.

(Gilles): (Howard), I hear what you're saying about the funding issue and maybe we could work out something because one of the most disturbing trends that I've seen in this country is the steady de-emphasis of publically funded research.

With the expectation that the market somehow is going to respond. Well, you know, the market's only going to respond when they see a quick profit. They're not going to put the basic research in.

And what we'd like to try to do is draft something that says that it should be an emphasis to put in the funding levels necessary to accelerate this line of research.

And perhaps you've got some wording that you can...

(Judith): All right my problems there. So here's the thing. If someone else has managed to come up with wonderful ways to rephrase this please say so.

But I'm staring at it and I can't come up with the phrasing that would make me happy and, you know, satisfied some of the counters.

So what I might say is, I think I want to prioritize to stay in there. But put a period just after other SADs.

It sends the message that we want to prioritize, you know, these things for preventing, treating, and diagnosing foreign animal diseases.

Which places the emphasis at least to somewhat on saving the animals rather than killing them. But it doesn't create a comparison to the issue depopulation.

It's just pure delete after the period. Sorry.

- (John): Don.
- Donald Hoenig: Sorry, (John).

(John): Go ahead.

Donald Hoenig: Just like to agree with (Kathy) there. It's exactly the edit that I would suggest because the actual management measures are going to be the result of a risk assessment albeit a fairly hasty one under less than desirable conditions.

> So and those management decisions are far out of our hands so I think that that one sentence just sums it up quite nicely.

Man: Sorry (Andy). Go ahead.

(Andy): One of the things that I want to point out when we look at motions like this and some of the ones we looked at yesterday is that USDA's going to have one pie to slice up and every time we say somebody's slice ought to be bigger we're taking away from other ones.

So, you know, all kinds of folks from US state can come through here and explain what they do and we're going to think it's important and needs to be supported, but every time we do that we got to think about the other one's that we're not seeing and what we're doing to their piece of the pie.

Man: It's a great point. That's probably one of the reasons why we are probably staying away from recommending amounts because, you know, yesterday we talked about the (NAHLM) \$30 million.

Well if we recommend \$30 million then you're absolutely right. The Committee says, spend \$30 million on the (NAHLN) what are you going to take it away from.

So yes. I think with this - yes we maybe having some recommendations here that tell the Secretary to prioritize a lot of things, but at same time we're - the Committee is taking a stand on this and saying we've heard these presentations we realize it's very important.

We said this morning we realize - I forget what the recommendation we came out with this morning after (Darell)'s presentation, but we said, keep going in that direction. And they have been, I mean, we're seeing some real progress here. We weren't talking about vaccination five years ago.

Some of us were, but, you know, I mean some people were in at least was working on it but now we've actually come - USDA has come out publically and said not only are we looking at vaccination we're looking at - you heard Dr. (Clifford) say this morning prophylactic vaccination.

And people have been saying for years, why can't we vaccinate for footmouth-disease?

Well there's a lot of reasons why we can't right now, but I've hard that - the second time I've heard this once in Buffalo about a month ago and then this morning prophylactic.

Of course it depends on the risk, but if there are cost effective vaccines for FMD that can cover a bunch of (serum) types then maybe someday we will vaccinate for FMD just like we vaccinate for (BVD) and IBR and (PI3).

We're not there yet, but we're talking about it.

(Judith): (Unintelligible) (Andy), you're absolutely right in terms of, you know, in terms of there's a limited pot of money. And that pot's shrinking and I completely agree with you.

For myself I can say that I don't have the budget in front of me and therefore I can't here's whose pot I think this should get yanked from and it might be hard to get that agreement within this Committee.

But for myself I can say, you know, I know what I personally and my stakeholders think even before I heard this presentation. This presentation gave me specifics.

But as in general saying, you know, the message my folks keep saying over and over is we want the ability - we want the government's focus to be -USDA's focus to be on how do we prevent these diseases from happening in the first place?

How do we treat them? We don't want to come up in this situation where we've got mass depopulations. And so both the (NAHLN) finding this morning, you know, this type of proposal I'm encouraged by what I heard and it certainly informed how I phrased this and how I approached it.

But the basic here's the, you know, priority one frankly from my perspective this type of let's come up with a preventative and diagnostics and treatment.

Man: And with that being said, I'm not sure we got - and I hate to be picking on a word here and there, but I'm not sure we're saying really what you're wanting there (Judy) because when we think about prevention.

Prevention of a foreign animal disease is not necessarily related to vaccine. And when we're talking about prophylactic use it would be in the face of an outbreak where you would go in and prophylactically vaccinate or treat animals.

And when we're talking - the way I read that prevention that's more referring to the border control and that sort of thing and I'm not sure that sends the right - and that's not under the (Baileywick) of view of (APHIS), right? That would be - that's under the Department of Homeland Security which is actually under (APHIS) is under now.

Right, or what - DHS, yes. So are we really asking to put more money into border control and customs and that sort of thing or are you trying to support Plum Island here?

That would be question I'd have. And I think what you're trying to do is support Plum Island and we need to change the words if that's the case.

(Judith): I think that prevention can take multiple forms. Prevention's certainly one aspect of prevention. One aspect of prevention is border control and I realize that's beyond the scope of this Committee and therefore I'm not getting into it.

> I do think, you know, we included the phrase vaccines and other countermeasure because there are, you know, rapid diagnostic test. Actually technically that's not a prevention on one hand. But on the other hand in some ways it is.

> If we can diagnose where foot and mouth disease is and immediately and that for instance I don't have it or my neighbor does have it, that informs how the response happens in preventing the spread of it.

> So I mean you're right that prevention can have different meanings. I think in this context it does have a meaning and I'd like to keep it there.

Man: That's mine my only. That the session started by talking about vaccines about (unintelligible).

And you're right prevention can cover a lot of things but if the group is interested in supporting and getting more support at Plum Island for vaccine development for foreign animals diseases, I think we need to state that more clearly.

Now I'm not sure. I'm not trying to say that that's what everybody agrees to, but that was the discussion we had before we started trying to...

Man: We could put at the end of it and in particular Committee supports the ongoing research in these efforts at Plum Island Disease Center.

Man: Don.

Donald Hoenig: Well there are some other locations where some foreign animal disease research is done. And although we obviously - Plum Island is at the top of the list, I wonder if we couldn't just - wordsmith it and the first line to prioritize foreign animal disease research.

Specifically the development of vaccines and other countermeasures for preventing diagnosing and then to further wordsmith it.

I'm not sure like the word treating as much as maybe a word like managing or controlling.

Because we're implying treatment of individual animals there and I'm not sure that's going to be possible or appropriate.

(Judith): I'm good with the first change certainly, but I mean I'd rather see us put controlling, you know, as an addition to treating because in some cases treating will be appropriate.
I mean we're not saying - I mean by definition especially since we're not talking just about foot and mouth disease here. I'm not trying to say that every single disease foreign animal is going to have a vaccine and other countermeasures that prevent it, treat it, diagnose it.

You know, it's - we've already agreed that we're talking about decisions that will have to be made on the disease-by-disease and case-by-case basis.

So I'm happy putting controlling it or managing it as an additional term. But for some of these, yes, treatment's going to be appropriate.

Man: (Judith) if I may. I would suggest that treating more than implies it states the fact that we're going to tolerate the persistence of a foreign animal disease in the United States and I think that would be intolerable.

So I don't think treating and the acceptance of the persistence of a foreign animal disease in the US, which is no longer makes it a foreign animal disease would be appropriate.

Man: What about doesn't controlling also include treatment? So if we took out treatment and left, you know, you might not like this, but if you took out treatment but left control.

