**WITS-USDA-OFFICE OF COMMUNICAT**

**Moderator: RJ Cabrera**
**February 24, 2016**
**9:00 am CT**

Coordinator: Welcome, and thank you all for standing by. All participants will be on a listen only mode for the duration of today's conference. The call is being recorded. If you have any objections, you may disconnect at this time. Thank you. You may begin.

Woman: Good morning. This meeting of the Secretary's Advisory Committee is now called to order and I'm going to immediately hand it over to (unintelligible).

Woman: Thank you. Good morning. Thank you all for all the work you did yesterday. As you recall, yesterday, we had a significant discussion around One Health as well as CWD. And under One Health (unintelligible) -- under One Health, we had come up with some recommendations that due to the (unintelligible) has helped edit it and organize, and wanted to again just kind of run through them quickly on whether there are some concepts that are either wrong or need to be expanded. I think we will do our report writing and our wordsmithing later. So I mean, unless there's something obviously really wrong or we've missed a concept, let's just kind of briefly go through them, and then be ready at 9:15 for the F and B discussion, realizing also that we

had limited timing on today to talk about thematic disease. We may need to expand that serious in the afternoon during the discussion.

So Linda, if you have a concept you wanted to add to the list around One Health (unintelligible) thank you. Oh, okay. Okay. Sounds good. And we'll go through these. Anybody that sees anything, like I said, anything that needs expansion or something we missed, or something we think needs to leave the list, just, you know, let's talk in kind of big concepts now. And if we need to wordsmith later, we sure can. (Steve), you're looking...

(Steve): It's a personal -- the (unintelligible). You mentioned (unintelligible) the last couple (unintelligible) these are not the same thing. Public health is sort of protection of a population and human medicine is a section of an individual.

Woman: Okay.

((Crosstalk))

Woman: I can change the slash to a comma.

(Steve): The goal of One Health is public health, not individual medicine. That's my understanding of public health and I guess it gets back to the whole concept of risk. A lot of (unintelligible) prioritized because there are limited resources and that means there's no zero risk. So I would prefer to do public health up there as opposed to human medicine -- slash public health, but that's a personal issue (unintelligible).

Woman: Anybody else feel strongly? I mean I'm comfortable saying public health is incorporated in the medicine in many ways. Do you want to just get rid of (unintelligible). And I think later on, and I'd defer this to John (unintelligible)

he's in the room. We do have a, I think, wildlife/environment somewhere that I had (unintelligible) that might be another one.

Woman: I don't remember that.

Woman: (Unintelligible) kind of drill down (unintelligible) environment. So we know that USDA has a One Heath working group, interagency working group, I think they would (unintelligible) is that they have an advisory group of two desk interagency working groups. Originally, when I saw that, I thought maybe C&E needs to go away, but I'm not sure that C needs to go away. I think D may be the one that is already being done. And you know, I don't think it hurts to leave it up there but...

Man: I mean D is kind of redundant (unintelligible).

Woman: Yes, and I think that goes to what we were, you know, a couple of the conversations yesterday, which is like we're all animal health people and we're trying to get a (unintelligible) on One Heath.

Woman: And (unintelligible) the federal agencies, but do they have a state engagement. So I'm not sure C is kind of redundant to what you're doing, but it may be expanding to the state.

Man: And I think that was put in particularly because of the wildlife approach, because wildlife is generally controlled at the state level and not at the (unintelligible) level.

Man: Yes, I was having a hard time (unintelligible) but (unintelligible) is what I heard this morning. I've spoken to (unintelligible) individual (unintelligible) over the last couple of days. I thought Joe's response was that that group is

about sharing information, not so much discussing what priorities (unintelligible) be. That's still for different things but (unintelligible) can you get that (unintelligible) let's keep meeting and beyond just sharing information, let's discuss as a group could we add...

Woman: That's a question for this afternoon.

Man: I have it written down (unintelligible) clarify what needs to be provided to you when (unintelligible).

Woman: And maybe it also means instead saying around (unintelligible) mutual interest, because I think you're -- what you're saying does capture what I was sort of thinking about this, something about priorities and, you know...

((Crosstalk))

Woman: Is there a possibility in gaining us an add try/

Woman: Sure.

Woman: Indeed because state, tribal, and federal agencies (unintelligible). Not in (unintelligible). Good point. I apologize for forgetting it.

Woman: And then somewhere, where's their mutual interest piece (unintelligible).

Woman: Well, 2C is one of them. One-B.

Woman: One-B. Okay

((Crosstalk))

Woman: Yes, so 1B I think where we talked about (unintelligible) executes in animal health to promote the development of mutually beneficial, do we need a (unintelligible) there that says for the farmer and the agency?

(Steve): I think that's why we included that specific...

Woman: Right, yes.

((Crosstalk))

Woman: You could just say goals and objectives beneficial to and take out mutually beneficial (unintelligible).

Woman: Okay, (unintelligible) or goals and objectives.

Woman: That makes me, yes, goals and objectives. See, I like that phrasing so how about...

Woman: (Unintelligible) goals...

Woman: And objectives that are mutually...

Woman: Beneficial.

Woman: Towards the farmer and the agencies.

Woman: But I still think we need to have (unintelligible).

Woman: Yes.

Woman: Can we change that to (unintelligible)?

Woman: Yes.

Woman: Beneficial for producers and the agencies. Yes, just and s, yes, for (unintelligible). There were go.

Woman: And would (unintelligible) objections that are (unintelligible). So yes, we're missing significant (unintelligible) behind goals and objectives, we need to space that (unintelligible) behind goals and objectives that are mutually (unintelligible).

Woman: Your computers do that too. I hate it when it does that.

Woman: But we have nothing to do with that.

Woman: I just don't understand why they do...

((Crosstalk))

Woman: Yes, and it's like (unintelligible).

Woman: Perfect. Now, let's go back down to two.

(Steve): I have a difficult (unintelligible) on the concept and I have it written down to ask (unintelligible) with the focus on non-regulatory (unintelligible). I think that's the focus of Joe's office in One Health desk, but I can't say comfortably that that's not -- that non-regulatory (unintelligible) the FDA, or the (unintelligible), or anybody else.

Woman: Right, correct.

(Steve): I think that is (unintelligible) we're focusing our recommendations on USDA. It's their approach, it's the hope to be non-regulatory (unintelligible).

((Crosstalk))

Woman: We're looking at USDA initiatives and One Health.

Woman: How about let's specify though, because we (unintelligible) maybe just specify (unintelligible) One Health initiative what the USDA is focused on...

((Crosstalk))

Woman: Yes. Good point.

Woman: I said the One Heath Initiative, with USDA focus on (unintelligible).

Woman: They didn't say their entire focus was non-regulatory. They said they were exploring new non-regulatory ways of (unintelligible).

((Crosstalk))

Woman: Well, then let's just take out that phrase. How about we take out that phrase?

((Crosstalk))

Man: No, I think it's really important that you leave that in...

Woman: Or how about then, the One Health Initiative with its emphasis on non-regulatory approaches.

Woman: No, I would say their (unintelligible).

((Crosstalk))

Woman: New non-regulatory approaches.

Woman: Interest. How about interest in exploring non-regulatory approaches. The One Health Initiative is interested in exploring.

Woman: I mean, you know, their regulatory approach to (unintelligible) is a One Health approach with regulatory.

Woman: Okay. Point taken.

Woman: I'd like to see that we put in there that they support this pure food supply (unintelligible) in their preparative planning.

Woman: Can we do that generically? Because I don't feel comfortable saying that I know about the (sands) of the specific secure food supply, but that ensuring a secure food supply is part of that. I'm suggesting lower case rather than upper case.

Woman: Because I'd like to see, you know, they should foster for more collaboration between (unintelligible) drills and things like that, and just saying go plan your emergency planning when they've got a template in place, maybe it's not necessary.

((Crosstalk))

Woman: Continue and expand development of the secure food supply projects.

Woman: Plan for secure food supply. Again, they've...

Woman: No, they've called -- they're calling for (unintelligible) plan.

Woman: Okay. But can we do this without endorsing the specific plans since the plans weren't (unintelligible)? I'm just saying that we could work it in.

Woman: Well, what I'm wondering is we may get into the discussion today under (unintelligible) about secured and supplied (unintelligible). So we may actually -- maybe we want to put that as a placeholder and say, after today's discussion, we may know more about the finance thing.

Woman: Yes, except that it's just not just footnotes. Like the nation just exercised the poultry (unintelligible) supply plan in the AI outbreak.

Woman: Okay, can we go back though? Because you had a phrasing also about -- you were talking about something about exercises or cooperative -- what was that?

Woman: That there should be more collaboration between agencies in the emergency planning.

((Crosstalk))

Man: Should we say something like support development of state and regional?

((Crosstalk))

Woman: Or here's what I quickly wrote, continue and develop more collaboration among agencies and producers to address secure food supplies, you know, during emergencies.

Woman: No.

Woman: No?

Woman: So how about if you go to senior development and expansion of the secured food supply plan, including expansion to minor species or non, you know, because I think what I'm...

Woman: They all need to be included.

Group: Right.

Woman: So far, there's only the milk, pure milk is done, pure pork, but beef is not done yet. They're still in development. (Unintelligible) is done but that turkeys is not completed yet.

Woman: (Unintelligible) done yet?

Woman: I don't think so.

((Crosstalk))

Man: It's real close.

Woman: But, you know, they don't have a small room in it. They don't have (unintelligible) in process and it needs to be included in this.

Woman: Right.

Woman: In this rule.

Man: So we really want state, regional but it's also interagency because we're talking about...

Woman: I'm capturing (unintelligible).

((Crosstalk))

Woman: Secured supplied plan. We'll think about that when we come back.

Woman: Yes, let's do this first. We're putting in something and I'm highlighting it to come back to.

Woman: So other emergency planning (unintelligible) that we need to also get something on exercise? I think that's crucial. Inter-agency emergency planning on exercises, or drills, or that there has to be. A plan is great but without (unintelligible) and practicing it, you don't know where the holes are. So and not only inter-agency but you've got to have producers and stakeholders.

((Crosstalk))

Woman: Could be slaughterhouses. We'll wordsmith, but...

Woman: Yes, you and I can look at our (unintelligible).

Woman: Okay. I think we're ready to go ahead to (unintelligible).

Man: Just a quick comment on 2E. Although I appreciate the need to reach out to (unintelligible) I think it's all vendor associations (unintelligible) should count because that's probably a fairly narrow group that's (unintelligible).

((Crosstalk))

Woman: So you'd have national, state, species, and holistic veterinary medical association. So you have ADMA, your state's DMAs, your special DMA, or your species...

Woman: Who are we leaving out? Because, I mean rather than delete holistic, I'd rather add whoever you think we're leaving out.

Woman: So to me, I would have national. So national is ADMA and state would be your state. Then species would be like CT, SV.

Woman: So you might need to stay special. So like, for example in poultry, there's a poultry (unintelligible).

Woman: Yes, so that's what I considered species.

Woman: Yes, but that's separate from the (unintelligible).

((Crosstalk))

Woman: But the problem -- my problem with saying all (unintelligible) holistic will get forgotten because that's what is going to happen.

(Steve): I appreciate that but I think there's lots of specialty groups out there that (unintelligible) with small groups or nontraditional groups.

Woman: Yes, I don't know what all...

(Steve): I believe that's representing veterinary, I really believe that. So that's why I don't want to just focus on one group.

Woman: If we had species specialty instead of species. So we've got...

Woman: I was just going to add specialty as another group.

((Crosstalk))

(Steve): Extension veterinarian?

Woman: Yes, extension veterinarians might be a specialty group that should be...

(Steve): I mean, they exist in a (unintelligible).

((Crosstalk))

(Steve): So there's lots of groups out there that work with the nontraditional groups. I just want to leave them out.

Woman: (Unintelligible) national, state, species, specialty, with commas in between each of those, and holistic.

Woman: Does that cover the (unintelligible)?

((Crosstalk))

(Steve): I wanted to make sure we captured that.

Woman: Three-A and B, and I would put cooperative extension first. I would name it.

Woman: Okay. Cooperative extension.

((Crosstalk))

Woman: Did I phrase that correctly, what (unintelligible) in current state county level funding. I'm trying to figure out how to use something besides bottom up. Okay.

((Crosstalk))

Woman: Conventional producers. I almost did that and then I decided it wasn't my place to make that (unintelligible).

(Steve): So the national level puts more skin in the game then. It's easier for the state of Michigan to put money in than it's easier for the county (unintelligible).

Woman: Okay. Are we good with the stakeholders? Okay, (Steve)?

(Steve): I have a question on number for, the one about (unintelligible) track progress. Is the concept is all we wanted to do was track or did we want them to track

and report for documents? So that, you know, you just want to (unintelligible) to track it. That's important but (unintelligible) tracking on.

Woman: Report.

(Steve): (Unintelligible) annual, you wouldn't -- if our goal or if our job is to recommend to them what we'd like to see.

Woman: I think report is a good one because then we -- the stakeholders can figure out what we think of where it's going (unintelligible).

Woman: Track and report.

Woman: Yes.

Man: Both track, report and (unintelligible) done.

(Steve): And what?

Man: And (unintelligible).

(Steve): And I just think maybe track -- the concept track wasn't brought up. I would like to see more than just (unintelligible) track, but (unintelligible).

((Crosstalk))

Woman: I think this is just to get -- look at concepts on Thursday afternoon, we'll have to expand. We'll have doctors (unintelligible) join in us shortly and -- or maybe immediately.

Woman: (John Zack), are you on the line?

(John Zack): I am. This is (John). Good morning.

Woman: Good morning. Are you not linking into the -- are you linked in yet to the document?

(John Zack): I've joined the Adobe meeting.

Woman: Yes, I didn't see you there yet. Okay. We're ready to go in a few seconds.

Woman: Yes, just give us two minutes, (John), and we'll be with you. Or maybe one minute even. So does anybody have any objection to what's on the screen under (Zynotic) and like I said, we can...

Woman: Relate complete.

Woman: Relate and complete, and we can add and expand (unintelligible).

((Crosstalk))

Woman: (Liz), I have a comment.

Woman: Sure.

Woman: When we've had the flu outbreak, a lot of the hospitals did a lot of their reporting. And when that dissipated and everything went back to normal, there was minimal reporting. So a lot of that was captured at the labs on the human side. But on the animal side, we're very proactive within our data and the

capture (unintelligible) on the ground. Is there anything that phased you on the human side where that is also captured?