To me control implies there might be some treatment in there. I mean (Elsie) was talking about (interferon) today and, you know, maybe some technologies come forth in the next three to five years that are promising in that regard.

So if we left controlling in there maybe it would be - well let's go ahead.

(Judith):	No I didn't mean to cut you off.
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((Crosstalk))

Woman:Could I speak to that for a minute? So in a veterinary community controlling
would potentially imply treatment if treatment was justified or appropriate.

So I'm also support changing that term.

The other thing I think we leave that research a short shift by not saying development of vaccines and other I'll figure out the word but something like immunomodulation tools or something because interferon is part of what they're doing and other - yes, there you go. Thank you.

We don't want - there's more to look at than just vaccines and thank goodness they're looking at the whole spectrum because they've make like you say huge strides.

(Judith): I think this may be as close as we're going to get to agreeing on it. I mean soI'll accept this stuff that's, you know, highlighted as being sort of acceptable as the group resolution.

I don't think I want to - I prefer to take that last sentence out about the support so ongoing research efforts at the Plum Island Disease Center.

You know the research - yes there's a lot going on at Plum Island. There's stuff going on elsewhere.

To me the point isn't supporting the facility as it is the concept that there needs to be publically funded research happening.

Man:	Gee I'm okay with that being taken out. Since I suggested it. So I'm pretty easy going.
	Somewhat.
(Judith):	Okay. So we have a new highlighted version. Let's see what we think.
Man:	So there's no further discussion.
(Judith):	I'll move that the Committee recommend as written.
Man:	Second. (Chuck) second.
	Further discussion. Good discussion. It was. All those in favor signify by saying, I.
((Crosstalk))	
Man:	Oppose same sign. Any abstentions. Motion passes unanimously.
	Okay, good.
	Anything else on this or on wildlife that wildlife disease topic?
	Hearing none. I think we can probably change focus to TB framework and (RJ) distributed some copies of the TB framework or the TB, yes, framework bullet points that you've all seen multiple times but now they're right in front of you.

So I guess I hadn't really looked at this topic in great detail other than when we sent it out.

So as far as how we work through it, you know, we can start from the top and go through the bullets and then see how far we get.

We - I mean we have most of the afternoon to do this till we take public comments at four o'clock. Correct?

So what's your pleasure? You want to stat on the first page, topic TB framework or tuberculosis framework enquiry.

We have a - we kind of - all right. Why don't let's start (Judith) suggest we start with topic TB framework the half page one.

(Judith): I think it was drawn from our last call so (unintelligible).

Man: Yes. So the first one is Committee may recommend that the (indemnify) calculator would include a loss of production, special genetics, breeding, collateral expenses of replacement.

And, you know, that kind of rolls into the, I think, the last bullet on the next page, which is the issue of indemnity in a context of the TB and brucellosis framework.

And (APHIS) is really specifically looking for comment on the use of a calculator to valuate animals in the need for an appeal process.

So, you know, maybe we can fold in the whole discussion of indemnity those two bullets, which are very related right now. (Chuck).

(Charlie): To mind those two topics. (APHIS) has made the statement most recently I heard it at US Animal Health Association that there is no expectation that there will be a replacement value placed on animals that are depopulated or indemnified that that probability is gone.

When I see this term calculator I'm not sure how that would be different than an appraiser. So if we're talking about an appraised value I'm not sure how that would be different than a calculator.

I don't understand basically what that term means when they say calculator in the communications. I don't know what it means.

((Crosstalk))

(Charlie): The cow is worth this many dollars? Is that what that would mean?

Man: Yes I believe that there's a table that would for dairy cows or swine or poultry there are certain tables that are used to, you know, if you have a four week old feeder pig versus an eight week old feeder pig or a one day old chick versus an 18 week old pullet, there would be various values.

I know in the avian influenza outbreak in '83 in Pennsylvania, there were calculators that were used from indemnity.

So, you know, a 45 week old laying hen was worth more than a 72 week old laying hen because of the potential for production that she had.

So while that's not really replacement value it is acknowledging the value of a hen at that age versus one at 72 weeks old.

Same thing with a pig, you know, although it might be different with a pig because an eight week old pig might be worth \$50 bucks and a five month old pig might be worth \$120, I'm not sure.

So it - but that's what I think. I see as a calculator.

What I'm not sure how the - and where an appraiser comes in I think is where you have registered stock.

And then you have - I'm not sure the calculator includes that. I know when we did this in England when I was there the commercial dairy farmers had and the sheep people had a calculator that was online and everything and you could look at.

But if they were pure bred then they brought in an appraiser. And we sat down at the table with the people and we came to an agreement. And it wasn't actually in a table but it was a back and forth.

(Charlie): I'd seen the figures that the economist at (CEAH) has put out and I don't plan those to be unreasonable. They use most current market value or most current market information when they calculate those.

> And if that's what the calculator means and I would - I don't see any problem with that, but I do think there's going to be need for an appeal because as you said they do establish for instance a current tuberculosis program has two different prices for pure bred and grade cattle and for dairy and for beef, etcetera.

So I don't see any problems with that as a base value, but I think there's going to have to be room for an appeal.

Man: I agree with (Chuck) I think the calculators are excellent to have and like Don said in swine and poultry in most cases they apply not all have the advantage of there's a generally accepted by the government you know, it's immediate.

> If it's in that chart it's good enough for you can go, but I'm not comfortable either with saying that's the end of the options if you have extenuated circumstances which often arise it's going to be awful hard to do a calculator on cows.

It works better in commercial swine and poultry.

So and where do we stand on the appeal? Didn't their last version recognize appeal again? We've been working on that awhile or is it still up for debate?

Man: I'm not sure. Is there anybody that knows?

Man: National Assembly took the position there should be provisions for appeal but.

Man: We don't have any for USDA (APHIS) subject matter experts here. Go ahead.

No decision's been made? Okay. Thank you.

(Judith):I was just going raise one more factor, you know, I don't know if we're going
to get to try and suggest factors that should be included in appeals.

But one of the factors that we run into in our type of farming the small scale diversified farming is often the productive life of our animals is longer than they are in the (cafes) situations.

So for instance what made me think of this was Don's comment about the difference in productivity between a 45 week old laying hen and a 72 week old laying hen.

You know, many of our folk's operations have four and five year old hens that are still productive layers, you know, that's not the situation, you know, in the commercial lots.

And so, you know, if we're going to get into the sets questions about what factors should be considered on appeal, the difference is in productive life is a very big factor for our folks.

RJ: Don I'd like to mention that Dr. (Thomas), (Leann Thomas) did say that the Committee could submit questions after your meeting today if we're unable, you know, there's some outstanding issues.

They did have a conflict of some sort. So if you guys wanted to gather additional inquires we could certainly push that out.

Donald Hoenig: Okay. (John).

(John): (Since) RJ just mentioned a possibility of raising some questions. And I bring this up mainly just to make a mention about it. We talk about indemnification of privately owned animals that are destroyed.

And we're also talking about surveillance of free ranging wildlife around facilities where TB is found in domestic animals.

And there's for historically been no consideration for indemnification for the destruction of those animals, which basically have to be killed to be tested.

Now if there were an oil spill or release of some type of gas and wild animals were victims of that as they have been in the past.

More commonly we'd probably see that with fish. There's I would hesitate to call it an indemnification but there is some type if enumeration for those animals that are lost.

And this is something we've brought up over the years particularly when we talk about, you know, like a response to foot and mouth disease if it's necessary to destroy a large number of wild animals in an area where they're in fact or believed to be disseminating a disease agent.

It's something I just kind of wanted to point out here and not to make a specific recommendation, but I think perhaps if we can ask questions one might be is indemnification or enumeration for the destruction of publically owned animals under consideration?

(Judith): (John) can you clarify for me who you'd see as being the beneficiary of that enumeration? I mean what I'm familiar with is when, you know, Exxon oil spill Exxon pays the government not for resources damages, but...

Man: And we would be talking about the government so it would probably be the State Fish and Wildlife management Agency that has the authority for managing and conserving those resources. Man: So we'll put that down as a question? All right.

Do we have questions on the appeal process or do we want to make a - and the calculator or do we want to make a recommendation on the appeal and calculator or the appeal?

The only issue is that I think there ought to be an appeal, but it ought to be quick.

It can't be dragged out in court. So the way that I see the appeal is the producer brings in an appraiser of their choice. The government brings in their expert and they try to work it out.

And if they can't then the way I see it is that the producer may end up on the short end of that stick. But I've seen the way it's operated in a couple of emergency disease outbreaks and it has to be quick with high pass avian influenza it's got to be immediate with FMD, it's got to be immediate.

And in most cases there have been fair indemnities that I've seen that have been paid to producers for pure bred animals.

And in the UK the commercial calculator was more than fair in my experience.

(Max): Excuse me.

Man: (Max). Next.

(Max): I would guess that they chose (goal) if, you know, they cannot resolve to get a two and a court appraisal to remediation. And I seen that to be done in Washington.

And it worked very well I think.

- Man: Can it be done quickly?
- (Max): Yes, sir.

(Judith): I guess the thought I had of looking to you and this is the lawyer in me coming out.

Is I hear what you're saying about the need for quick action unfortunately if it is a situation where the government decides on depopulation and it's determined depopulation needs to happen quickly, I don't know that the discussion or the appeal over the value has to stop because the animals have died.

I mean I don't know that that certainly it's relevant in deciding on depopulation what sort of valuation would have to be paid, but I don't know that the producer's ability to defend their view of the value of their animals should be cut off when the animal dies.

So we, you know, the appeals process doesn't have to be tied to the event.

Man: And that is a legal question. I know that and the limited number of indemnities that I've done we need to have assigned form. I don't know what it is but there's an acceptance of the appraisal that's signed by the owner in order for the government to issue a check and take the animals.

	Without that I always have been under the impression that the government can take the animals and would still pay for them, but I don't know whether what the challenge could be after that.
	It's a legal issue. I can't - I don't know the answer to
(Judith):	And it's not my field of expertise. I can't say, but just that sort of a general approach, you know, I think that it could be possible for the government to say, okay we have to (do the) depopulation now.
	The producer says, I refuse to accept this valuation and the dispute over the evaluation continues after the depopulation.
Man:	And as I understand I think you just correct it. Could occur that way but limited experience would say USDA's current policies.
(Judith):	I don't like that.
Man:	You don't like that?
Man:	Well we may not have to get into that level of detail in a recommendation other than we could make a recommendation that some sort of appeal process be outlined in the framework.
	And that provisions be made for animals of high value and differencing circumstances based on different production systems.
	So that, you know, we just are recommending that there be some process put in there for appeal.

Man:	Yes I think I agree with that. And, you know, their policies would probably change if we were dealing with a disease like foot and mouth. And when you're dealing with TB you can sit on the herd and talk, but.
Man:	So you got that actually, didn't you, (Kay)? Wow.
	Okay. Other - it's I mean I just threw that out there, but I think that I certainly would be in favor of the Committee recommending some sort of an appeal.
	Go ahead, (Wood).
(Wood):	One minor thing isn't this framework cover both TB and brucellosis and do we need a limited for TB?
Man:	I think it does, doesn't it?
(Wood):	So wording wise we may want to broaden it
Man:	Yes.
(Wood):	for (unintelligible) and
Man:	TB / brucellosis.
(Wood):	With that appropriate correction I'd be happy to make the motion.
Man:	Okay. Is there a second? Second by (Cindy). Okay.

Man:	Don. Does that clarify that this motion imply the support for a calculator or is that a separate issue in your eyes?
Man:	That's a good clarification.
(Judith):	I'd say it just doesn't say anything either way.
Man:	It doesn't say that they're against the calculator but as long as the calculator process includes appeal in addition to. It doesn't oppose a calculator.
	It opposes it as a final solution without having view of appeal.
Man:	I haven't seen a whole lot of heartburn about a calculator. But I have seen a lot of heartburn about some sort of appeal.
	I don't even know whether we need to say that. That the end there, (Kay) about the, you know.
(Judith):	Yes as part of the discussion.
Man:	(Gilles).
(Gilles):	Just word smithing stuff. That provisions be made for valuing animals of higher than average market value and for consideration for differences in production systems.
Man:	Yes. More edits? Any other discussion? Going once, going twice.
	Okay all those in favor say - oopps. Sorry.

Oh good one.

Yes, good. Okay. Good. Thank you. All those in favor signify by saying, I.

((Crosstalk))

Man:	Oppose same sign. Any extensions? Motion passes unanimously.
	Okay. Good.
	Check off indemnity. List. I like making check marks. All right. The next one on that half page there should the Committee recommend use of approved feed lot facilities where TB affected herds could still market calves with a price differential.
	(Max).
(Judith):	Microphone.
(Max):	Excuse me. I think it's a really bad idea it goes against all our principles. I believe, you know, that should not be allowed.
	That's my personal opinion.
Man:	Could you explain that (unintelligible)?
(Max):	Well we should be raising and having and fostering animals that they are sick somehow, you know, I really think that it should not be allowed.

(Charlie): I imagine that I'm probably the one that made that suggestion and that is because the difficulty that a herd owner has during that quarantine time is marketing their calf crop, that's their production. That's their source of income.

Those animals the vast majority of those animals will not be infected but are affected by the disease existing in that herd of origin.

So there - they either have to be destroyed or put through a marketing process and developed as a protein source.

And if we do not have approved feed lots to control the potential for those animals to expose other animals that could reenter the population then I think we're going to have a very negative impact and without depopulation and indemnification for the calves the owner's going to have to expect those cattle to be marketed, fed, and put through a (harness) process.

So there's no way. We currently do have - we do not have quarantine feed lots because of a phrase in the brucellosis regulations.

We have approved feedlots. And I think we need to assert the necessity for those potential outlets when a herd is affected.

The herds in Minnesota in the TB affected area of Minnesota did not have to deal with the market issues on their calves because the state indemnified those herds and they also indemnified all of the production of those non existent herds so long as that area's under quarantine.

But in Michigan they can go to approved feedlots because the state's not depopulating the herds.

(Judith): So (Chuck) can you explain what's the different in between the status quo and what you intended with this with this idea? I'm trying to understand if we already have approved feedlots. Is there a difference or are you just saying you're looking for support for that continuing that practice? (Charlie): The only place we have approved feedlots in the present time is in Michigan. Man: Okay so if... (Charlie): And that's because the disease is endemic in that five county area in Michigan. With this process in using a decision matrix on depopulation or test and removal we're going to have herds are going to be maintained for the prediction is currently two years or three years or less but in reality the herds have been under quarantine for five to eight years. That's a long time for those calves to have to fight for a place on the market. And if there's no approved feedlot they can't go to a regular commercial feed lot. They cannot because they're quarantined restricted animals. So I think we need to specify that we do need those facilitates as an outlet to keep those herds variable that are under quarantine. Man: (Max).

(Max): I would like to see if somebody can tell me an estimated number of animals that will be infected that way.

Man: My recollection is the most recent diagnosed TB affected herd in California was 4000 head or 6000 heads. Does anybody remember?

Man: It was big.

Man:It was big. Assuming it's 6000 head that's 3000 steers a year because they'renot going to spend money on sex semen for a herd like that, (Max).

And that's just one herd.