Woman: That's sort of where I was trying to go with number two because we brought that up. I think there's other language or...

((Crosstalk))

Woman: We could put a placeholder in there to talk about influenza (unintelligible) because I think we'll need to talk influenza for birds and pigs as well as people. And so I think (unintelligible) a placeholder, we need to discuss on Thursday when we've got time.

Woman: I'll add that note and highlight.

Woman: Great. Well, with that, let's put One Health to bed until Thursday or maybe tomorrow or later on this afternoon, we'll have a little more discussion on (unintelligible). But anyway, we will turn it over to (John) and (John), if you want to introduce yourself briefly and then get into the discussion, that'd be great.

Woman: Actually, (John), I still don't you have in the room, the Adobe room.

(John Zack): All right, so maybe I'm in the wrong room.

((Crosstalk))

(John Zack): Because I'm in the one that says SACA meeting day one.

Woman: We're in day two.

(John Zack): So I guess I will have to pull up the right link. If you guys give me a minute.

Woman: Okay. Yes, it's your day one. It's our day two.

(John Zack): And I've got to apologize. My computer crashed so I'm doing this off (Sharon)'s. She's sitting here with me. Yes, but I need to get to the right...

Dr. (Sharon Fisher): RJ, do you have the link and maybe you could send it to me, (Sharon Fisher), and then we might be able to pull it up just direct out of email.

RJ Cabrera: Sure. So we send it to Annette?

(John Zack): To (Sharon Fisher).

RJ Cabrera: Send it to both of you.

(John Zack): Yes, my computer is down so thanks.

((Crosstalk))

Woman: (Annette Jones), are you on the line?

((Crosstalk))

Woman: (Annette Jones)?

RJ Cabrera: I guess (unintelligible) that as we're waiting for John, do we want to have a couple minutes of philosophical discussion on CWD as (Judith) and I have talked. I think we're uncomfortable that we may not have a lot of expertise I

the room to provide direction to ASIS. It sounds as if they've reached out to the industry and gotten the (unintelligible) industry input. And so I guess I'd open it up to see if we want to make specific recommendations or whether we want to suggest that they take the recommendations that they received from the industry. That's just a, you know, that's the one thought I've had but it's definitely open for any thoughts that the rest of the group would have on CWD.

Man: I would add, I don't think -- I don't know if anybody around the table is qualified to answer questions on behalf of the service industry. But questions four and five, and seven and eight ask us how -- ask us from the perspective of our industries or our sectors. So question four, what's working, or what aspects are most beneficial to your industry. It doesn't say the service industry there. So it might be an opportunity for us to comment on things from the perspective of our industries. That's one suggestion. But most of this applies to -- the questions are directed from the perspective of the service industry, and Sean's not here today, and he's not a member of the committee. So I don't know if (unintelligible) qualified to represent that industry from here.

Woman: (Belinda)?

(Belinda Thompson): I was not really aware before we came here that basically we were given the survey that they intended to use at the meeting the day before with the service industry. And there wasn't -- there weren't really questions prepared specifically for us. And that's basically what she told us in the talk. So, you know, when I voiced my concerns about (unintelligible) the environment indicated that they have more work to do. I would like them to have to ask those same questions relative to stewardship of the environment and wildlife, and make sure that the USDA programs are appropriately addressing that as well. Because USDA stakeholders aren't just service (unintelligible).

Woman: And (unintelligible) with talking from (John) this morning, I don't think -- we don't -- I don't have his expertise to talk about the CWD program (unintelligible) playing off of that. The two people I heard back from, you know, we have produced (unintelligible) towards using hunting as a way to bring in extra income on their farms and they're very concerned about the spread of CWD and whether the movements are endangering. And so would it be -- no one had a (unintelligible) recommendation of here's what we think you would need to do. But a comment to USDA from my focus of we want to make sure you're not just talking to the farm service industry. We want to make sure you're taking into account, you know, the hunting and agro-tourism industry, and the impact on it.

Woman: Yes, the farm service, the demographic (unintelligible) it's less than 2% of the deer and elk population of the United States. And there's a whole other demographic that needs to be protected or needs to be considered. So we need to consider free range (unintelligible).

Woman: And those are their last (unintelligible). Something in environmental (unintelligible), yes.

Woman: So the program deals with farm service but needs to consider free range (unintelligible) environmental...

((Crosstalk))

Woman: Yes, take the impact (unintelligible).

Woman: John, you ready to go?

(John Zack): Sure. So I can see all of you. Thank you for having me this morning. Hope you're well and if you've got any questions along the way, let's answer questions. We'll have a good conversation. I think for the secretary advisory committee, I think the background I'd just like to start with and then hear from you is that I think the year before and the prior year before that, we had good discussions about the current state of the North American FMD vaccine bank, which is a shared vaccine bank between the United States, Canada, and Mexico. We also had good conversations about the quantity of vaccines that are currently in the bank and that I think that from the USDA perspectives as well as the industry group's perspective, as well as the owner/grower perspective that no one feels comfortable with current amount of vaccine that's in the bank.

And I think that based on probably the work of, you know, this committee, some stakeholder engagement activity led by the industry group, some of it led by ASIS but, you know, all of us working together. Just as a reminder to everybody, back on February 11th of this month, the -- (David), I'm not sure how to pronounce this. It's either (Rouser) or (Ruser).

Woman: (Rouser).

(John Zack): Yes, from North Carolina, the Chairman of the House Agriculture Livestock and Farm Agriculture Subcommittee held a public hearing to examine the preparedness of the United States in the event of an introduction of foot and mouth disease. So and basically, I know that (Howard Hill) presented (Cindy Wolf), Dr. (Jim Ross), and a couple other presenters. I think it was really great because the conversation that we've been having internally here at ASIS, that we've been having with the industry association group has now been elevated to Congress as an issue for them to look at related to the funding requirement for a satisfactory vaccine bank.

And I don't know -- I would just like to pause there and if anyone was able to watch those hearings or had been tracking the progress of this, you know, your take on it.

Woman: I did watch (unintelligible) and I was very pleased with the questions that the senators posed, their (unintelligible). So hopefully, it caught hold with somebody that it needs some action.

(John Zack): Yes, that was very much, you know, our impression too that it was very good questions. I think the seriousness of the issue was apparent to everyone, you know, in government, in the private sector as well as, you know, the academic centers. And I think that, you know, for this year, for the secretary advisory committee meeting, I thought that all the work that had been done -- again, by this group to make recommendations, other groups, USAHA -- I thought that the next phase for our preparedness efforts for foot and mouth disease would be not to forget about the vaccine issue because it's very important and it hasn't been resolved yet in terms of, you know, who's going to fund the bank, how is it going to be funded, you know, what is the relationship between the other two countries.

You know, we basically need to modernize that program and I think steps are underway to, you know, hopefully eventually get that sooner rather than later. But I think the other conversations we need to have the industry groups and stakeholders, producers, growers is that, you know, what is actually going to happen God forbid the day we detect foot and mouth disease in this country. And do we really have a common operating picture on what is going to happen and that's to the broad question, but what is going to happen in terms of the impact on states, the impacts on the industry, the individual producer, the grower, as well as how are we going to respond to it.

And I think that, you know, coming off of a very, you know, a moderate to large sized high Path AI outbreak in the Midwest last year then coming off of, you know, much smaller incident in Indiana, I think we're learning a lot about, you know, incident management, how to work with the poultry industry, how to work with the state, and again, with the individual owners, growers, company on response for high path AI.

And I think that one of the concerns that I have and some other people have is, you know, as difficult as it is to respond to high path AI, we have a lot of experience in this country in dealing with low path AI and we have had more frequent outbreaks of high path AI in our history than we have FMD. So in terms of what is the international reaction, what is the domestic reaction, what do the state responders and the federal responders do, how do the industries respond -- I think that we need to start having, you know, more engagement together on what are actually going to be the response activities, strategies, tactics for food and mouth disease. And then depending upon the type of outbreaks or the phase of out the outbreak, how those strategies, tactics, procedures may need to change.

And I know that, you know, one of the -- and that's what I wanted to just talk about today is that I was hearing folks say we need to exercise. Absolutely. And I think one of the key things for any type of FMD, tabletop, or exercise is that when folks start talking about an FMD outbreak, very often somebody from the dairy industry is thinking about, you know, an outbreak in, you know, their state, their region. Sometimes people are thinking of a focal outbreak, a very small outbreak that's kind of contained. Other times, people are talking about a very large outbreak, like the Palo Duro outbreak.

So I think that getting back to what is the common operating picture or consensus across the board, we need to start developing our, you know, our terminology and hopefully it's not, you know, too wonky. But, you know, a common terminology as well as a common playbook for how we're actually going to respond to an FMD outbreak other than just, like, you know, oh, crap. You know, that'll be the first thing everybody says but then what are the immediate next steps.

So I guess, RJ, am I driving this then?

RJ Cabrera: Yes, you should be able to. There you go.

(John Zack): So that's just, you know, kind of a brief introduction to the topic today and we can, you know, stay at a high level or dive down into, you know, the weeds as you want to, you know, as a committee. And, you know, this is something that, again, came out of our experience when we were at Palo Duro and going to the Dairy Management, Inc. exercises and, you know, a bunch of other exercises for FMD. We realized that, you know, we need to have some way of describing, like, a hurricane or a storm system, or in the medical terminology, you know, is it something that's, you know, para-acute, acute, chronic. You know, we needed to have some kind of way of describing what an FMD outbreak might be for everybody in the country and also in Canada and Mexico because it's going to be a North America issue, you know, how we respond.

And again, depending upon the size of the outbreak and where it is, you know, the strategies and the tactics to handle it may need to change or pivot. I think we all know that if this disease ever comes to the United States and gets established in our -- or have an outbreak in our animal agriculture -- it's not going to be a good event. So I think that a phase is just talking about the time

period for an outbreak, you know, early in the outbreak to later in the outbreak. And then the type is basically trying to describe the size. So, you know, on this particular side, you see the green tree.

RJ Cabrera: It's actually grey and white.

(John Zack): But it says phases. It's kind of like an arrow with blocks. Is that what you're seeing? Yes, okay. So I mean this is, you know, this isn't rocket science and the good news is right now, we are in Phase 4, U.S. declared free of FMD or actually not with -- we've just been declared free of FMD without vaccination. That's our current status. That's the status you would like to have forever and I think that in terms of if there was an outbreak, you know, tomorrow or today in Canada and Mexico, we would then suggest that we need to immediately move a heightened alert phase and that would have subsequent activities, critical activities and communications that need to occur.

Phase 1 would be the actual confirmation of a case of FMD in the United States. Phase 2 would be the surveillance and (unintelligible) of the extent of the outbreak and, you know, Phase 2 then is a little bit more not easily defined because defining the extent of an outbreak could take a period of days or weeks depending upon the outbreak. And then Phase 3 would be a recovery phase when -- depending upon the outbreak, whether it was large or small -- you feel you have a handle on the disease, that you're controlling the disease either through a combination of stamping out or vaccinations, or whatever the strategy is that you actually are beginning to have the disease under control, moving back to Phase 4, which would be free of FMD.

And, you know, what we've learned is that when you have outbreaks you can't do stuff fast enough. And the problem with doing stuff fast is you really need to be prepared. And then the other aspect of doing stuff fast is some things the

80% solution works, some things maybe the 50% solution works. Other things, you need to have it nailed down really good. So there's always that tension depending upon the critical activity between speed and accuracy.

So this is an interesting figure and I think it's trying to show on the X-axis that your response strategies really need to shift depending upon the size of the outbreak. And that the, you know, on the Y-axis here is the size of the outbreak. So and I think that, you know, the most recent example that I can think of would be the outbreak in South Korea, where for a number of -- for several outbreaks or incidents they had a small outbreak and they were able to contain it, control it, eradicate it. It didn't spread widely across the country and, you know, they had a history of having several of those incidents or outbreaks.

Then their most recent outbreak, you know, basically it got out of control, really became an epidemic or epizootic. It got extensively into their swineherd and they were following a stamping out strategy to get rid of the disease. And I think it's very interesting because South Korea really doesn't export any pork. I mean they're a net importer of I think food for their nation, but they still stuck to a stamping out policy until they I think depopulated about 10% of their national swine herd. And I think for some folks that were following along that depopulation effort was very traumatic for their country. I mean I think folks probably are, you know, not all of you but some of you have probably seen the video clips of, you know, pigs, you know, being buried, some of them still alive, the disposal technology where the things they did resulted in contamination of ground water. I mean there were reports of, you know, some of their water being reddish, you know, from the dead pigs, the blood, and the (unintelligible) and things like that.

So that is an example of, you know, a country that had, you know, a couple Type 1 or Type 2 outbreaks and then certainly ended up with a large scale outbreak where they really went away from the stamping out strategy to a vaccination -- a blanket vaccination strategy. And I think the other lesson learned from that was the vaccine they needed just for Korea -- South Korea -- which is probably about the size, you know, of one or our states or one of our small agricultural production states. They basically, you know, had to go purchase a vaccine from the North American FMD vaccine bank and other vaccine banks and, you know, basically all the vaccine sources around the world had to offer up some vaccine to help cover that outbreak.

But I think that was the other lesson learned I think for a lot of people was when we talk about the outbreaks, a lot of people have a lot of knowledge about the outbreak in England, the U.K. There's a lot of experience with the outbreaks in South America and how South America has predominantly used a vaccine strategy to declare many, you know, parts of their countries or their countries free from FMD with the vaccination strategy. I think that the one thing in the United States we really need to pay attention to is because, you know, we have sheep. We have a lot of cows and we have a lot of pigs. And I think Korea was an example of an outbreak where, you know, some folks have said, well, you control an FMD outbreak by only vaccinating the cows. You know, in England you have a huge, very large sheep population. You really need to, you know, pay attention to the sheep.

I think here in the United States, we've got to pay attention to everything. You know, you have a few sheep that are infected. They're stealthily moving around without, you know, huge clinical (unintelligible) spreading disease. That's a problem. You all can describe to me how large our, you know, our beef cattle and dairy cattle industry segments are, and we also have a very, you know, large, robust swine industry and we have a lot of concentrations,

you know, swine in the Midwest and (unintelligible) on the East Coast and everywhere in between.

So I think that we really can't ignore or, you know, look at an outbreak in the past and say that that's how it's going to occur in the United States. I think we really need to be smart about our own backyard, about our own states, and what our own animal agriculture looks like. I think that for some of these things, you know, a Type 1, a focal outbreak, I think everyone will kind of understand that if we had one farm, two farms in one state where we had detected FMD and that's day one of the outbreaks, and then one day two, day three, day four, let's say we get really lucky and it was contained to, you know, one or two farms in one state that would be easily definable as a focal outbreak that's contained to one or two farms in a county or a couple counties.

And I think everyone kind of, you know, conceptualize that pretty easily. For the Type 2, like the slide up here now, you start talking about a moderate regional FMD outbreak. And I think that we can all visualize, you know, a state where, okay, I can visualize, you know, the animal agriculture in this state is kind of separate or segregated, I can see it being kind of a regional outbreak maybe across a couple states.

Other parts of the country, like when you get into the Palo Duro system or some of the Kansas, Colorado, Nebraska cattle systems, you get into the, like, the New England secure milk supply, the Mid-Atlantic secure milk supply, the movement of the milk and the animals. You're already at a regional network system.

So I think that, you know, again, you know, this is something that we need feedback on. Conceptually, do people kind of think this is an okay way to describe it. Does it need to be more granular. Are we better off, you know,

just having it, you know, at this type of level. I think that the key feature when we start talking about a Type 1, a Type 2, basically, you know, through a Type 1, Type 2 and probably getting into a Type 3, you're basically -- we're going to try to stamp out FMD. The trouble there is we all know that the virus moves very quickly. The people, and animals, and equipment move very quickly that by the time you detect something, quarantine a farm, you know, depopulating cows, and pigs, and sheep, and goats, and other, you know, animals, exotics on the list or, you know, it's very difficult.

It's very difficult, one, because just technically, it's very hard to do. And then you have to -- we have these tremendous disposal issues we all know about. But even more importantly is, you know, the cost of that in terms of the community, the producer, the financial cost, and then the long-term recovery that you have to do with large quantities of carcasses and things that you may have to deal with in terms of the environmental impact.

So going back to a One Health type discussion, you know, then you have the mental health of the producer, the owner, the grower. You have the economic health of the community and then we're back to kind of, like, that Korea analogy. At what point do you stop stamping out because you're starting to destroy your national herd to save the national herd. And it's a very difficult question. And I think that it's something that, you know, each state and livestock industry needs to work through these scenarios in their mind as to, you know, what for you is the trigger that depopulation is no longer going to work as a strategy.

And I know the epidemiologists are good epidemiologists across, you know, everybody, you know, no matter where they sit, in government, academia, or in the industry, they all remind us that the reason to depopulate these animals is to stamp out the virus so the virus can't replicate. If you can't actually stamp

out the animals quickly then the virus replicates. You have our environmental contamination. You have all your lateral transmission threats there and by the time you get around to depopulating the animals, the could very well already be recovering.

So we're going to depopulate animals that are already potentially starting to recover from the FMD. And I compare and contrast this to high path AI where when we get high path AI in, you know, domestic poultry, you know, there is the rare occasion like the case in Texas where you can have a laboratory high path AI virus that acts like low path. But that's kind of like the rare exception. For the most part, when we get high path AI in domestic poultry, those birds are dying and from, you know, we had a horrible experience out in the Midwest where, you know, if a turkey barn got infected on, you know, day zero, by day seven to nine, you know, 8% of them could be dead. Because in some cases, depopulating turkeys was difficult enough until you search the appropriate resources, have the right people there depopulating, you know, just turkeys -- which are large for poultry but small compared to any, you know, other livestock -- is not easy to accomplish.

And I think that that's why for HPAI, you know, ASIS, the state, the poultry industry, you know, for a disease that's going to kill the bird that every day you let the bird live and create more virus, we're doubling down on the depopulation as a method of dealing with HPAI. To the extent now where we're adding more foaming equipment, whole house CO2, and in those instances where we can't meet, you know, the start depopulation in 24 hours, we've actually added ventilation shutdowns to the policy. Because the experience with high path AI is if you can't depopulate the animals quickly, you have this virus. The virus replicated in the live animals that are infected. You create more environmental contamination, which can result in vectors,

you know, the wind, environmental (unintelligible) lateral spread. We all know this, right.

With FMD, the challenge is going to be we have, you know, both pigs, and cattle, and sheep all replicating the virus. The pigs are identified as amplifying species but, you know, cattle do tremendous environmental contamination. And I think the other lesson learned from the high path AI outbreak is that we had some layer facilities which had, you know, 3 million, 4 million, 5 million layers on them. The indemnity costs for those could be anywhere from $7 million to $9 million but for that original outbreak, you know, the cleanup costs for some of those farms far exceeded the indemnity cost. And that's driven ASIS and the industry to come up with, you know, this calculator to come up with a cost sharing mechanism where now ASIS can go out and say, for the virus elimination cost for a premises for high path AI, here is what ASIS and USDA can contribute to that environmental cleanup.

But that same situation is going to exist with, you know, cattle, sheep, goats and in some of these cases, you tell me where -- how you keep your animals -- how easy is it going to be to do a facility cleanup to the extent that how can we control the spread of the disease if you have 50,000, you know, yard that's infected or you have a 2000 cow dairy that's infected, or if you have sow units or grow out units that are infected.

So I think that, you know, the continuum of activities from the detection, you know, it's easy to say you're going to stamp something out on paper but it's incredibly hard to do and it may never actually be the right thing to do depending upon, again, are you at the Type 1, are you at the Type 2, are you at the Type 3. I think the other activities that will occur depending upon these types is, going back to that Type 1 example, if you have a farm or one or two premises that are infected, you know, you're going to have a very severe

quarantine and movement controls in that area because the number one goal is going to be to contain, control, and eradicate that virus. And the only way you can do that is with severe movement controls.

The question is how long can we put on severe movement controls and what are you severely controlling movement of? Is it -- I think a lot of people agree, well, if you don't have to move breeding animals this week, don't move them. Well, what if you have animals going to slaughter? Well, I can hold them for so many hours or days. If you have milk, what am I doing? Can I move the milk? Is the default position I move milk or not? What is the size of the control area (unintelligible)? Is it 10 kilometers like the U.K. and you shut everything down for five, to seven, to nine days, you stop all movement. You do you detections and you do your little 10 kilometer zones. Or do you throw on a 10 county, you know, zone or a 30 kilometer zone, a 60 kilometer zone.

Those are the kind of conceptual to reality type decisions that are going to have to be made and that goes back to the next phase in preparedness where we all need to have kind of a consensus as best we can, or at least a discussion on what are we going to do day one. How big is that control area? What are we going to (unintelligible) moving for how long? And that relates back to the secure food supply plan, but that is one component of the overall, you know, planning and conversations that need to be had.

So I'll just pause there. Any questions?

(Liz Lastrom): John, this is (Liz Lastrom). I'm going to ask the first question because I -- in looking at the materials you sent out, some of the questions I think you're asking appear to already have been covered or part of the fast prep document. So are you rethinking fast prep? Are you thinking it's not specific enough but,

you know, why revisit some of these questions if they're already considered in fast prep?

(John Zack): I think what I'd like to do is get to the -- a deeper level of planning and conversation engagement around, you know, I think some of the things that have been developed, and again, a lot of it's been developed in a -- with engagement, you know, with the industry groups, sending things out for comment. But I think the reality is, Liz, we haven't had FMD for 80 years, right.

(Liz Lastrom): Right.

(John Zack): And so I go back to that analogy of high path AI where if we have high path AI, you know, it's bad for that state. It's bad for that county. We know the countries that are going to shut off the whole, you know, the countries that are looking for the opportunity to shut off the entire U.S. We know who they are, you know. The countries that want to work with us as good trading partners will, you know, take the trade-in pack down to the county or the state.

So, you know, everything from people's understanding of what's going to happen initially with trade and how awful it's going to be. And then so when people then say, well, when you look at the OIE, if you use the vaccine, some people think that's going to decrease your time to get back into international commerce. And if whether, you know, if we had a small, focal outbreak, we stamped it out quickly, if we could get it done in 60 days, 30 days, whatever, it would probably still be a year to 18 months before many countries would allow us to restore a trade.

So I think just the consequences everybody kind of knows, but I think some people in the industry, they're very busy going about their lives. I guess what

I'm saying is a lot of what we've developed in fast prep, we really want to become the state plan and the industry plan. Because the biggest lesson learned is if you don't have a unified state federal response, you've got nothing.

So we agree that there should be exercises in planning, but I guess what we're really looking for -- and I think part of this is what we're going to try to do. We're going to have -- we're going to start some more stakeholder engagements to kind of dig into these questions and, you know, go to the, you know, either through our district, you know, going to the different regions or sections of the country and the different commodities to get feedback on, you know, what do we need to do on hour zero so it's not a surprise to anyone. And then get feedback what people think are the triggers for their commodity for vaccination. What is their threshold? Is the population even achievable in certain situations.

You know, we all say, well, if it's on the first farm take it out. What if that first farm is 50,000 cows. You can, can we do it? I mean it's one thing to say, yes, we want to do it. But then you have to -- if it's Nebraska, it's Dr. Hughes. You know, is that -- what is it going to take to do that or is it even worth trying to do it. By the time you get organized to do it, you know, the cows are starting to recover.

So I think that that's really what I'm driving at is that we've had great conversations about we need to increase our vaccine supply. Absolutely. And I think that hopefully will play out in a -- with a -- in a successful way to everybody's satisfaction. But right now, we can't control that. But the good news is it's been elevated to the appropriate level to be resolved.

I think that what I would like to do, you know, with this group, with the industries, with the state is go back and just, again, (unintelligible) responses are local, you know, by state, by industry, you know, what is the plan to contain it, control it, and what are the triggers for the different strategies. And so we have laid some of that out but I think we're looking to go to the deeper level of planning and engagement and make sure that we're bringing everybody along. Again, hopefully this never happens but you know how it is. The day it does, there's going to be high expectations for everybody.

(Liz Lastrom): Great. (Steve), I think you had a question.

(Steve): Yes (unintelligible).

(Marianne Kneeble): Dr. (Sack), this is (Marianne Kneeble). Who initiates these exercises, these planning stages, these getting everybody together to do this? Is that not your job? Are you saying it starts at the state level?

(John Zack): Well, I think what I'm going to say is that we're planning with Iowa State University to do -- I think this year maybe going into next year -- doing -- renewing stakeholder engagement to get at these questions. So last year's stakeholder engagements we had was really around the vaccine issue, which is very important. We don't want to let it go but I think what we're going to do is do, again, working cooperatively with, you know, Iowa State University as one of our partners was to reach out to the industry, the state.

So we're hoping to lead some engagement activities but, you know, we follow -- get out of the way -- if, you know, like the DMI had a bunch of communication things a few years ago, which were excellent. So we're also willing to participate or collaborate with, you know, other activities that are driven by the industry or, you know, a state exercise. Like I just heard, you

know, I think this month that there's going to be a Palo Duro 2 coming up this summer. And that'll be a great opportunity to go back, you know, this many years later and say, well, what's new and improved and what's still the same as we look into that Palo Duro outbreak that was, you know, back in I think 2007 or 2008 we did that one. And that was, you know, basically done by the Kansas, Texas, Oklahoma.

(Marianne Kneeble): Well, I know Kansas just had one a month or so ago with another exercise. But and this is where I get a little confused. If someone has to initiate this and if it's not you then who is it? And --

(John Zack): Well, you know, that's a fair question. So I think on the government side, we're very concerned and we're doing the most with what we've got. I think that the industry -- if my livelihood depended upon the disease status of my animals, I know in the industry, because I was in private practice a fair bit of time, you are so busy. There's so many other issues to worry about. You know, this is kind of the boogeyman out there. This is the bad day boogeyman that hasn't happened for 80 years but I would just saying that we want to have every opportunity to work with industry and the states.

I know folks kind of look to us to develop some plans and plans are great, but plans are only as good as your capability and capacity to implement them. And again, any SMB outbreak in this country is going to be a shared problem across the states, you know, USDA, and the industry.

(Steve Crawford): Good morning, John, (Steve Crawford). The goal of (unintelligible) is to get -- maintain or get back to trade status. Can you speak for a minute to how the type and phases in this draft might help with either geographic regionalization and/or industry compartmentalization to maintain or get back to trade more quickly for parts of the country or for certain industries that may be unaffected

or less affected? Or is this just the type of phases (unintelligible) unrelated to that?

(John Zack): I think that for me, Dr. Crawford, the first thing first is how are we going to handle this domestically and then how are we going to handle this with Canada and Mexico. And I think that, you know, your question is that the more organized we are, the better response we have then that'll help us initially restore trade with Canada and Mexico and then if we can get ourselves sorted, then you can go make a case internationally. Again, if it was an outbreak on the East Coast, if you're a year into it and it's contained (unintelligible), looks like you're cleaning it up, is there some way to regionalize the other part of the country. I think everyone will be trying to do that. But I would just remind people how we have treated other countries when they have had FMD.

So I think that Canada, the United States, Mexico, we all share a border. We may all share the same disease status pretty quickly. So I think this might help with some regionalization efforts but I think that I'm pretty pessimistic that until you have the outbreak under control, you know, that restoration of international trade across the water, across the pond, I mean that's going to be a high climb.

(Steve Crawford): Okay. Thanks, John.

(Don Ritter): Yes, (John), (Don) here, (Don Ritter). You know, in the AI experiences, I would just -- I would offer the following. I think you need clarity in your response. You can't be playing Monty Hall, Let's Make a Deal when stuff happens, okay. So you're suggesting that there can be very limited capacity for stamping out, and limiting desire to stamp out due to a lot of reasons. So I would -- I think somewhere there needs to be written down that you're going

to stamp out X amount of animals. That's the deal. And if it's more than X then you've got a plan B. And plan B may be the best bad idea you have depending on the situation, you know. It could be 50,000 cows. It could be 100,000 dairy cows. I don't know.

But if you don't have these things written down and agreed to by the stakeholders, and the state, and the Feds then it's going to be a total cluster when something happens.

(John Zack): Agree, Don, and I think the other issue that will come up immediately will also be the movements of products, certain products like milk and the movement of, you know, animals and well. So we agree and I think that's type of playbook that we want to get to that outcome as best we can.

(Linda Thompson): So this is (Linda Thompson). No, I agree with what Don says and I think the USDA has received fairly strong messages both from this committee previously and from stakeholder groups about vaccinations. And a lot of the questions that were asked on (unintelligible) priority of vaccination use are even difficult to answer with the current vaccine situation. So it's not even doses available to meet some of the priorities that might be suggested by the different agencies and the different stakeholders.