(Max): Do you think it will be economic or feasible to keep facilities going if only those number going to be affected?

(Charlie): Approved feedlots are managed under the jurisdiction of the state in which they're located. And they meet specific standards for assuring that the animals that come in under quarantine are accounted for and they leave and they're terminal animals and they do not provide exposure to any animals that would go back in to the general population.

So it does not limit that facility's operation to those calves only.

It merely restricts - no it does not restrict. It merely specifies how those animals are handled when they come into the facility, how they're accounted for, and how they go out. It does not affect the facilities of business or does not prevent them from receiving other cattle.

When brucellosis was a highly prevalent disease we had quarantined feedlots in nearly every state.

Every state that was not brucellosis free and that made a very manageable process for marketing the calves. But with our system where every state in the US is now brucellosis free they are forbidden by rule to have a quarantined feedlot.

A quarantined feedlot cannot exist in a brucellosis free state.

So a brucellosis affected herd on this market as calves can castrate the males, spay the heifers, but a TB affected herd does not have that advantage.

(Judith): So and I'm sorry (John) I just want to ask (Chuck) to make sure I understand what this is.

So the problem seems to be that what we're in a situation critically as most places are brucellosis and TB free that you still even in free states will occasionally get a herd, you know, and they can be a very big herd.

And so long as the free status is maintained the owner of that herd is put in just an unattainable position.

So what you're suggesting I think is that we take off that restriction, allow these quarantined feedlots to exist even if state is disease free status and therefore, as things come up they can be managed? (Charlie): I think approved feedlot might be better than quarantined feedlot, but yes that's effectively to establish a potential for the outlet of the production from a herd under a test and removal agreement with US government because of tuberculosis. Man: (Gilles). (Genell): (Genell). Man: Oh (Genell). Sorry. (Genell) go ahead you were first. (Genell): Okay so there's that say my farm comes down with TB or something in North Carolina. And there's not an approved facility there in North Carolina. Then what would be what are you foreseeing as the recourse? Would those animals be approved in a locked trailer to be able to be shipped to the feedlot to this approved feedlot in another state or they're not going to be allowed across state lines? So since North Carolina doesn't have any cases of TB, therefore, I don't really have an option if I come down with TB. Man: Currently exposed animals move in sealed vehicles. (Genell): Okay. So a lock and (unintelligible). Man: There's, you know, there's a set of seals and documentation that...

((Crosstalk))

(Genell):	And they can cross state lines?
Man:	They do now.
(Genell):	Okay. I wasn't clear on that.
Man:	Yes, ma'am they do now.
Man:	(Max)?
(Max):	Do you know I'd really wonder how economically feasible will be to maintain a herd of cattle, you know, feeding them for a long period of time. I think it will be cheaper, you know, there quickly, you know, than keeping it there for a long, long time.
	Look at the price of feed.
Man:	I think the issue is that the government isn't going to pay indemnity on these large herds anymore. There isn't the funding there. So you're going to have herds - correct me if I'm wrong, (Chuck). But you're going to have herds large herds that are going to be under test and removal for period of many years, correct?
(Charlie):	I would say, yes.
	The last projection I received from USDA on discussion on this topic they feel that with their depopulation - with their matrix that determines depop or test and removal, they feel they can TB affected herds out from under quarantine in less than three years.

But I can say from experience that is not what we found with TB affected herds.

In a herd that has one reactor in 6000 cows, we might want to bet on a year or two that we're going to come up clean.

But a herd that has ten reactors out of a hundred cows I wouldn't agree with that and if that hundred cows happens to be a pure bred herd where the indemnity's high the matrix may choose to deny the - no the matrix doesn't make a decision.

The matrix may suggest that depopulation's not the best way.

Dr. (John Fischer): We recently had this situation with a dairy in New Mexico. They - and I say recently. It's probably a five or six year - is a five or six year where they opted to test out. So they had a certain amount of steer that need to go to an approved feed yard.

And that approved feed yard was set up in such a manner that there was a there was a section of that feed yard for those steers. And it was isolated from the rest of the feed yard. And I think that's kind of what we're talking about here.

But that was a test out situation where that dairy took five or six years to test out. And it would - you would have had to have that option of an improved feed yard for those steers to go somewhere. So that's a scenario that just - it will come up and especially, you know, in a dairy situation, you know, this is a 4000 head dairy. In a dairy situation that's a lot of steer case every year that we have to do something now if it's a test out situation, which we're going to see more of because we have less money to depopulate those dairies.

- Donald Hoenig: And that's what you're talking about (Chuck) right?
- (Charlie): Yes.
- Donald Hoenig: Yes. (Gilles).

(Gilles): Is it appropriate for us to recommend to USDA to have approved feedlots all over the United States or is that primarily a state by state issue? If it is a stateby-state issue, what would be appropriate for USDA to do is to develop the standards for what an approved feedlot is?

- Donald Hoenig: (Chuck) do you have an answer for that. And I would think they would need to be where they needed to be, not all over.
- (Charlie):My thoughts would be that in the TB/Brucellosis Rule that there be a
provision and specifications for approved feedlots. That's what I'm asking for.
- Donald Hoenig: That's his recommendation right there. You got that?
- (Charlie): We currently have that.
- Donald Hoenig: Okay. Got that wording.
- (Charlie): In the TB UM&R we currently have that in the Brucellosis uniform methods and rules on how we do that. But I've not seen that in the TB/Brucellosis Rule. While that may be a detail, that could be that deal breaker we were talking

about earlier. If there's nowhere to go with the calf's production, then I can't tolerate quarantine.

Dr. (John Fischer): And I think the - I think the guidelines for an improved feed yard are probably already there. They already exist. So that's not something we need to be concerned with.

- Man: Make sure that (unintelligible).
- (Charlie): I think they just need to be incorporated in the TB/Brucellosis Rule. That term and that condition (Charlie), that's what I believe. It needs to be specified in there because if it's not said, then it didn't happen.

Donald Hoenig: So you got it (Kay) almost. Just need to combine those two kind of phrases or combine that last phrase in with the first sentence. That what you're talking about (Chuck)?

- (Charlie): Will do.
- Donald Hoenig: Second?
- (Charlie): Right.
- Donald Hoenig: (Charlie) second. All right. Discussion? No more discussion. All those in favor signify by saying Aye. Aye.

((Crosstalk))

Donald Hoenig: Opposed same sign? Abstentions? Motion carries unanimously. Great. All right. A checkmark.

Woman: You like your checkmarks.

Donald Hoenig: I like them, yes. It means we're making progress. All right. Should the committee make a recommendation which defines wild animals as captive once captured? Status of the animal once released without identification, are they no longer regulated? How are diseases managed in those animals being trans-located?

I have a feeling that Dr. (Fischer) might have some input on this.

Dr. (John Fischer): With respect to current tuberculosis regulations, free ranging (cervids) are regarded as captive as soon as there's a rope or a fence or a trailer around them. So they fall under the tuberculosis regulations that way.

Once they are released, they are again under the authority of the state Fish and Wildlife Management Agency with possible exception of some situations where they would be on federal land or under the management of a federal agency.

So they are no longer under the authority of for instance APHIS, which has the authority when we're moving animals interstate. They are more or less permanently identified on an individual basis as they go through this process.

So this was kind of an issue that I discussed privately with Don yesterday that - regarding traceability these animals although we heard from (Neil) the traceability rule applies only to farm raised animals while the (cervids) that are captured for translocation on an interstate basis fall under the TB program rules so they're covered that way. Is that clear as mud? Woman: Quick technical question and forgive my ignorance. Would (cervids) include some of the exotics or not?

Dr. (John Fischer): Well we're referring here to wild animals and the exotics there could be wild exotics.

Woman: They get out and are...