So and I find the phases, and the types, and the descriptions really appropriate but I find the accomplishment of the goals in them a little difficult, particularly Phase 1. So it specifically says that there's a goal of less than four days to accomplish the goals and we know we don't have premise ID information and animal ID information that allows the kind of trace backs that we would like to do in that period of time. And we -- and so there's a question when you go down the list in Phase 1 that says identify the strains and folks can (unintelligible) decide whether to activate the vaccine bank.

I think the message has been that the vaccine bank should be activated ASAP because you already indicated that we could guess wrong. On day four, we could find out that the outbreak hasn't gotten beyond the local stamping out. I mean all the tabletop exercises that have been done since the U.K. outbreak indicate the high likelihood of spread beyond the local outbreak in almost every commodity group that's out there.

(Liz Lastrom): This is (Liz). To add onto what (Linda) just said, when you activate the vaccine bank, you don't necessarily have to activate the vaccine bank to have a vaccinated national herd. You can activate your vaccine bank to vaccinate, kill, to try to close spread. So I think that that's another priority to consider. There is the (unintelligible) paper that lists how we (unintelligible) might use vaccine dependent on these phases and types. And so I think that's something that we need to also consider. Yes, that chart right there.

(Linda Thompson): Yes, so I would think that the vaccine bank has to be activated on day one.

(John Zack): Yes, and that's an excellent, excellent point and we'll correct that. And that's part of the reason why I wanted to circulate this to this group because this one's dated -- this draft one is from 2013. We're in the process of updating it now. The red book -- I mean you're absolutely correct and Dr. Clifford and now Dr. Sheer, you know, the minute that, you know, me and (unintelligible) and all, (Beth Botner) can type that out, if we have it in our bank we're going to start making vaccine. And if we don't have it in our bank, we're going to go around the world looking for it.

So you're absolutely correct and we'll change that because that's -- you're correct. That policy needs to be written correctly there.

(Glenda Davis): Dr. Zack, this is (Glenda Davis). Another comment with some of the tabletop exercises has been animals in transit. There are hundreds of thousands of animals that are moving. What's going to happen to those animals? Will they be stopping at the state borders? Will they be unloaded in certain areas? And all of those details have not -- it came up in a lot of tabletop exercises but I've never seen any after action or solutions as to what's going to happen to those animals.

(John Zack): I know the pure pork supply was writing a recommendation on that and I know it's -- and again, this goes back to I think some of the points people have made. If you have a plan, you know, maybe one person's plan A, somebody looks at that and says that's really a dumb idea. Because I think that our original thought was if you have trucks on the road, they either need to go back to where they left from or they need to move to where they were going to. Because if you stop them in route, you are just creating new problems with animals that are in route stopped now that have no place to offload. You're getting into humane issues.

The way I would say, if these animals were going to slaughter, slaughter plants decide to shut down that's, I guess, their choice, right. So a part of this is a cascade of effects and people buying into it. Animals are moving intrastate then the state veterinarian can say, you know, if they're moving intrastate, you know, if they're halfway, wherever they are, they should continue on to where they were going or they need to go back to where they're going.

If, you know, Kansas -- Bill Brown says, Dr. Brown says, I am not letting any of these trucks into my state, or I think what they would prefer to do with their exercises is actually, you know, stop the trucks, take their information to find out where they originated from rather than just turn them away. But you're

absolutely right, I mean and I guess my thought is that right now, we don't have consensus probably by commodity and by state how to handle that. I don't know, Liz, if you remember what they -- I think what the pork plan came up with was continue on to where you're going or go back.

(Liz Lastrom): Correct.

(John Zack): And then very often, people said, well, if I moved them, I've already can't take them back, you know. So..

(John Fisher): Jonathan, this is (John Fisher). This may be a little bit out in the weeds, but I don't see free range and wildlife mentioned at all in what you have put before us here. And I know we've talked about in the past and we've got a lot of susceptible wildlife species out there, depending on the location, primarily whitetail deer and (unintelligible) swine. And those animals generally are under the regulatory (unintelligible) fish and wildlife management agencies. And so has there been consideration and involvement of them in the planning process and in the response?

(John Zack): Yes, absolutely and you brought up -- the good news when you look at other SMD outbreaks is that the deer have never been implicated as a species where the virus remains as a reservoir, I guess probably the best way to describe it. But you know what, that's not the United States, right?

(John Fisher): Right.

(John Zack): And so, I mean, you're absolutely right that the -- we have some ideas how it might work in deer based on, like, how it was in the U.K. or other European countries. You look at Africa, well, you know they've had issues with the water buffalo. So I look at Texas. What are those animals called? Those --

what are they called? (Unintelligible). I remember them. We had a malignant catarrhal fever wildebeest strain operate there. How many wildebeest are in Texas? You know, so you're right...

(John Fisher): More than we think, I'm sure.

(John Zack): There's a lot of them. I was shocked. It was -- because it's a great -- this is the greatest country in the world. You know, people can follow their dreams but we end up with, just like you say, we have not only the wildlife but we have these other types of populations and, you know, in some states nobody wants to claim the feral pig. The Ag department doesn't want them and the DNR doesn't want them. Nobody wants them.

Woman: Neither does the pork industry. When you say Texas, FMD and Texas, the first thing that comes to mind for me is feral hogs (unintelligible) in Texas.

(John Zack): Yes, so you're absolutely right and that's all part of the -- you know, I think the initial response, we need to have a focus on the livestock industry but like you said, if you're up in Michigan or Minnesota, you know, I mean the states where the deer are really intense, deer populations, it's going to be a laboratory. So some of these things I guess what is it, the cliché, the known unknown. But again, it's a big (unintelligible) in terms of including, you know, the wildlife people and the DNR people.

The other folks that are going to be highly impacted by this are your grain commodity folks because they'll probably be some countries that shut off our grain exports and they're very unhappy to hear that, you know.

(Linda Thompson): Okay, it's (Linda). So you mentioned the grain and one of the kind of logistical nuts and bolts issues that all the commodity groups are addressing

moving pork and, you know, for high (unintelligible) moving eggs and the secure milk supply. But the movement of feedstock is a tough one and it created huge animal welfare issues and the U.K. animals starved to death when they weren't exposed to putting out the feed, and they were left on grazed lands where there was no feed left, and the horses couldn't get food.

I think a little bit more logistical information needs to be incorporated in all the plans in how feedstock will be moved and how those trucks will be sanitized. I don't think whether the -- I've attended a (unintelligible) some of the logistical discussions that what some of the supplies are that are in the veterinary stockpile,. But I think a lot of commodity groups aren't aware of whether there will be portal truck washes set up and how feed companies and places like that will identify those.

And I think that information needs to be shared widely and needs to incorporate the commodity groups that are not susceptible to some of these diseases because they need to know they can get feed to their animals or the feed companies can still sell feed and can move feed out of control zones like they did in the high path AI issue. So when a control zone gets closed the feed company that supplies all the livestock in the area may be in the middle of the control zone. And those kinds of logistics really aren't discussed in the FAD prep. They're more in the secure commodity group plan.

(Peter Fineo): Hi, (Peter Fineo) from Arizona. A couple questions and again, also may be down in the weeds, but just wondering where are you going to get the personnel if you have a multisite problem? And the second part has to do with diagnostics and with the national animal health laboratory network, the funding going down. Is there going to be the surge capacity to do the diagnostics that you may need for this kind of situation? And I guess the third

part of this, coming from Arizona where we have feral swine on the border, and with wildlife, what about some of those types of issues of border security?

(John Zack): Great questions. I think I'll start with the NAHLN. The good news is that over the last five years, the -- we now have, I forget the exact number, but I think it's 36 or more, maybe up to 40 some now, NAHLN laboratories actually have the capability to run the SMD PCR test and that those laboratories now are assisting the state veterinarians and ASIS with foreign animal disease investigation. So we have -- it's not uncommon now that if there's a foreign animal disease investigation with a (unintelligible) lesion that the NAHLN labs actually have the capability run the SMD PCR to assist the investigation.

And your -- the second part of that question you had was the surge capacity. And I know Dr. (Lotner) and Dr. (Tomlinson) and all the great NAH lab directors, I don't have the exact number for sure but I know we did an exercise a while ago. And I think they said that they could run 40,000 SMD PCRs a day. And it may be a slightly higher number or a much higher number now. So you're right, with all the restrictions on the NAHLN that has been identified as a higher priority to get one, the assistance for these FAD investigations where we really try to get diagnostic results quickly. So in addition to flying stuff to (Battle) or (Aims), now we have the NAHLN labs that can actually assist in the FAD of investigation of the state and animal health director and the NAHLN director want to participate and run those samples. And they've been working very hard on the surge capacity. They even had developed like a surge capacity calculator and I think they even have the NAHLN activation plan where if, you know, one NAHLN lab gets overwhelmed, you know, how to turn on another, you know, NAHLN lab to take a sample.

So that's key. In terms of resources, really good question. Again, I think this comes back to there is no federal workforce, you know, or even state workforce that's going to be able to meet the demands for an FMD outbreak. I think at the high path AI outbreak in the Midwest, you know, we had like 3000 people out and about working. And, you know, the majority of those were contractors. And when you turn on contractors for an event like that, you get variable results. I think that we've learned a lot from that and so we'll try to improve, you know, our relationship with the contract service providers we have.

I know we did one exercise back a couple years ago. I think it was the multi-state partnership and they requested, I believe, over 100 incident management teams and a bunch of strike team personnel. I can tell you right now that between the ASIS, the USDA, FEMA, there's not 100 incident management teams out there. So then we're back to working on how would we rationally handle that. You know, we're probably going to need (unintelligible) command system and I know there's exercises going on with that now with the multistate partnership and some other groups.

So you're absolutely right, you know, the incident management system, the NIM, as well as the folks that are going to do the work. And again, I think that it's going to be a shared activity. And I think the one thing we learned from the high path AI was like for the cleanup, we're now moved to the -- for the virus elimination step on the poultry farm, we have this calculator where we go to the owner of the buildings and the land and say, "Here is the money that the USDA will give you to clean up. You clean it up yourself or you subcontract someone," as opposed to having the USDA contractors come in and then people felt like they had no control with what was happening on their own premises.

So I think that each outbreak, we learn more about how to manage the resources. But FMD will be off the charts. Just think about the surveillance activities that folks will want to conduct on day, you know, one, that you have a detection day and then day one. You know, all the surveillance activities people are going to want to conduct, whether they're passive surveillance, active surveillance, the testing to move products. Yes, it's going to be huge surge requirements for personnel and that's something that we're trying to put down and I know Dr. Jones was on. I know that they had worked up out in California their (KHEMS) and I think they may have had some personnel estimates that they would need for California. So it's a great issue that needs, you know, still more work.

Woman: (John), if you look at search capacity, and lab capacity, and things like that, are you looking at the IP issues? You cannot effectively transmit Excel spreadsheets with positive results and, you know, we learned, you know, the differences messaging made in PED. But when we were taking weeks to get excel spreadsheets into a system before we had messaging would have been a huge -- it would have amplified the NFMD disaster tremendously.

(John Zack): Absolutely and thank you for bringing that up because that's one of the hard sells institutionally is you have to make the investments in information management. And like you just hit the nail on the head with the lab messaging is such a no brainer thing to do and now, we're starting to do it and we need to do it for more diseases and continue down that road. The other thing that for information management we're making improvements on now again, coming out of the high path AI is determining request processes. We're creating a gateway where the producers themselves, you know, if you're a producer, think about it. If there's an outbreak, you don't even know what the control area is, right. So you don't even know if you need a permit.

Once you have that communication of, well, what is the control area and in a dynamic outbreak, you know, that control area could be changing daily. So you're absolutely right, the information management from the diagnostics to the tabulating the surveillance, even the negative results have tremendous power, let alone the positives. And then the permitting aspects, all of that, you know, we're trying to improve and make significant investments as the resources are available.

RJ Cabrera: Other questions for John? I tried not to ignore that corner. I just can't see you guys down there very well.

Man: Could you open this up again? I (unintelligible).

(John Zack): Anyway, so I really welcome the opportunity. I know I talked too much, didn't listen enough to you, but going back to one of the first questions I think Liz had is like what do you want this committee to do. One, I just want you to know that as busy as we have been with high path AI, we have not forgotten about FMD. We have not forgotten about FMD vaccines but we want to take the HPI experiences and lessons learned (unintelligible) everything and everybody, continue on with the next level or evolution of SMD planning.

And we're going to lead some of that and we want you to participate, and we'll follow you or get out of your way as you develop, you know, your exercises and plans and what you want to do. So I mean that was kind of the big take home thing today -- message today.

RJ Cabrera: We have one more question here, or at least one.

(Linda Thompson): (Linda Thompson) again . Am I correct in that all the vaccines that we would have available to us, we still don't have a (DIVA) vaccine so if we

chose the strategies of vaccinate to live, we can't necessarily differentiate a vaccinated from an infected animal with the testing that we have today.

(John Zack): With the high potency vaccines that we have from the companies we currently have the conventional killed high potency vaccine, we can do (DIVA) on a farm basis. So if you did do vaccinations, you can do the (DIVA) strategy. There may be some individual animal variation obviously with that type of approach, but we actually -- what I'm told is that we have the technology to do the (DIVA) strategy. So that if we did a vaccination on a farm, we could go back later and determine that oh, was this farm truly not infected? Was this farm a mix infection.

If you had a few weird reactor animals you might just take those out and that would help you with your farm trade then. So yes, we're very, you know, interested in having each generation of vaccines to come out. That's a high priority as well is to make sure you can have it not only in a herd basis, but as best as you can on an individual animal basis.

(Linda Thompson): So the reason I asked that question is I'm a from a non-lab and that diagnostic testing has not been rolled out to the non-lab. So the only serological testing that's been rolled out to the non-labs was a pilot to compare two different (unintelligible) tests to see -- and the negative cohort study -- to see the level of specificity of that test, to make sure that they could understood the likelihood of false positives. Plus no (DIVA) serology testing has been rolled out to the non-labs. So from a...

(John Zack): I think that's a good point. We could follow-up with Dr. (Lotner), Dr. (Tomlinson). Do they have hat sitting on the shelf ready to go? Is that a funding issue, where exactly we are because you're right, just having NDSL the capability to do that is not enough.

(John Mahoney): Jonathan, it's (John Mahoney) here. Just a quick question. It looks like almost in any scenario we're looking at unless we are just incredibly lucky, vaccination is going to play a pretty significant part in controlling any FMD outbreak that we have in the United States (unintelligible) by any scenario, correct?

(John Zack): I think that's a logical conclusion.

(John Mahoney): Right. And if I listen to the public hearings correct, listen to the pharmaceutical or the biological firm that there's enough capacity right now in the world to produce the vaccine that we would need from a worldwide perspective if we had a massive outbreak in the North America; is that correct?

(John Zack): I think that -- I won't speak for Steve Parker but I know that -- I don't know if somebody else -- my understanding of this is that if you -- vac is like frozen orange juice. I'm going to use that analogy. So if you want to serve a party with 100 gallons of frozen orange juice, if you don't have your vac supply that it will take 12 to 14 weeks. If you run all that orange juice and get it all made in like a week or two weeks, it's going to take 12 or 14 weeks to make more orange juice. And 12 to 14 weeks is like, you know, Death Valley. That's the valley of death, right, in terms of remaking it.

I think what Steve was also -- Mr. Parker was also saying was that if the United States is really going to start -- go to 20, 30, 40, 50 million doses they need to tool up this facility in Leone, France, however you say it. So they -- that they would actually then -- because that would be, I think, the biggest vaccine bank in the world if we ever -- if we got to Jim Roth's proposal level

or somewhere in between, that would be a (unintelligible) bank that didn't exist anywhere else in the world. So that they would (unintelligible).

RJ Cabrera: (John), Steve Parker's in the room.

(John Zack): There you go. You can tell me I'm a liar now.

RJ Cabrera: (Unintelligible) going to give us some comments but maybe we'll go ahead (unintelligible).

((Crosstalk))

Man: The shelf life of these vaccines (unintelligible) years ago, there was a (unintelligible) that didn't have a good shelf life. Has that improved?

(John Zack): I mean, I don't know, Steve, what is it, a year to two years? I mean, no, it isn't great. The frozen vac -- the vac will last five years. So and then I think the way we're heading is you have your frozen orange juice. It's good for five years. (Marielle) or the other company will buy it back and you rotate the vac. That's a better way to handle it.

RJ Cabrera: So would the committee like to have Steve gives his comments after questions (unintelligible) plan side? So (Steve Parker), if you'd like to -- I don't know if you were going to give comments but come on up and visit with us. Grab a chair if you'd like.

(Steve Parker): Hello, Dr. (Zack). This is (Steve Parker).

(John Zack): How's it going?

(Steve Parker): Fine, fine. And I want to thank you first for -- I know that you and your staff are working hard and we appreciate that effort. For the committee, I was part of that panel that testified in front of Congress. Just a couple of points about FMD vaccine. Yes, there is no current capacity that exists anywhere by any company whether it be my company. Merck is the other company. Biogenesis is a South America company that produces conventional vaccine. No company today has excess capacity. There is no magic spigot that you turn on and FMD vaccine flows out of. There is no excess inventory beyond the banks that are already in existence and those are relatively modest banks when you consider the size and scope of a North America outbreak. There have been instances where some banks have shared their antigen with other countries, but that's not really -- given, again, the size and scope of North America -- don't count on much (unintelligible) from that. That's just not reality.

So if the outbreak were to occur this afternoon, it may be two to three years before vaccine becomes available. That's just the stark reality. We at Marielle, and this is what I told the committee, we stand ready to work with the government on solutions. We've not been asked an official question yet. I know Dr. Zack and his staff are working on that and there is a document circulating that hopefully will come out for public acknowledgement soon that we in the industry could respond to and say, "Given this set of circumstances, this is what we can do." But we need to be asked that question and we've not been asked that question yet.

So that's the stark reality.

(John Mahoney): (John Mahoney) here again and I think that's a critical point. And obviously, a lot of the things we're talking about are absolutely critical too in terms of preparedness, getting our secure (unintelligible) supply plans, getting cooperation between states, federal government, local, and that includes going

down to I suspect even the state police, you know, in terms of working on issues.

But, you know, if we don't quickly address this issue of availability of vaccine, you know, I'm concerned we're extremely vulnerable.

(John Zack): Yes, absolutely. And again, you know, it's again, I think one of the highest priority or the highest priority, you know, strategic issue, or infrastructure issue, or logistic issue for SMD response. So again, I'm not trying to forget about that as we -- but I think the good news there is we've had a lot of conversations about it for a few years. At least we got it -- at least it's been elevated up to Congress now. So however our democratic system works to get resolution, you all tell me.

(Steve Parker): And John, to that point, just -- this is really not a Marielle comment. This is an American taxpayer comment. The idea of who pays for it is still in question. I know that (AFIS) has a certain opinion about how it should go forward but the idea of a right sized appropriation request or a plus up from Congress or caution from the commodity groups, that's all still in play as to how an appropriate response plan is funded and implemented. So that that is as much of an issue, I think, as some of the other things.

And (unintelligible) too about the (DIVA) capabilities. I can only speak for my company, but Marielle conventional vaccine are highly purified. Therefore, there is the (DIVA) approach to identify either the presence or absence of non-structural protein. It is not a pin-side test but there is the capability to differentiate. But that model needs to be further explored to bring the diagnostic capabilities to the forefront. And that should be probably a consideration in any question about vaccines.

((Crosstalk))

(John Mahoney): I have another question. I know it was early highly debated even at the public hearings in terms of funding for the vaccine, yet it seemed like the congressional members were always trying to slide in, you know, joint public and federal funding for vaccines. But, you know, my understanding is part of the homeland security (unintelligible) directive nine was mandated that an adequate bank would be funded through federal agencies; is that correct? Maybe you don't know, but...

(Steve Parker): I probably should not comment.

(John Zack): Well, I can tell you that the HSBD 9, which I think goes back to President Bush 2004, I believe, that funding to achieve all the goals in that has never been there. I know that our ASIS leadership related to the congressional hearings I don't -- we didn't -- nobody's made this actually participated at the briefing that day. But I know that the message they have conveyed to the committee is that, you know, this is a very important issue but that ASIS cannot redirect funds from its current program to solve this issue. And it's a significant in a way to meet the right sized or the vaccine bank that depending upon if we all got together and came to a consensus, it would be much larger than what it is now.

I know that the actual investment that each country is making is going to increase this year but I don't -- that's just to meet the cost of doing business. That's not really going to achieve a more robust numbers of doses or frozen vaccinate concentrate.

(John Mahoney): Just another question follow-up (unintelligible) asked this to folks yesterday. Has there been work done, and it sounds like not directly within this

(unintelligible) partners, in terms of looking at maybe a more accurate assessment of what it would cost to fund that vaccine bank? Is there any work being done on that?

(Steve Parker): Dr. Zack, I'll try to answer it from my end if you want to follow back up on that. But we've run scenarios already. I mean I can only speak for my company. We are ready to start today. As soon as we get the question asked, we've assumed several scenarios. We have cost already developed. We're ready to break ground on a brand new F&D plan, but we're waiting on the United States and North America.

One thing corporations do not like and that's idle industrial capacity. You can't plan to a promise or a potential. You actually have to have something in place in order to justify the capital expense. We are ready to start now and we know how much it will cost based on the several scenarios we already have.

(John Mahoney): Can I ask you a follow-up? Obviously, you've been very impressed with the work that (Jim Ross)'s group has done at Iowa State and I think his estimate was $150 million over a five-year period. Would your assessment for initial projections be in line with that, less than that?

(Steve Parker): I'll take that $150 million right now.

(John Mahoney): We can do it for less.

((Crosstalk))

(John Zack): I would say, and I think Steve mentioned this, that (AFIS), the program is written up (unintelligible) request for information that goes out in the federal register for the vaccine companies. And then that has been written up by the

veterinary service programs, and that is now going through clearance processes. So I can't speak to when that will become available, but I would say that we all understand hearing Mr. Parker speak that the next step for him is to have request for information that him and other vaccine companies can address, like you said, the questions being asked for quantities and capacity.

And then the next step after that will be a request for (unintelligible). So I think that, you know, the step wise there may be a step that -- I know Dr. (Ross) had done a great job estimating, I think it was, for the 23 stranger topo types for the $150 million a year for five years. With our current capacity, getting to $25 million for 10 or 14 topo types would be a tenfold improvement roughly.

So there's -- like people are suggesting, there's probably a couple different approaches to get to the right size of bank. And I think that, like, the -- I'm sorry I missed -- I think a couple people had indicated, like, you know, the studies to see how much would it cost. I think that kind of goes back to the question I asked. You know, we need to her from the industry is that if, you know, we hear very strongly from the dairy industry. They're like, I do not want to lose my dairy cows to FMD. I have a long-term investment in my dairy cows from the time that the calves are born to the time, you know, that they're (unintelligible) on the milking line. I need to protect that investment.

So I think that by commodity, and you'll hear breeding people that have valuable breeding stock, you know, I would kind of like to get a number of, you know, to protect and genetic stock or certain industry groups, what is the baseline vaccine that if you're in a region that is exposed to the threat, if we're going to not only use vaccine to control the outbreak, but if we're going to use vaccine to protect certain types of animals with certain value (unintelligible) for livestock, what are the base numbers we might need there.

So that kind of gets to the next level of conversation, and engagement, and planning. But, you know, yes, I think we've all kind of recognized the current capacity and capability is not satisfactory.

(Linda Thompson): Well, John, I think -- this is (Linda Thompson) again. I'm just speaking for myself here. Certainly, we have not enough vaccine. We all know that and we can't vaccinate all the dairy cows and we can't vaccinate all the breeding beef cattle. And we can't even, in the Palo Duro exercise, we can't even necessarily vaccinate the animals at the center of an outbreak. But it seems like we're all agreed that we want to do whatever we can to avoid a catastrophe. And if the only vaccine we have is to try to do a (unintelligible) vaccine to stop the spread of it, it seems like that's got to be the highest priority with the current vaccine until we finish this job of making sure we have a sufficient vaccine bank.

We have to do whatever we can to respond domestically to avoid a catastrophe.

Man: (Unintelligible) what would be the plan B then for the producers in the meantime if they have to wait a couple years to get the vaccine?

(Linda Thompson): Disease management.

Man: Excuse me?

(Linda Thompson): Disease management. I mean that's...

Man: And who is going to establish that?

(Linda Thompson): I'm not saying I like the answer.

Man: (Unintelligible) need to be (unintelligible) education to the producers and in this (unintelligible) they're going to be more effective a number one (unintelligible) to isolate (unintelligible) one to another like (unintelligible) or whatever. But there needs to be something in place to educate the producers.

Woman: Dr. Zack?

(John Zack): Sure. I think what I heard was if we had an outbreak and there's not enough vaccine, what do we do? Is that the...

Woman: What is the plan B was the question?

(John Zack): Well, I mean, I had a really brilliant epidemiologist here. He retired and when he walked out this door, he said, "Thank God there wasn't FMD when I was here." That's what he said to me and, you know, he basically said, you know, (unintelligible) he was very experience and I took the words to hear was that, you know, FMD will be -- it's a very difficult production animal disease. And I think someone I the room said it, you're going to have to manage it. And, you know, the younger animals -- some younger animals will die. Some species will be more hard hit, depending upon the strain they tell me, sometimes that will have an effect on how hard it hits animals.

I think for some of our livestock production units it'll be, again, the laboratory experiment. In theory, some animals can recover from this but will they be able to get the nourishment and the water they need to survive let alone their -- obviously, their production growth will be severely impacted. But would they be okay to survive? And so, you know, I guess what that epidemiologist called it was you're going to have a burn through. When you see a naïve

population exposed to a highly contagious virus that we know is going to move, I mean we've seen this with other diseases. I mean no one should be shocked or surprised that we have FMD come into this country and that if it -- by the time -- we hopefully will have early detection, and we'll have early containment, and early control. But no one should be shocked to see this both highly contagious disease of animals that affects so many different species potentially spread very quickly.

And you're absolutely right, and I think that, you know, the other aspect is we can talk about biosecurity, but you tell me for your industry segment, what is going to be an effective biosecurity plan or procedures to follow and how long can you sustain them? And again, when you talk about effective biosecurity, the number one thing to do is stop movement. And somebody brought it up earlier, okay, does that include feed trucks. So you're going to starve your animals to save them.

So I mean there has to be a triage of what movement you're going to allow immediately ,what mitigations you have to do immediately. And, you know, so like if Steve painted the picture where if we couldn't get enough vaccines to handle the problem then it becomes, like someone said in the room, I think, then you have to -- it's an animal disease issue that you manage with the tools you have.

RJ Cabrera: Any last questions for (John)? I think we're probably going to jump into a 15 minute break here and then come back and do a little...

((Crosstalk))

RJ Cabrera: Well, I wanted to (unintelligible) complete the -- it looks like we have four or five more pages. Did we want to continue to (unintelligible) that up or are we good?

(John Zack): No, I think we're good. I mean I'm fine if you're all fine.

RJ Cabrera: Yes, I think we can leave your -- we've got your slides here too, right, if we wanted to.

(John Zack): And I think you all are connecting the dots faster than I can put up the slides. You know, almost ever response strategy -- you have stamping out, focal. After that, you're going to have some kind of vaccine requirement for your response. More than half the world has FMD and we all know that they handle it -- if they can't stamp it out, they use vaccination for their control measure. So it's...

RJ Cabrera: Well, we're going to go to a 15 minute break, come back and discuss. You're sure welcome to stay on the phone if you'd like.

(John Zack): I'd love to, but I've got to run on other meetings here. So thank you.

Woman: John, can we reach out to you if we have questions that come up during the discussions, you know, I'll send you an email (unintelligible) or you could be available between now and tomorrow?

(John Zack): Yes, send me -- that's okay.

Woman: Okay. Good. Thank you very much.

RJ Cabrera: Great. Thanks, John.

(John Zack): And I look forward to working with all of you and let's keep it out of the country, right. Being lucky is the best strategy.

RJ Cabrera: We timed this just right. It's the top of the hour. Can we come back at quarter after?

((Crosstalk))

RJ Cabrera: Okay. Thanks everybody for coming back quickly after break. We are theoretically supposed to be going over the last year's -- responses to last year's (unintelligible) or last year's recommendations. I think as long as we still have (Steve Parker) in the room, as long as we have (unintelligible) hall talk outside about FMD. Maye we'd like to have just (unintelligible) capture a few themes around FMD and then we can obviously have more discussion time and really refine some of what we would like to say on Thursday. (Charlie)?