Dr. (John Fischer): Yes. Yes.

Woman: ...(unintelligible).

Dr. (John Fischer): I prefer to call them (fair) over exotic.

Woman: Okay.

Dr. (John Fischer): But I think what they're...

Woman: Exotics that aren't still captive.

Dr. (John Fischer): I think the question her pertains to free ranging native wild animals. And then the last question there, how are diseases managed in those animals being trans-located? Those animals that are trans-located are handled generally speaking under protocols that are developed by state wildlife agency and animal health agency officials.

> So an example, this past year would be the capture of wild elk in Kentucky and then translocation to Missouri for release. And there's a health protocol developed by the Missouri Animal Health both Missouri Department of Agriculture and the Missouri Department of Conservation with a long list of

disease agents that should be tested for and there is hopefully background information on the populations of origin of these animals as well.

So it's something that's taken into consideration and certainly just like livestock producers these agencies have no desire to introduce a disease into their native wildlife populations.

Donald Hoenig: Do you have any draft language for a recommendation?

Dr. (John Fischer): I don't and I'm not sure that we need one because the animals are covered under the TB program rules.

Donald Hoenig: Okay.

(Charlie): (Unintelligible).

Dr. (John Fischer): Right.

- Donald Hoenig: Use your mic (Chuck). Yes.
- (Charlie): My comment was that the TB/Brucellosis Rule is going to replace all of our existing rules on TB and Brucellosis. So those program standards would no longer exist and have to - they're going to have to be redeveloped under this rule apparently.
- Dr. (John Fischer): Okay. I wasn't aware of that. I assumed that since we were told yesterday the TB program rules or the individual disease program rules would apply would preempt the traceability rule. We would...

- (Charlie): But the TB/Brucellosis Rule is that specific disease rule now that they're proposing. Thank you sir.
- Donald Hoenig: So would you want to make oh well I was just saying would you want to make a recommendation that the TB/Brucellosis framework give consideration to the status of wild animals once they become captive within the framework within the rule or something like that. Is that what you're essentially what you're asking?
- Dr. (John Fischer): Sorry. Again this is something that's worked out I the states of origin and the states that received these animals. So they would look upon anything that we would develop here as potential guidelines for them. But ultimately just if they were coming to Maine, it would be you Don who was deciding on what kind of hoops the animals need to jump through...
- Donald Hoenig: Yes, they wouldn't be.
- Dr. (John Fischer): ...for them to get there. But I could work on something here instead of...
- Donald Hoenig: All from Kentucky? No.
- Dr. (John Fischer): ... free thinking some language.
- Donald Hoenig: Yes. I'm sorry. (Gilles).
- (Gilles): Could you address or give us an idea of the situation with bison particularly the state of Montana they've been capturing quite a number of bison every year keeping them in confinement, testing them for Brucellosis and then some of those bison have been redistributed to other parties, some of them private parties.

So there's a lot of concern among the producers in our region about these animals kind of going into a captive free-range situation. And are they captive bison or are they wild bison?

- Dr. (John Fischer): Well the Greater Yellowstone area is a long ways away from Athens, Georgia. And I don't really feel qualified to answer your question on that but can certainly recommend some people for you to talk to there and I wanted to star with Marty Zaluski, your State Veterinarian and then personnel with the Montana Wildlife Agency there as well.
- Donald Hoenig: Well if we didn't come up with a recommendation, I mean the minutes of the committee will reflect that we discussed the issue of wildlife and once they're captive.

And I think the issue of bison in the Greater Yellowstone area and how they manage them is very pertinent as well as the issue of the elk moving between states. You know, I mean because there's one disease there you can't really test for, chronic wasting disease, so, which the USDA is backing out of too.

So we don't have to come up with a recommendation on everything unless they're, you know, we're not going to wring one out of the committee. If there's not one to come, then there's not one to come but it will be reflected in the minutes.

Dr. (John Fischer): Well I could maybe come up with some language here if you give me a few minutes. But what I'm thinking of would be along the lines of encouraging the secretary to promote collaboration between the fish and wildlife management agencies and the animal health agencies to mitigate the

risks involved with movement of animals just as it's done with privately owned animals.

Woman: And (John), if you want to make that recommendation I'm happy - you know,
I'll listen. I will admit just personally right now I sort of feel very out of my
depth and I feel a bit confused as to what even that recommendation would
mean.

And so if you don't feel strongly, you know, the question would be would it be enough that the minutes reflected this discussion or if not, I'm - I'm having trouble getting my mind around this discussion. And so I'd need more explanation and more clarity about the implications of this and what we're doing.

- Dr. (John Fischer): Well let me try to draft some language her. But basically it would be something that would recommend that all of the parties that are involved in these types of efforts work collaboratively to reduce potential risk of disease introduction to a level that's acceptable to everyone.
- Donald Hoenig: And if you do that over the next few minutes, we'll put this further discussion on hold. But there's another bullet on the next page, which covers surveillance of wildlife and how the activities might be funded. So in order for us to include that - check that off the list just you might make some reference to addressing the issues of funding diagnostic testing in wildlife.

(Gilles): It's (Gilles). (Gilles).

Donald Hoenig: Oh (Gilles), yes.

(Gilles): Perhaps we could put this wildlife issue on a - on the agenda for a future meeting. You know, we talked a lot about the traceability Brucellosis and TB. Well, we've licked Brucellosis except in the wildlife population of Yellowstone Park. And so it's costing producers a lot of money and a lot of resources from the veterinary services dealing with a problem that another agency is or is not addressing properly.

You know, there's a whole management issue there of how the bison and the elk in Yellowstone Park are being managed or not managed. And their, you know, their spillover is causing problems to me. And it's a very important issue and I think we should block out some time in a future meeting to get a briefing on it and a discussion.

Donald Hoenig: I think that's a great idea. You're absolutely right. You know, that's been going on for years and may go on for more years. But I endorse that but also I don't know whether you want to - what's your pleasure (John) too?

Do you want to - the TB/Brucellosis framework is not a published rule yet. It's a framework. It's something that we can comment on as it goes on. There's a little bit more time there. So, you know, perhaps we have somebody come in at our next call and then in the meantime you develop a recommendation or whatever you want to do.

Dr. (John Fischer): A couple of things regarding what (Gilles) said there. The Greater Yellowstone area situation is hugely complicated with the involvement of numerous federal agencies and the animal health and fish and wildlife management agencies of the three states.

> You have the National Park Service thrown in there. You got Fish and Wildlife Service as well as APHIS and Bureau of Land Management. So if

we're going to try to address that issue, I think it would be good to try to have some expertise to brief us on those things.

Regarding the funding of surveillance activities, wildlife in the neighborhood of a positive livestock operation. I think that would probably best be addressed through collaborative efforts and combined shared funding between animal health and wildlife management agencies there.

On our last conference call I mentioned that there are some considerations with the use of fees from the sale of hunting licenses and also a federal wildlife restoration program fund that the states receive for management and research wildlife through a federal excise tax that we all pay on firearms and archery equipment and ammunition.

And these types of funds can be used for - could be used for this type of thing under the discretion of the state Fish and Wildlife Agency. But if the Governor or the general assembly were to prescribe this or dictate this, it would - it could mean it would be regarded as a diversion of federal funds not meant to do this in which case the state could lose that funding. So it's an important consideration here.

Woman: That sounds like we - actually what we probably would need is we going to need - make sure we have the information resources on what's going on with the budget and funding mechanism with the actual disease and also with the different interagency reaction or coordination. So we'll need to try to make sure we've got information sources on all of that for the next meeting.