(Charles Rogers): This is (Charles Rogers). You know, back to our first response, the first herd. If let's say that first herd is 6000 (unintelligible). There's a problem with using that in this herd and (unintelligible) for several reasons, environmental and maybe our best option at this point is slaughter. There are 6000 herd of dairy. There's probably only a one or two day slaughter for most slaughter plants. Is that not a (unintelligible) at this time, and then do we -- because there are so many other restrictions with environmental and everything.

And plus, the vaccine is not available. We just found that out so we're in this position at this time that we have to move. I believe we have to move to the slaughter position immediately and as our herds expand, this herd moves to the next herd, same thing, we move to slaughter. Because that's our least

amount of environmental impact. And it's -- I believe it's our best option at this time. Any discussion on that possibly?

RJ Cabrera: Yes, I'm going to add a couple questions at some point (unintelligible). One, I think we need to make sure we've got -- and (Judith) and I were talking about this -- that we've got the scientific literature understood well enough to understand if there is -- how long FMD might be in the muscle of the various commodities or species so that we could prevent potential spreads through illegal garbage feeding, but still garbage feeding.

And so whether we have that literature so that we'd be able to say that that meat is safe to, you know, enter into Congress would be I think a point to round that. And I've lost my second point, which is fine. Anybody else have anything they'd like to add to the (unintelligible) for slaughter?

Man: Obviously, there'd be certainly a change in philosophy where it's immediately just shut down that zone, that area around the infected herd because obviously, you're going to have to put them on drugs and send them to a plant to be slaughtered. And kind of the issue with some of the big dairy cows is they don't necessarily fit in those -- that cattle slaughter plant. So there typically are more cow kill plants, things like that, that reach capacity generally not as high.

But logistically, I see where you're going because it makes a lot more sense to try to salvage some value out of the animal, not create an environmental mess, not create, you know, more humane concerns about how these animals are put down, et cetera.

Man: (Unintelligible) you can kill, in just a few hours, you can kill a few thousand dairy and (unintelligible) very environmentally sound (unintelligible) moving that way out, spread (unintelligible).

Man: I would also add that I don't know what the inactivation temperature is for the FMD virus. And my concern would be all of the byproduct is going to go through a rendering plant, and how is that -- whether or not rendering is sufficient to inactivate the FMD virus. If not, how did the slaughter plant then end up having to dispose of that material is a question that needs to be at least answered.

Man: I would like to add (unintelligible) what they did in England (unintelligible).

Man: They did many things. They started by incinerating (unintelligible). In the end, most of the animals are going to landfills. Once they -- once the capacity got overwhelmed, but (unintelligible) there was this big public outcry about burning animals and, you know, the media perception of that. Just back to the slaughter thing, you know, again speaking in Michigan where we had to (unintelligible) herds from tuberculosis, it's difficult for us to have the capacity that we could populate smaller dairy farms rapidly in Michigan, to be honest with you, unless we commandeered the slaughter facility. I mean it's very difficult.

And I think that would be hard, to be honest with you.

Man: (Unintelligible).

Man: As far as what, I'm sorry?

Man: Who is going to make the decision what we do with the (unintelligible).

Man: Are we talking about food and mouth disease or -- yes, I'm not -- I doubt it's the producers (unintelligible).

RJ Cabrera: Yes, it'd be your instant command structure (unintelligible). I do think picking up on what Max was saying, I'm not sure that we got that, is that I know that the USDA has -- and some states -- have an environmental assessment of animals disposal, but to make sure that every area where there are animals, there's some idea of environmental -- the environmental limitation for disposal of animals. Because in some places if your (unintelligible) table is too low or too high and you're not going to be able to dairy and others (unintelligible) a whole host of (unintelligible). Exactly. So Peter?

(Peter Fineo): I think there's also another thing we have to remember about this particular disease and that is the animal welfare component. These animals are miserable and the question is, I mean, would some animals even be ambulatory enough to go to slaughter. (Unintelligible) because they can't walk in the plant.

RJ Cabrera: So then they may not pass inspection when they go there to be disposed of.

(Peter Fineo): Right, so I think that's the other thing we have -- even when the discussions earlier today was about animals that survived, I had the opportunity to do a USAID project in Egypt and was actually on several dairies that had had an outbreak of FMD a year before. And they vaccinate every six months their dairy cattle for FMD, and this was a slightly different strain than what they vaccinate for.

And this one dairy had a large (unintelligible) close to where the office was -- this was a year later -- of essentially non-ambulatory dairy cows as a residual effect of the FMD that they experienced a year before. So I don't want to belabor the point, but there is -- this is, for the animal, a very debilitating and painful disease and we need to keep that in mind as well.

RJ Cabrera: (Unintelligible) on your welfare consideration, which I think is an important point is that the welfare considerations (unintelligible) movement (unintelligible) where you're meeting pigs and moving them every day. You can keep them around for a few days, but at some point in time you're just going to have too many animals and, you know, you can start (unintelligible) and things like that. But you -- it's still a (unintelligible) stopping (unintelligible) is a welfare consideration as well as the keeping sick animals alive.

(Unintelligible) current phases and your pork supply, your beef supply for AI, your egg and (unintelligible) supply, your milk supply all have some provision for allowing animals to move to slaughter. I think you're correct in that (unintelligible) should not be (unintelligible) where that could be avoided and where it's already been detected. The decision is made that those animals don't move while they're (unintelligible).

Man: So I just want to kind of bring the conversation back to the issue about vaccination. It's clear to me that should an outbreak occur here, you know, vaccination is going to be a key to eventually controlling the disease. (Unintelligible) welfare implications and so on. And so one of the things I guess just thinking out loud is despite what Dr. Zack said where he wanted to focus on something other than vaccination, I still think that that has to become a clear focus from this committee, recommendations saying that we've got to figure out this vaccine.

And I was part of the committee last year, but I apparently had some big discussions but nothing's changed, right? And so, you know, I don't know what needs to change but, you know, something -- recommendations coming from this is we need to get past ground zero and vaccination is a clear thing we need to talk about.

(Steve Parker): Absolutely, and I think that that goes back to the issue, if you're going to discuss this as a committee, is personnel and mobilization personnel. (Unintelligible) from North Carolina has done a lot of work looking specifically at North Carolina and what it would require just to do ring vaccination in that state to sort of get the hog -- swine industry in that state to survive. And I think that makes a really good model for us to look at what would be required not just, I mean not only in the vaccine, but also in the personnel and traffic control and everything else.

I mean it is as massive logistical undertaking and that's --

Man: And if I can add to that, it's not just personnel but it's the ability to actually get the vaccine into those animals because it's (unintelligible) to handle, to be able to catch them and, you know, and we again learned this with TB in Michigan, in Northeast Michigan. The vast majority of the facilities up there have no facilities to handle animals.

Man: Dairy cows in a barn with (unintelligible) is pretty easy.

Man: But a beef in Northeast Michigan that has nothing is a whole different ballgame.

((Crosstalk))

RJ Cabrera: The other issue that did not totally work at it is because we don't have the vaccine capacity. But if we had the vaccine capacity for distribution of the vaccine, I know (Annette Jones) did an exercise and I don't know if she's on the phone or not, she could speak to it, but, you know, we're -- as a veterinarian and the veterinarians I talk to -- we're not into logistics of

(unintelligible) and maintaining that, and neither is the USDA. But we have companies that supply all the rest of the vaccines we need in animal agriculture and those companies may need to be incorporated into the fold and (unintelligible) the vaccine. Most veterinarians don't really understand that they're going to be able to play a role in that. They think the USDA is going to handle it.

You're not going to get the vaccine into the animals unless every bovine practitioner in the United States is involved and every (unintelligible) and every -- and the (unintelligible) people here at the table are already saying they can't get a veterinarian. How are we going to get the vaccine (unintelligible) and I can't get it. Yes, I think producers are going to have to be -- they're going to have to consider producers to vaccinate their own animals. You've got this missing -- you've had your hand up and have let other people talk, so (unintelligible).

Man: Well, no, I appreciate all the comments and I want to say this as diplomatically as I can, but if we consider the fact that the total herd size continues to increase along with lack of plans and emergencies. And I will use AI as a good example, it floors me that we have so many large facilities with battery cages, knowing full well you can't easily depopulate animals under such housing conditions to the point where ventilation shutdown becomes, in some people's mind, a viable option.

I guess where I'm going with this is we have to be more attentive as a nation to the fact that, you know, gathering animals in a place to feed them out and produce them for food is only part of that equation. And thank God we're talking about FMD, but there a whole slew of other diseases that will clearly threaten this nation under the models that we're currently operating under where you gather animals by the millions or tens, hundreds of thousands, and

have no ability to shut down a highly infectious pathogen that may, in this case, be (unintelligible).

So I guess what I'm saying is if there's one thing we should learn from having to address the FMD is that embedded in that is a revisiting of the entire approach to animal agriculture. I'm not being specific. I'm just saying if you're going to put them all together in a housing situation that makes it very difficult to address a disease outbreak, that's stupid in my mind. And I say that very undiplomatically. We should be smarter than that at this point. We've learned a lot over the decades and you just can't play with fire like that and not get burned eventually.

So moving them to slaughter, generally a bad idea because you spread the microbes in the process, depending on the microbe. A virus is going to be different from a bacterial organism and so there's no one answer. I'm just saying the answer has to be going forward, I think a good answer has to include a focus on just how we are housing these animals to start with.

RJ Cabrera: So I wanted to (unintelligible). I'm setting up all sorts of stuff. I'm putting this for further discussion. Certainly, I mean everybody agrees with everything that was said and we (unintelligible) that became an issue last time. So this is going up right now. We will continue to discuss.

Man: That's well captured. Thank you. That's what I was trying to say.

(Liz Lastrom): Well, no, I think you get size of concentration but you also have the ability to (unintelligible) for it. So, you know...

Man: Yes, in some ways more idyllic setting, you know, beef cattle in Michigan and pasture, happy cows, green grass. But no way to handle the animals if they get sick...

(Crosstalk))

Man: But just to be clear, I didn't say that. I'm not talking about happy cows on pastures. I want to be clear. I'm a little sensitive about that because most people seem to think that folks who care about animal welfare want to see the idyllic they're all out there on a pasture. No, I believe confined animal feeding operations will continue to be necessary given the demand for animal protein. They're not going to go away. But when you start getting into these humongous operations with no plans, ability to how you handle the sheer size of volume of these animals under those -- and that's where we are.

So it's not about the pastures. It's everything what we have today.

Woman: I tend to agree specifically with the pasture thoughts. When we do herd services on the reservation, there are a lot of farms and ranchers that have no facility. So it's an all-out radio. So if there was an issue with treating these animals, they need to have a facility. They need to have a plan. They need to have something to be able to work the animals.

So I think both sides of it we need to look at the small rancher as well as all of the huge facilities and have people responsible for taking care of their herd.

Man: As we go forward, we have one other consideration we need to all keep in mind. We have food safety but we also have a growing population that needs more food and we're going to be in charge of providing that food. We want to be careful about making recommendations that impede commerce or -- yes,

cost. We need cheap food. We need cheap food for the consumers in this country. We don't need to increase cost. Food safety and food abundance have got to go together somehow.

Man: I agree. But the assumption that I think is embedded in your comment is that that must involve animal protein in the proportional levels that we see today. And if we just take greenhouse gasses and you mark this, within the next five years, probably, the number one contributor to greenhouse gasses will be (unintelligible). The transportation industry continues to try to address how do we reduce greenhouse gases from transportation, you know, even electric vehicles. But if you do the math and you keep adding the number (unintelligible) that's on this globe, at the rate that we're doing, we'll screw the planet.

RJ Cabrera: I think that's probably outside area of the scope of discussion, and I think it's a discussion we have...

((Crosstalk))

RJ Cabrera: Yes, I think we do need to get back to some basic things we can advise USDA because I don't think we can advise USDA on (unintelligible) it's outside USDA's scope on numbers of animals we keep, et cetera. But...

Man: It shouldn't be.

RJ Cabrera: But what...

Man: It should not be. I'm sorry. I disagree. As an American who pays taxes, I think that's what we're looking for the agencies to do. You don't just -- if I wanted to

be in a different type of business and I'm going to screw my community with my product, you're saying nobody should care about that?

RJ Cabrera: No, I'm saying that (unintelligible) the scope of this discussion is foot and mouth disease virus control and so, you know, we probably need to stay back on that scope. And so what other concepts around FMD (unintelligible).

Man: I think we've -- oh, sorry -- a discussion about managing the bank, you know, (unintelligible) a discussion. I read the notes to last year that they made a recommendation that they consider a contractor to manage the foot and mouth (unintelligible) virus bank. And I think the response back was they were interested to go forward about that. So I think is there an opportunity to position potentially (unintelligible) what they were doing in managing FMD vaccines throughout the world. Encourage the secretary to consider sitting down at the table and talking with potential partners like that.

RJ Cabrera: I'm going to go to Linda and then (unintelligible) because (unintelligible) had their hands up.

(Linda Thompson): On Navajo, we did a full scale veterinary stockpile of exercise and so that was way back. And just wondering if they have -- what's their capacity and what their inventory is for FMD, and if those -- if that inventory needs to be looked at differently, whether we're going to have the truck vehicle washers, all of that equipment to address if there's a (unintelligible) to a certain area.

So I don't know if that is something that's already been looked at, already been...

Woman: I think I missed the very beginning of your thing because I'm not catching context for this.

(Linda Thompson): So to review the veterinary stockpile and what it has in inventory to address FMD.

RJ Cabrera: And for those who aren't familiar with the stockpile, the stockpile is actually the needles, the syringes, the supply...

((Crosstalk))

(Max): What is the (unintelligible)? What is (unintelligible)?

((Crosstalk))

RJ Cabrera: What's the time between identification of the strain and the first doses of finished vaccine, three weeks?

Man: If you have the (unintelligible) in the bank then you're able to get four days convert (unintelligible) into concentrate for the final vaccine.

RJ Cabrera: That doesn't include shipping time, though, does it?

Man: We make it available at our loading dock to be sent to the United States (unintelligible).

RJ Cabrera: But we'd have -- right now, the way it's managed it has to be shipped from some island to you and then back.

Man: That's correct. So you'd have -- we manipulated four days once you received it. Right now, it has to be shipped from some island to Europe (unintelligible) U.K. We take four days to process it and we make it available (unintelligible).

So that's the exception. All other types of the world (unintelligible) back and forth.

((Crosstalk))

Woman: Your capacity to turn that around in four days is how many doses?

Man: We can process four days probably (unintelligible). I said (unintelligible) four or five days, but that...

Woman: Twenty-five million.

Man: Agreed.

Man: That's all that's in the back.

Woman: That's it. Yes.

Woman: Is that staying static or is it rotating?

Woman: It's static.

RJ Cabrera: So one of the things as I've listened to the discussion, and one of the things that came out of the hearing the other day is that AFIS has -- and TJ talked about it yesterday -- AFIS has said they will or committed to getting a request for information published that would actually figure out how much they would actually cost. What TJ told us yesterday is that request that they're getting ready to try to publish (unintelligible) topo type at 25 million doses where from Dr. Ross's paper, we're talking about 23 types and wanting 40 million or 50 million doses.

And I'm wondering if this committee might want to consider recommending that they expand that request for information and they can always buy less, but they at least would know the cost of true protection.

Man: I think that's what we're asking because it's time to have USDA approach industry -- potential industry partners and sit down and put together a (unintelligible). Give them the go to get the numbers to them.

((Crosstalk))

(Steve Parker): I don't think we're at that point. We just (unintelligible) that this committee could push to get that thing out, we're ready to respond (unintelligible).

Man: Is there a legal restriction about the antigen being available from outside of Plum Island? Is that -- will that have to be revisited?

(Steve Parker): The only legal restriction or regulatory restriction that I'm aware of is a (unintelligible) United States with the exception of Plum Island.

Man: Right.

(Steve Parker): I don't think there is any regulation that prohibits storage of (unintelligible) for the United States of America (unintelligible) that's a decision, as I understand it, (unintelligible) that was made (unintelligible).

Man: That may be a (unintelligible) question for Zack (unintelligible).

RJ Cabrera: Or what regulations are there related to the antigen.

((Crosstalk))

Man: We keep the concentrated product, you know, within our control.

Woman: Right. So I had just a couple more based on just where I see (unintelligible) highlighted during conversations. So it's not (unintelligible) activate that team bank immediately, identifying measures to get the producers on how to manage the disease if we have, you know, including (unintelligible) limited feed stock. So those were things that I'd had in my notes from when we were discussing.

RJ Cabrera: I'd go back to that (unintelligible) question about where you would keep a bank. Because if we're going to keep antigen, which will last five years and still having to be rotated every 18 months, there is then the requirement that antigens go back to a good manufacturing plant to reconstitute it. And so even though could store it, but (unintelligible) whatever, you still are going to then have a good manufacturing facility who can reconstitute it. And I don't know that you're going to be able to just pick up a line somewhere, the vaccine plant in the United States is going to reconstitute 2.5 million doses. So I think that's a consideration as well.

Woman: So the suggestion for the comment was that all the rest of the world gets to store their antigen bank at the vaccine manufacturer and why don't we?

RJ Cabrera: Correct.

Woman: And do we have regulations that would prevent that, that would have to be revisited.

RJ Cabrera: Yes, I totally agree. I think we should capture that in some of our recommendations on (unintelligible) prevention. I know on the TV, AFIS did a root cause analysis early on. We did some (unintelligible) information, really considering whether it appeared to be involved with either feed or the transport of feed, but (unintelligible) we've had ortho (unintelligible) virus. We've had two or three other viruses, all of Asian origin. And if they're coming in through whatever open door we have, it's also very likely that FMD could come right through that same open door.

And so...

Man: Exactly. There's not enough money to go down the whole list of agents that could threaten our industry. Got to get on the front (unintelligible).

RJ Cabrera: Okay. With that happy note, (unintelligible) we'll be back at 1:00.

((Crosstalk))

(Liz Lastrom): So thanks everybody, hope you had a good lunch. We have with us Dr. (Brian McClusky) who used to be Chief Epidemiologist (unintelligible), executive director science technology analysis services and the (unintelligible) comprehensive integrated (unintelligible).

Dr. (Brian McClusky): All right. Good afternoon, everybody. Thanks, Liz. I appreciate it. And I just go by Brian (unintelligible). I know a good portion of you in the room and I'm looking forward to meeting the rest of you. Really one of the reasons why I thought it was important to actually come down and meet with you face to face is partially because I want to make this (unintelligible) partially because I really did want to get a chance to visit with you this afternoon. And I am part of the veterinary services executive team. We -- and

as an executive team have had a lot of conversations about this committee and really want to find ways to get a lot more out of the committee and figure out a way to really connect better with the committee, since you obviously represent a fantastic variety of our stakeholders and have very -- a variety of experiences that we feel are really important to help us move ahead.

So just a little bit of my background and why somebody from the executive team is going to talk about surveillance is I'm an epidemiologist by training and I really came up through veterinary services on the very scientific, technical side. As Dr. (Lastrom) just mentioned, I was chief epidemiologist for ASIS until last September when I moved over to this job. But this job has actually allowed me to maintain a lot of connection with the epidemiologic services that we deliver.

One of the centers, as I mentioned to my -- to you all yesterday on our introductory remarks -- one of the groups that's part of this SDAS is the Center for Epidemiology and Animal Health, which is in Fort Collins, and that's where I'm stationed. So I do a lot of work with (unintelligible). So what I'm here to talk about this afternoon is this idea of comprehensive integrated animal health surveillance. And I know that some of you here have probably heard about this before.

And sort of the qualifier to the title here is the enabling part. So we do a lot of animal health surveillance in the United States for lots of different things. We've been doing it for a long time. I think we have parts of that that we might be -- that could possibly be considered comprehensive by some. But we have a really long way to go and one of the things that I'm leading right now is trying to develop a strategy around managing animal health surveillance data and also emergency response data in a way that's comprehensive and integrated.

And this is -- for those that have dealt with this very directly -- we really do struggle with data and getting -- collecting it -- and integrating it, and then using it, and analyzing it, and reporting it, and making sure that it's valuable to you guys and to us. So kind of to start with, let's talk about the concept of CIS, or comprehensive integrated surveillance. So this is sort of an approach that we've taken probably since 2003 when I was the director of our national surveillance unit that we sort of stepped off into this. The idea of comprehensive is we don't want to be siloed to a particular disease.

So if you're familiar with our (unintelligible) surveillance program, it's been around since the '30s, that surveillance was done pretty much just for (unintelligible). We collected blood samples at slaughter. We collected blood samples at markets. We did a lot of on the farm testing. And those samples were tested with some data associated with them and that was the (unintelligible) surveillance program.

And then we had a TB surveillance program. And then we had rabies. And so we were really looking at these very siloed (unintelligible). Part of the idea here is to make that comprehensive in looking at multiple (unintelligible). And we do that by potentially testing a sample that we collect some place for multiple diseases of interest, instead of just one.

The integrated part is we're trying to move towards this idea of being what we call stream centric, looking at surveillance streams. And so one of the surveillance streams might be samples that we're collecting as (unintelligible). And that's a stream now that allows us to collect samples of various types potentially and test them for multiple diseases if we deem that appropriate working with industry as to which of those diseases that we want to set them for.

A part of it needs to be efficient which means we need to be - to have this way of constantly evaluating it. And this is where the idea of data quality, data standards becomes really important because evaluating a bunch of spreadsheet data gets difficult. We're going to talk about that more. It needs to be scalable. So you know we may have some baseline of surveillance for something like classical twine fever which we do. In the event, God forbid, that we get classical twine fever in the United States we're going to need to ramp up really fast. (FMD) might be another - we're going to need to scale up really fast. And so this system needs to be scalable.

I welcome questions any time so please feel free. So we call it the (5R)'s we kind of messed around with this one a little bit and made it (5R)'s instead of (4R)'s. So obviously data needs to be represented. We have to have data that represents the population of interest, the sample that we collect must be representative of that population, it's got to be reliable so it's as accurate as it can possibly make it. Obviously real time surveillance data would be fantastic but there are very, very few real time surveillance systems of any kind. Animal health, human health, you name it. It's difficult. But we want to push towards as close to real time as we can get.

It needs to be resourceful or efficient so you know we - you all are sitting here representing a particular interest group. Dr. (Ritter) of (unintelligible), Dr. (Wagston) (unintelligible) industry and etcetera. You have to remember that when we work for (ASIS) we are representing all of those and we're representing the tax payer. And so we have to make sure that the money that we're getting for surveillance for response activity we have to use it to the maximum degree. And while we love to be able to put all of that money into building this system for client surveillance we have to make sure that we're - we've got money that can cover (unintelligible), etcetera. So we have to be as

efficient with the surveillance dollars, the fairly limited surveillance dollars that we get.

And then the way we can be very efficient is if we start doing surveillance based on risk instead of just - a great example of that is again (unintelligible). We - that's kind of the system I came up in. We used to collect a blood sample from every single adult cow that went through water plants in the United States and tested it (unintelligible) who was I don't know nine, ten million, and these are adult cows, now (unintelligible) cows, nine, ten million a year. And many of those tested in a livestock market so we would test them twice within the space of three days. And there was really not based on any risk, we were just almost doing survey work.

(Liz Lastrom): Quick question, doesn't that kind of depend on why you're doing surveillance. Or if you were trying to do surveillance in - you're going to laugh at me but (unintelligible) surveillance less than one in a million (unintelligible) in the United States that has (unintelligible). You want that one in a million not targeting the highest risk that would be (unintelligible) numbers.

Dr. (Brian McClusky): Absolutely and you led me into the next bit here really well. So what (Liz) is getting to is surveillance it's not a one size fits all thing, right. Whether it's for - you can look at comprehensive swine surveillance and we're going to and we're collecting samples from different risk populations because of the disease of interest. We're collecting it from a different stream because of the disease of interest but also based on the objective. And so what you'll see built here over the last - the few - on this slide is this idea of what comprehensive integrated surveillance structure is. So really it's the foundation of that or the objectives of your surveillance so it's rapid detection of our emerging or forwarding (unintelligible). That's a really big one obviously. Outbreak response, substantiation disease (stats). So that would be

supporting similar - supporting claims as a (unintelligible) of how much surveillance do we need to do and what population's to say that we're free of (DSF), that we're free of exotic (unintelligible) disease, that we're free of (unintelligible).

So objectives really drive sort of how you really plan for this. Then the next tier up here is the sources of that surveillance information. So a big one for us obviously as a lab base, we get a lot of data from laboratories. We do some work on farms, (unintelligible) surveillance, certification programs, (water), livestock markets, import/export data, these are all those sources of information that we've got to figure out then how to get into some systems and systems may be an air quote here but - and these acronyms not really important but these are some of our major data systems within the USDA that we either flow data through or store end to end.

Partner interaction is I mean obviously none of this goes without the interaction of partners, of the industry, (unintelligible) practitioners, animal health officials, academia. And all of that really leads to the decision level. And a big one for the USDA is trade and support. The disease control ratification, whatever it is you all need and tell us you need. And then really around the planning and budgeting so we're using those dollars as efficiently as possible.

So what we have today and I'm going to use two examples, one for the swine surveillance and one for cattle surveillance to just show you just what I said before that we have different objectives, we use different surveillance streams. Some of the systems are a little bit more mature than others. What we would design for surveillance for the (unintelligible) culture industry is going to be dramatically different than what we would design for the (unintelligible) industry or for the poultry industry.

So we're going to - I just wanted to quickly go through a couple of these to kind of give you the flavor of where we are. I think with integrated surveillance for swine we're probably further along with this one than we are with any of the other industries. The industry is a fantastic partner, they are not shy to tell us where they would like to see dollars spent, they're not shy in telling us what their priorities are. And that's great. (Liz) is giggling because you know it's not all you know strawberries and cream when we get together. I can tell you there's disagreement. But because they're invested obviously very invested they are able to give us really good (unintelligible).

And so the objectives, you could name all those objectives on that first slide would be ones for anybody that's trying surveillance. Our sources of information here you can see them yourselves are data systems we use a number of different data systems and where you see NSD1, NSD2 and NSD3, NSD is sort of our acronym for non-structured or not standardized data. And so otherwise known as spreadsheets, hard copy forms, that. So what we have right now in for comprehensive swine surveillance as I mentioned highly engaged stakeholders and that is a great - we have a laboratory network capable of testing for foreign animals diseases, academic diseases and it's scalable. We'll talk a little bit about some laboratory messaging if you haven't already I think I heard it mentioned in some of those recommendations.

Surveillance screens already identified and operable so we do have a bunch of those streams that you saw just on the previous slides. So here's sort of the streams - these are the sources of information. And a lot of those are working well. Variety of data sources and levels of standardization so over a dozen different sources and somewhat limited geographic and population strata representation. So this is - it makes it a little bit difficult sometimes to characterize that risk where we might not in the surveillance data we're

collecting have a granular data about location maybe or about production site. Although I think this is getting much better. The swine and (unintelligible) virus diseases really matured that I think to various degrees.

So here's just an example of this - these data streams and kind of pop through these. So PRV for those who are not familiar with some of these acronyms, PRV, is Pseudorabies Virus. So here for information sources or data streams for Pseudorabies Virus. You can see that three of those are the non-structured type spreadsheet. For CSF we've got (feral) swine coming for wildlife services which is our own issue coming onto spreadsheet. For swine influenza viruses we've got spreadsheets, for (unintelligible) we're not getting, this is an older slide. We are actually not getting spreadsheets from the (unintelligible) lab really anymore.

But you can see that there are one, two, three, four, five, six - if you count this one there's actually seven diseases that we really have surveillance underway for, different surveillance streams. Again I'm not saying it's all perfect that's for sure but there's definitely data coming in allowing for some level of analysis and some level of reporting.

So what's missing for that? We're getting better for data standardization but have a long way to go. The messaging part and this is laboratory messaging, the idea being the laboratory can electronically send a result with some associated data directly out of the lab through an electronic message into our system or into anybody else's system for that matter. Associate that with some level of field epidemiologic data and then it's stored in a database somewhere where it allows us (unintelligible). You can read through some of these other things.

So really what we're considering our limitations to grow for right now, for confidence of integrated swine surveillance are driven by those data management decisions. Some diagnostics limitations that demonstrated really helping with that identify what those diagnostic limitations are. And some capacity although I'm not sure that's necessarily a big issue but is data management efficiency will come up again and again. That's kind of what I want to talk to you about today.

That'll not probably be quite as robust or mature. The system I think as swine similar types of objectives. Some similar sources of surveillance information so we do some on farm (unintelligible) not as much as we used to. Animals with water is a big one. One that's actually not on here is livestock markets we don't - we do a lot of livestock market surveillance, not so much anymore. Diagnostic labs really become fairly critical.