Dr. (John Fischer): What I was really wanting to say there is obviously it's in the interest of the wildlife managers to know whether they have tuberculosis in their wild herd and they are willing to pay to find that out. But if it's a matter of

livestock producers pressuring the Governor into dictating the surveillance and the use of those funds for it, it could be disastrous for the state to lose this funding.

Woman: Okay. So can we put that as planned for the next agenda and maybe hit one of the other questions or is there more discussion right now to be had on it?Okay. We're on the second page.

Donald Hoenig: Excellent. All right. So I guess we'll start out at the top. Do stakeholders support the approach that APHIS proposes with respect to test and removal? If not, what alternatives do stakeholders suggest? This was a question that came directly from Dr. (Clifford) oh; it was probably in the July conference call I think.

> I just - I put it in here because I wrote it down almost verbatim. This is where he was looking for some feedback. Because this how the program's going to change in the future I guess and I think there's a couple people - probably (Chuck) can speak to this a lot more in detail than I can. And unfortunately there's no state veterinarians here who have had TB. Neither (Boyd) or I have had to deal with it thankfully.

But when I was on the USAHA Executive Committee there were three veterinarians on the Executive Committee who were dealing with TB so I'd always just kind of sit in the background on that. (Chuck), do you have any input on this question? We talked about it a little bit.

(Charlie): The major issues that we have in the beef cattle industry is the access to markets for the calf crop for the beef cattle. Dairy herds while they do have cash flow with the milk check, they still have roughly half of their calves born are going to have to be marketed directly as beef. So I think we need to be sure that we have market access and that we use a credible matrix when we go into this decision on whether we're going to depopulate or whether we're going to use test and removal. I think that decision has to be carefully weighed because of the long-term impact not only on that producer but the whole industry.

I'm not opposed to test and removal. We did test and removal on Brucellosis for the first 15 years or 20 years - 20 years of my career. And at that time the indemnity for reactors was \$25 and depopulation was 50. Obviously we did not depopulate a lot of cattle herds for \$50 over salvage value.

So we have a lot of experience in Missouri with test and removal. Tuberculosis is a much longer process because the disease can transmit at any time during the life of the infected animal. So that leaves a lot greater risk for an extended or a protracted period of quarantine.

As long as we can maintain marketability of those calves if those guys' are going to have to take a 30% hit to be able to sell his calves, he's not going to do that very long.

Donald Hoenig: So do you feel like the issue - this issue has somewhat been addressed in our recommendation on approved feedlots?

- (Charlie): I do. I feel that gives us a valid outlet for those calves. If the producer or the home state of the producer, excuse me, is left to fend for themselves on finding a way to market those calves, that would be atrocious, so.
- Donald Hoenig: And that I mean the bullet point Number 3 is related too because that just kind of spells out details a little bit more. As I read through that it seems like

that we've been talking about this issue of marketability and the approved feedlot issue.

I - the middle bullet point under that is are there any additional factors that APHIS should consider when determining whether to implement a test and removal plan or herd depopulation in a beef herd. I think that was probably what you brought up but we've considered that. Correct?

(Charlie): Yes.

Dr. (John Fischer): You know, there's one other thing to consider. Going to an approved feed yard with a calf crop you may not get market value for that calf at that time. Is there going to be an incentive program from USDA to cover the difference between market value and what you might have received going to an approved feed yard? Because there is special handling in an approved feed yard for these calves.

So to that feed yard they're not worth as much. So there is a price difference or is there something - are we going to recommend that we use a calculator at that point?

- Donald Hoenig: I don't know. We can recommend whatever we want but, you know, it's a good point. I don't know. I'm not that familiar with the issue so I defer to others who may be.
- Man: I'm certainly not the expert but I do believe I've heard this question answered before and...

((Crosstalk))

- Man: ...happy to stand corrected if other people have more information. I believe they only pay for putting an animal down. They don't pay for production losses. And that may be by either by a federal law or by federal regulation. So we could recommend a way but I don't know that that's going to change. The whole purpose for this new framework is to reduce expenditures and not find new ways to spend it.
- Dr. (John Fischer): But if you're but if you are moving from depopulating to testing out, I mean there you may have to have something like this to convince somebody to test out.
- Man: Well the thing's shifting. It used to be people would try to save their herds and we were trying to depopulate them and the arguments now people are pay to depopulate be depopulated and being refused under this thing for that very reason. But (Chuck), isn't that right? That's all they can pay for is the value of the animal that's put down.
- (Charlie): I believe the layers were the only group that got indemnity for production. I'm not quite sure production loss. That's true. I think that what we will see is with a small herd (unintelligible) that has great difficulty marketing ten calves, they may end up in a voluntary depopulation without indemnity because the cost of operating under the conditions of quarantine are greater than the losses they would suffer from depopulation and reentering the business.

So I think we're going to see some herds negatively affected. I'm trying to decide what I would do with my cattle. I'm not quite sure where I would go because all of my neighbors are going to have to be tested every year and that's not going to make my neighbors very good neighbors.

Man: Yes.
(Charlie): It doesn't just affect the herd - the individual herd. It affects the - that community of animals. And in grazing if they're in an area where they have grazing associations, those cattle are not going to be allowed to graze in a grazing association. So they're going to be out of that.

> So I think there are other considerations that - I don't know how to word other considerations that need to be taken under advisement before merely what it's going to cost the government to depopulate or test and remove. I think there's more involved in that than just that simple basis to make that decision.

I think we've got to consider the community, the - obviously the herd owner but also that community of herds as well as the impact on the state resources to maintain the testing and quarantine enforcement and control and paperwork and et cetera, thank you.

Woman: So I'm actually now trying to understand and, you know, someone can slap me upside the head and tell me it's in the framework and I didn't see it. But I mean what some of this conversation is raising is almost what is the decision making process and who are the decision makers.

> So, you know, my herd tests positive for TB. State says they'll pay me X amount per head to depopulate. Wait, they don't want to depopulate. They, you know, because they don't want to pay that amount. I have, you know, for me I have unique genetics. I'd want to test and remove. Okay. Maybe I'm not. Maybe I am more like what you described, someone with ten commercial head where it doesn't make sense to do test and remove.

How - under current law, how does this play out in terms of who's the decision maker? And does anyone know how that plays out under this framework?

(Charlie): I guess to start with, the only state that I know of that had any mandatory depopulation rule was Kentucky had a mandatory depopulation rule. I think it's still in place for Brucellosis. No one - no other state and certainly USDA does not have mandatory depopulation in their program. They offer it to you and you either accept it or you decline as the herd owner.

Woman: And that will continue under this framework that way.

- (Charlie): Under this they would offer less frequently if I might use that phrase. Their offer would be less common for a depopulation. And if they choose not to offer you depopulation...
- Woman: I can't choose to depopulate.

(Charlie): You can't twist their arm and make them do it.

Woman: So I can choose to test and remove and USDA can offer to depopulate and that stays with him under this framework.

(Charlie): And in some cases the state animal health agency will add money to that enticement. But the owner owns the cattle.

Man: (Unintelligible).

Donald Hoenig: Oh, okay. So I don't see any - (Genell).

(Genell): Maybe this doesn't make sense at all but I was thinking about when I grew up on raising tobacco, there was a - I recall (just) stabilization service and there was a base floor price on tobacco. And either a company bought it or of course that is more money coming out of the, you know, the government having to cover.

> I'm just wondering, you know, for - it would still be up to the producer whether they were going to handle the, you know, go through depopulation. But what is the potential for any value in some kind of base for price being guaranteed on those TB infected animals? I don't know if that's even - is that a possible solution or not?

Man: As I understand what (Chuck) said and the discussions I've heard, this is being driven from the other side for the exact opposite reason of doing that. They're going to have a matrix that looks at government expenditures as well as disease control.

It used to be primarily disease control but due to lack of funds, one of the factors will be how much money do they have for indemnity and how big the herd is. And some of these thousand cowherds have changed the dynamic and I can understand that.

So one of their factors is they've got X amount of money. They can't pay a flat amount no matter how many cows anymore because they don't have the funds appropriated.

(Genell): I was thinking maybe still doing the (colon) in the cowherd but I was thinking about a guarantee of a full price for calves that are on the ground at that point sending them to a quarantine facility. Is that necessary or any help at all?

- Man: Well, to just current policy doesn't allow it. You know, if they choose to depopulate, they pay for it. And in some cases they can negotiate on salvage value if there is any in addition to the indemnity. But if you're under test and slaughter, then test out then you're not, you know, they're not paying anything about what you animal's worth.
- (Genell): Okay. And do you have any kind of idea what the price differential is between a non-TB infected animal and one that has to go to a quarantine lot?

Man: (Chuck) and (Charlie) might know better than I.

- Dr. (John Fischer): I think that varies. I did notice that the dairymen that I'm talking about I know him and I've talked to him several times. And as time went on and he had more and more of those calves and it put more pressure on that on this approved feed yard to handle these animals. I know the price got less and less. So it just it varies. The situation is going to vary. Price differential is going to vary.
- (Genell): That's what I was suggesting maybe if there was some kind of way to stabilize that price but I guess that's the problem. There's not funds to...

Dr. (John Fischer): I think it was...

- (Genell): ...create a floor.
- Dr. (John Fischer): ...kind of around 35 to \$50 a head. You know, kind of start out at \$35 a head and then it was 50 and...

(Genell): Okay.

Dr. (John Fischer): And it varies with the situation.

- (Genell): Okay.
- Donald Hoenig: All right. So any recommendations coming out of this discussion? Doesn't seem like it. There's more opportunity I think to discuss this as time goes on because the clock is not ticking on this one as it is on the or as quickly as it is on the rule.
- Woman: Can I ask that maybe we try to get some information from USDA before out next meeting to clarify whether the restriction on not only paying if you kill an animal as opposed to trying to make some sort of market differential whether that's policy, regulatory or statutory. And that way we'd know whether there was room for further discussion really on that.
- Man: (RJ)'s got it.
- Donald Hoenig: Yes. Okay. This last kind of bullet here sub bullet is what options do stakeholders think should be available for mitigating risks of disease transmission while allowing the continuity of operation in the herd - in the herd if a test and removal plan is used? Was that yours (Chuck) or was that - I forget where the came from.
- Woman: I think the original list came from the TB program...
- Donald Hoenig: Okay.
- Woman: ...manager. This is the original list.

- Donald Hoenig: I'm not anybody have any input on that? Mitigating the risk of disease transmission.
- Man: I just have a question. Maybe (Chuck) you can answer this. In these let's say a moderate size herd and whatever that is. You can define it maybe in the answer. But how long in these test and removal programs, how long do these last? And then after they declare the herd free, how long do they continue to test?
- (Charlie): For, excuse me, for Brucellosis it's typically three calving cycles would be what you'd expect to go through before you come up with a negative test that you would have confidence in. Three calving cycles after the last exposure. So that's going to be depending on where in the production cycle you find the disease.

On Tuberculosis I'm told that the decision matrix they're using for depop or test and removal is expected to clean the herd within two to three years. I remember APHIS insisting that we have the extended six-year quarantine period on the TB affected herds because of - in other word, because the disease - the disease did not reoccur. The disease persisted in the test negative animals beyond that two-year period or three year period we used to use.

So USDA asked for a longer quarantine period. Now they're saying that with their matrix, and that includes the whole gamut of how many infected animals, herd size and management. There's a lot of things that go into that decision making model. They're saying they can have the herd free of infection in two to three years and off quarantine. Man: So after a herd gets a clean test and they're going to continue to test, are those calves then still under the quarantine? They can't sell those calves. Is that correct or can they then sell the calves in the open market there?

(Charlie): The quarantine would restrict sale of the calves. When the quarantine's released, then the calves could be sold unrestricted but there would be what they term post-quarantine release tests for the next three years - three or four years that they would test the herd annually.

And I assume the herd plan would include asking the owner where - asking the owner to keep a record of the sales out of that herd. They wouldn't have to know who the buyer was but they'd have to - I think they'd be expected to know where they sold and when.

So obviously a private treaty sale you'd know the buyer. If we go to (Charlie)'s then we're not going to know the buyer but (Charlie) will. So that - it can be a protracted experience and...

Donald Hoenig: Yes. Go ahead (Cindy).

(Cindy): I'm not sure if this is what this question's asking for but some of the things that we did in Minnesota to mitigate risk of the disease transmission was to pay for stack yard fences to be built. And that goal was to keep the deer out of the beef cow hay.

> We paid the state I believe, and correct - I'm sorry if what turned out to be federal but somebody else's dollars other than the owner's paid for the RFIDs to be put in the ears at the time of testing because other techniques were not accurate enough.

But owners had to get a passport for movement. That was, you know, their expense. And then we drew that zone as I think you do every time there's TB outbreak, right (Chuck). And so there was testing within the zone and so forth. What other things did we do in Minnesota that might be considered ways of mitigating that you can recall - or Michigan?

(Charlie): Minnesota had the good fortune of state appropriations to buy all of the affected herds. And all of the exposed herds in the area that were willing to depopulate voluntarily, those were purchased by the state of Minnesota. I believe three herds remained in production. The rest all sold out. And that buyout or mitigation process included annual payment for the calf crop even though there was no calf crop.

Donald Hoenig: From the state.

(Charlie): From the state. The state reimbursed the producers for what would have been - I believe it was their net. They probably defined their net so you don't have any expenses. You don't have to pay back expenses you didn't have. But there's got to be buy it in (unintelligible) and sell it in Texas, right.

So there were some really bold and unprecedented steps taken in Minnesota and it really was I think an excellent example of how the process was shortened. Also the wildlife in that area had really strong surveillance. And the beef producers in that area just got TB free status.

And while we were at U.S. Animal Health Association they announced free status for Minnesota. So they got their free status back. And now they can go back in the cattle business.

Donald Hoenig: I think you hit the nail on - I think (Cindy) hit the nail on the head.

(Charlie): And New Mexico got their free status the same day. I'm sorry (Charlie). I forgot to mention that.

- Donald Hoenig: That's what I believe that's what they're getting at. So whether we want to make that in the form of a recommendation or, you know, just have the minutes reflect that we discussed this or say something like the committee recommends that the secretary consider such mitigating measures as were used in Minnesota to expedite the eradication or control of disease, which would include X, Y and Z. Yes, (Chuck).
- (Charlie): I'm still trying to get in my head around this concept. I've operated with Brucellosis and the TB program since 1975. So it's a little hard for me to make an overreaching generalization document. And the details if I understand right are going to come out in the program standards, which are going to be less difficult and less slow to change.

So I'm not sure how much of our stuff that we're talking about details would go in this TB/Brucellosis program original package and how much would come out later as we develop those program standards.

For instance, there is a depopulation matrix designed for tuberculosis. That process would not translate over for Brucellosis. It's - there's no way those two diseases could be evaluated risk wise together. So I'm not sure how much of these details - and I agree that we need to encourage that these mitigation processes be somewhere in those program standards but I don't know if this is the place to do it. I don't know. This is over my head right here, so again.

Woman: I'm also a little concerned going back to something we've talked about more than once in the last two days is funding. And at this point I'd worry about listing, you know, here are mitigation factors that should be included when frankly at this point it is far from clear there would be funding for those.

And I do not want to be in a position of saying, "Yes, we should be having producers built stack yard fences through RFID tags, et cetera, et cetera, et cetera." I mean I'm real concerned that there's just not enough information here for us to make good recommendations without partly the risk of it coming back on our producer's heads.

Woman: I think the biggest hang up for me about including them is that we can't in this room know which makes sense from an epidemiological standpoint. Some of these are more minor costs and some of them are more major costs and they all have - I mean, you know, I look at the fact that we no longer have appropriate amount of funding for our public school kids.

> And, sorry, but when you take from somewhere as has been mentioned before, something else suffers. So I think they make sense epidemiological and they need to be decided on a case-by-case basis outside of this room.

Woman: And to use an animal health example, you know, Texas just discontinued first point testing for Brucellosis. And the sole reason for discontinuing it was lack of funds. So our state budget is not (in that good a position).

Donald Hoenig: Okay. So as I said earlier, we don't have to make recommendation on everything. But the discussion will be reflected in the minutes. So I - with that being said, I think I have all my checkmarks. Is there - are there other issues to come up under the TB/Brucellosis framework? Okay.

I think that brings us to the end of our agenda and I don't know whether - do we start the public comment period early or is this something that we all have to wait around until 4 o'clock to see if - to see if a crowd shows up?

- RJ Cabrera: Don, this is RJ.
- Donald Hoenig: (Hi).
- RJ Cabrera: We may properly invite the public to speak right now if that's okay.
- Woman: You want to do a discussion of the steps?
- Donald Hoenig: Yes. Yes. I did. But if the public would like to speak right now, I'd certainly be happy to hear them. It doesn't seem like they're lining up at the microphone - all two of you, three of you.
- Woman: What can you say?
- Donald Hoenig: One of you has already spoken, so. All right. Well we'll just close the public comment period then and move on to discussion of committee administration, future direction of the committee.

I think what we had wanted or we talked about wanting to discuss was how we conduct business between in person meetings. And in my opinion this has been a extremely productive meeting. And I thank everyone for your input and the - just the way that the discussions have been conducted cordially, respectfully, politely and I certainly appreciate that level of discourse. Just it speaks well for everybody on the committee. So thank you for that. Realizing that we probably won't have another in person meeting maybe for another year, I would say, you know, I don't know maybe until the next fiscal year. Is that correct? Yes. That's correct. Yes. Okay. (Michael) is shaking his head yes. Which would be after October 1. But that doesn't mean that we don't conduct business. So do we continue with the - what is it, the quarterly conference calls or every two month conference calls...

((Crosstalk))

- Donald Hoenig: ...bimonthly? Do we want to do the bimonthly conference calls? Do we want to do less frequency than that? I'm sure nobody is clamoring for monthly conference calls. I'm not. But I'll open it up. I'll open up the floor.
- Man: One thing that's difficult for me and I know maybe I've got a little ADD but after three hours, I lose a little attention to detail. And I'm - yes, I'll admit I'm multitasking while you're talking Don, you know.

So it looks like to me - I mean from my standpoint, I would maybe rather have more frequent and have them like max two hours because I really - I don't know about the rest of you, but can - how many of you can keep your attention for four hours? I really struggle with that.

Woman: The other thing that had occurred to me that I'm just tossing out here, not for or against. You know, there are pros and cons to doing some sort of subcommittees. And (Michael) can correct me. I'm not sure I'm even talking formally. But I think one of the problems has been - or one of the issues I've had on these calls is we sort of get to a topic and then I don't feel like we've got quite enough ready to do anything with that topic.

And, you know, would it help to have a couple of people, two, three people, you know, sort of pre-work - doing some of the pre-work on a topic before the call to sort of help move it and put it more concrete on these calls. There are pros and cons. I'm just - it's one thing that's occurred to me.

Donald Hoenig: (Liz).

(Liz): And I probably should remember this from our last meeting but the list of topics we're working through - I know we had this laundry list. But, you know, I - it would I think be time well spent to re-look at that laundry list and say what are the urgent issues? What's the top priority?

> I mean we talked at dinner last night that with all the discussions on budget cuts and we've heard rumors around D.C. that there's an APHIS reorganization that may change life the way we know it or whatever. Those are things that have come up since that laundry list was developed that would be I think of interest.

Donald Hoenig: Yes, I agree. I mean maybe we do a three question poll or something that just doodle poll or something like that to help solicit people's input or maybe we have a - at the next conference call send out a list and have people offer what their priorities are for future topics of discussion.

We've already heard that we want to go with a more in depth discussion of wildlife with reference to in particular the Greater Yellowstone area. But - and we realize that the TB/Brucellosis framework is going to be an ongoing thing.

So and I - I'm sure there are many other issues that are on that list, so. I'm certainly in favor of shorter conference calls. I don't think anybody likes the 4-1/2 hour conference calls.

Woman: You know, Don, I might also suggest that future calls involve specific questions in inquiries. Doing presentations by conference call is a little challenging and especially when there's more than one. So it might be driven by making recommendations, looking at something very specific and making recommendations.

Donald Hoenig: Yes. I think that's a great suggestion. I mean this committee is not shy about making recommendations as we've seen over the past couple of days. Once we get our minds to it, we can crank them out. So let's try to focus on that. Other thoughts on future direction of the committee? Any - I know it's like the end of two days here. Everybody's like all right, let's get going here.

Any other thoughts on this meeting? Did it meet your expectations? As I said, it certainly met mine certainly yesterday, which was a long day but I think we got a lot done.

Woman: I know many of you probably are not in a location for VTCing but I think it's' worth throwing out there. Since you can't meet face to face and the conference calls are very difficult, who would have access to videoconferencing facility where they - whether they have it in their own office or whether they could go somewhere to use it?

Would that be a viable option? At least you'd have some face-to-face discussion via telecommunications.

Donald Hoenig: Yes. I don't know how many of us want to be on camera but I do at some place. Yes.

- Woman: Another option which doesn't solve the monitoring people's multitasking but at least possibly give some interactions. I don't know if there's a way to set up sort of the equivalent of a Webinar where at least we'd be able to have documents in front of us at the same time...
- Woman: Absolutely.
- Woman: ...and have written communication, you know, visible communication.
- Woman: APHIS can certainly do that.
- Donald Hoenig: On that videoconferencing, can that also utilize something like Skype?
- Woman: We'll look into it. I can't say that I know the answer.
- Woman: I'm not sure about Skype. That would require the computers to have cameras and unless we're all in the same room, I just don't know if that's usable or even useful.
- Man: Yes. I think Skype is point to point but I believe Google has some multiples. But this size would be a challenge. It works well for three or four for a subcommittee.
- Woman: Maybe we'll look into some of the options around the IT area for you and throw them out via email and let you take a look at what we come up with.
- (Michael): You'll find USDA is a little more restrictive than private citizens are in the kind of options we can use.

Man:	(Michael), are options - is the GoToMeeting option as a Microsoft or
	Windows GoToMeeting.
(Michael):	Yes, we can use that.
Woman:	We can use that.
Man:	That's a way we can all see the same document at one time on our
(Michael):	There are other options like FoodSHIELD that
Woman:	Yes. (That we can use), right.
(Michael):	we can use. I don't know if you're familiar with that.
Man:	No.
Woman:	Similar, just newer product. But maybe we'll look into some of the IT options for you and I think that might be - you might find it more productive than just being on a telephone call. Or at least do both and switch them up.
Donald Hoenig:	Okay. Any other - well I guess we're adjourned then. Thank you very much. Safe travels home and
Woman:	Thank you for all your hard work.
Donald Hoenig:	see if - all right.
Woman:	Won't ask what the (pause) was for.

((Crosstalk))

Coordinator: This does conclude today's conference call. You may disconnect at this time.

END