Data systems are somewhat less for tele-surveillance as for swine. And here you know one of the what we do have is really strong separate disease surveillance programs that TB and tuberculosis programs are probably our longest standing legacy programs. Tuberculosis since the '30's, TB we had a program anyway since 1917. So these are long standing programs. The partnerships with the states are good for TB and tuberculosis because those have been - because they're long standing programs, they're long standing sources of funding that have gone to the states to support a lot of those activities.

So that's sort of the intro to what comprehensive integrated surveillances balances. Next little section is kind of why I wanted to come talk to you and really start to with that background help you understand that you know TB, this surveillance whether we're collecting it for normal surveillance purposes or during emergency respond is really one if not the primary reason the USDA

and (ASIS) and veterinary services sort of exists at this point is to be able support disease control. And so data management strategies having your cake and eating it too so I'm sure when some of you saw that somebody's coming and talking about data management and you knew you were going to see some kind of you know IT thing like this. And particularly after lunch everybody starts to go oh gosh, really, you know you pull out your iPhone and you start doing your email.

And I don't blame you, I mean I am not an IT guy, I'm an (unintelligible) I want to use the data that comes through all this stuff to help, right. So to me this is what it's really about, right. So unless its data and we have to turn it into information. So the data is sort of the raw ingredients and we need to turn it into information. And then we need to actually present it to you somehow. Present it to you or present it to us in some way that it can be (unintelligible), right. You can ingest it, you can take it in and you can turn it into knowledge. And that knowledge then helps you supposedly we hope make a decision. Make a decision to not do something, make a decision to do something, make a decision to spend more money over here, make a decision to not spend money over here. Helps you guys make decisions about what you want to tell us is a priority. So to me this is what it's really about.

And in the short write up that I sent ahead of time sort of right now in the state of management strategy and development I really want to come up with a better term for data management strategy because I'm telling you people do not care about data management strategy. They really don't.

But the three parts to this are the collection part, so this is where one of those requirements about surveillance and the surveillance planning process how do we have information technology solutions that allow that data to be collected and collected accurately in a timely way. So what does that sort of look like?

Are those mobile information management technology, can we start to do stuff on smartphone apps and yes you can - you guys all I'm sure heard that, seen that, of course you can. And so what does that look like? What do we need to leverage to make that happen?

And then there's the integration part. So if you remember on those slides that had the building blocks you know for swine we had all those different surveillance information streams kind of coming into probably three, four, five different IT or data systems, plus all those non-structured ones right the spreadsheet. So somehow we have to figure out how we integrate that. And we have people that spend a lot of time messing around with data trying to make it integrated before we can actually do something like this.

And this is what you know as the end users, I'm looking at most of you as end users of all of this, includes internally we're end users of all of this is this reporting part that really becomes important. This is sort of the state of surveillance is the reporting part.

So I actually started thinking about you know you can't sit here and tell us like you all get into the (unintelligible) of data standards requirements and why that's important for accuracy and all that kind of stuff because you don't care. I think what you probably care more about is these types of things which you actually get from us. These are situation reports that we've put - we've been putting out for outbreaks (unintelligible). We've been putting out since June of twenty-thirteen and we do one every week when stuff works right which is 98% of the time. We've been putting one out every week.

And I know the swine industry used this extensively for making decisions because when we do put one out one week I got 15 calls about wait we've got to have that, we've got to know about placement and we've got to know about

that. Particular (unintelligible) situation, we put that out every week. And then obviously our high path AI situation is a weekly situation.

So I got to thinking about how good of a job I think we do with these situation reports and outbreak situations. And how I think we've heard that's very valuable for stakeholders to have these. I know that they're valuable because when we skip a week we get hammered for it so somebody wants to see them. So how can we make something like this for TB, for tuberculosis, for Pseudorabies, for you know whatever we will find a report on. And that's one of the questions I think I posed into this group was what kind of information or reporting coming out of all this surveillance that we're doing is important to you, you know, to help you all make decisions.

So what I wanted to show you is I guess what we're hopefully moving towards - okay why isn't it - weird it's showing on my computer but not showing...

Man: (Unintelligible).

Man: Yes that's a good idea.

Man: (Unintelligible).

Man: And now let's go here, okay. So we have been collecting along with some help from our public health colleague's information about Triple E, West Nile Virus, these larger (platform) viruses and for a number of years actually.

And we created what's essentially an almost an interactive report option here and we used this one to start with because it's fairly innocuous at least for most industries the equine industry is going to be (unintelligible) to be showing this and public health is and think this is a great idea. And so this to

me you can start to consider this to be maybe a situation report on steroids or performance drugs. This one is - I can kind of walk you through some of this.

So you can see that this is just sort of an overview, tells you a little bit about it. So if you want to know where the cases are, select and in this case you're only selecting between these two diseases so we'll just leave it at each. And let's just choose where I know there has been, we can choose (unintelligible).

So here it says Florida and you can - it's for all year and it tells you the total number of cases in that all years and I think this is '07 to '11, is that right, '07 to '15. So 447 cases in Florida for all the years that we have data for and then it will actually tell you the number of cases by county. And what we're really trying to do here is make this more valuable to the people that will use the information. So it'll also allow you to look at changes over time so again you can pick one particular state and here it shows you in 2006 there were 20 cases, '07 18, '08 89, 75 and so forth. What we're starting to do even now in this particular software called (Tablo) and it's becoming pretty powerful for us for reporting we're starting to try and move some of those4 other things like CSF like swine influenza, like where we have some good data sets towards doing this. And at this point it's probably more for our analyst and so we can get the permissions and all that stuff to make this available you know to industries. But what I've been trying to tell our folks from a data management strategy development standpoint is let's start at the end.

So the end is the reporting part, what people are interested in seeing what they want and then let's work backwards towards the data collection part and the quality part. You actually may have data quality to make quality reporting. But if you just make sure that you tell people you know all the caveats around the data when you're showing a report we just have to be very clear about that.

But you know this is - we really need to make it available and we need to make it powerful and we need to make it what you want to get your support for the first part of it which is the data collection part. What will you be willing to provide as an industry let's say in what level of granularity you give (unintelligible) information. And does it need to be at the state level and that kind of thing.

Dr. (Fisher)?

Dr. (Sharon Fisher): Maybe I'm a little (unintelligible) but you mentioned classical swine fever as an example but that would be zeros all the way across that graph. Are you talking about sample numbers?

Man: Right, sample numbers.

Dr. (Sharon Fisher): Okay.

Man: Yes, yes, we would in that case be showing we collected this many samples and the zeros - the zeros are important, they're absolutely important and we don't really show I mean we say zeros for classical swine fever but if we had a report to show to international partners to our own folks, zeros out of a thousand samples that we collect.

Dr. (Sharon Fisher): This seems like very often descriptive process. Comment a little bit on probably the integrated steps that developing predictive models because I think that's where is a lot of (unintelligible).

Man: Right so we at the Center for Epidemiology for Animal Health we have a whole group that is - are the modelers and they actually do those predictive models. And for predictive modeling you know they can use retrospective

data for doing predictive models. And so a lot of the - they run some models now for high path AI to help us help support vaccination policy I think is a great example. So we used the high path AI data that we had from last year's outbreak in developing those predictive models. But that was actually very good accurate granular data from that outbreak because it's an outbreak of a foreign animal disease, USDA, along with our state partners have access to really good data and we're collecting that data ourselves mostly. And so the data's pretty accurate in some of those models that have you know pretty tight - as tight as they can get it around uncertainty and all that stuff and model that.

So yes predictive modeling is really an outcome - one of those is an outcome of select (unintelligible).

Dr. (Sharon Fisher): And would that include taking something like (unintelligible) but applying those data to - with respect to some of the other viral things. That's maybe not on...

Man: Yes right, yes I think you could do that.

Dr. (Sharon Fisher): I think we should. I mean they've pretty much behaved similarly in nature and...

((Crosstalk))

Man: Yes.

Dr. (Sharon Fisher): And so I think that would be a good just (unintelligible). One last question, yesterday and we talked a little bit about access. And I know producers, some producers, are probably not very comfortable government

prowling around on their premises collecting data. What - where do you think we are with that information?

Man: So I don't think we've had much issue with the collection of the data. You know I think in many cases particularly if they understand what the data is being collected for the collection of the data has not necessarily been the issue what we do with the data and how we report the data becomes obviously very important to them and understanding it.

Dr. (Sharon Fisher): Yes.

Man: And so the ideas of confidentiality around you know if we're getting you know I'll use swine influenza as a great example. I mean there's a lot of issues around influenza virus obviously. There's human health, there's (unintelligible) health, there's (unintelligible) health. And so not wanting to necessarily implicate any particular farm or production unit or company because it could have detrimental effects to this bottom line and that's fair enough. But at the same time being able to understand how flu viruses might be moving or mixing or you know going from flying to poultry or etcetera, understanding some of that is important for a (unintelligible) and I think for some of the predictive stuff you're talking about and some of the planning stuff. And so finding the balance is always you know where we continue to work.

And I mean I've heard her say it so I won't put words in her mouth but I've heard her say it that Dr. (unintelligible) you know with our swine (unintelligible) virus outbreak. You know we wanted to be very careful that we weren't going to hurt a really important industry, it wasn't a reportable disease either internationally or domestically. And so we took a little bit of a measured approach to begin with and our initial opportunities that the data

collection and granularity that data collection are probably not what they could have been. And once we had a federal order in place it would be nice to not have to do that but once we have federal order in place for certain levels of collection I think we've got a much better understanding of where it was and how it might move.

And so there's tradeoff, there's absolutely tradeoff. And it took us a while to make sure we weren't going to detrimentally affect the flying industry by necessarily having mandatory reporting, etcetera.

Woman: And yesterday we heard a little bit on One Health above the nationalists and reportedly on diseases. Do you view in all that - how (unintelligible) is comprehensive surveillance?

Man: Well so what I think (unintelligible) does and again I think we'll definitely need to find some balance. But I just talked about you know we put a federal order in place to require certain recordings for PED and first time (unintelligible) virus. And it actually included certain data elements and certain types of standards. And again I think we were able to learn a little bit more about the distribution, etcetera from that mandatory report. The (unintelligible) does that for other emerging diseases as well as this list of certain diseases that we're going to require reporting for.

Not every disease on that list is going to require reporting, we've got to be clear about that, right. There's some monitored diseases on there. But for an emerging disease we're - we will be able I think more quickly to get to the point that we eventually got to. And it's filled into that all of the implementation plans that we're talking about for that will include very deep long conversations with our industry partners, with our state partners about what we should report, what does that need to look like, or when do we need

to collect first of all. How do we integrate it and then what do we study for and back out again.

So that's the list I think - and I'll just from the veterinary services perspective it's going to be very helpful.

Woman: So that was a question of mine was will this feed into this and I can't see a reason why it shouldn't.

Man: Yes.

Woman: And then that data would be collected and that becomes a model for adding things. So the monitored things could be added you know the speed with which they're reported might not be as quick but even if they only get on this quarterly it's helpful and I see this list as being a way to help all stakeholders. You know when we struggle, we have so many diseases that are not reportable that are just production effective diseases. And we struggle with (unintelligible) and we struggle getting people who are new to agriculture, (unintelligible) to understand the value of vaccines and some other things. And we're seeing trends in re-emergent diseases that show up in backyard settings that were under control by more conventionalized culture that need to know about. And this is a mechanism for all.

Man: Yes.

Woman: We have the (unintelligible) for reporting some of these from a laboratory perspective and we're not releasing that data in a way like this where it's really useful. You know most of the time we don't need it more on a state level. You know cattle producers may want to know how much (BDD) there is in the United States and if it's in every state when they're making decisions about

purchasing vaccines. But for things like equine and (unintelligible) where there's (unintelligible) surrounding a vector you maybe have a more granular level.

Man: Right and I think that for me emphasis the point I made before. It's not a one sided signal and we're not going to collect the same level necessarily same level of data around a monitored disease that we would with a merging disease. And all of that requires very direct conversation with industry partners to take part in what level of information can be shared, will be shared, want to be shared. There are states that have state laws. And some allow them to share certain kinds of data with federal government. And we have to work through all that.

Woman: At the laboratory level we get calls continuously. How much (unintelligible) is there? Well I don't 'know that's not reportable or that is reportable, whatever it is. And there's only so much information that because we don't have a system like this in place that we're able to share with the larger stakeholders who really are hungry for this kind of information in managing the health of their animals and that crosses not just the livestock issues but the companion animal people, the equine people just started their own database. They have a thing now, the national reporting system online where state veterinarians can report various diseases because they didn't look at before this kind of information (unintelligible).

Man: So a question regarding reporting. How comfortable are you with being able to in a straight forward manner report what data are telling you? Versus leaning to like that message (unintelligible). It's not necessarily a question.

Man: No I get it.

Man: And when I say you I don't mean...

((Crosstalk))

Man: Yes I mean we want - we're your government. So I mean we are, we're your government so we don't - the role of veterinary services in (ASIS) is protecting American agriculture again thinking back to what I said at the beginning we're protecting all of American agriculture so that includes swine and agriculture and cattle and everybody. So what we're doing over here we want to make sure we're not harming over here. But we talk very directly with industry about you know we don't want to put something out that's going to harm that industry. At the same time we have obligations to international partners, we have obligations to tax payers, we have obligations to other industries that sometimes require a report of something.

I think in general and the stakeholders in here please speak up if you've seen this happen differently. But in general if we have bad news that we have to report on we're going to let the industry know ahead of time that we're reporting on it. I don't know if I answered your question or not.

Man: You did, you did and I appreciate it. It was a good answer. I mean towards the reality of the public (unintelligible) it's not too much like a politician.

Man: No.

Man: I appreciate you being responsible in your answer. I understand that. But I represent a constituency of which might reflect most Americans. That the way our government is actually working for the big players. And little people are in fact not part of that equation. And so I hope you know in going forward that reporting will not appear (unintelligible) to ignore some obvious things just

because you don't want to upset a big player. Because more of us will get hurt by that.

Man: I guess I would just (unintelligible) that by saying you know we're a science based organization. Our science is I think top notch science and we're not going to alter science to fit somebody else's particular need nor will we...

((Crosstalk))

Man: It's the political arm of the government.

Man: Sure.

Man: That I don't trust.

Man: What I was going to say is sometimes there are other influences that...

Man: Yes thank you.

Man: Appreciate the time very much.

Woman: Any questions for (unintelligible)?

Man: Maybe just a quick question.

Man: Yes?

Man: Have you had any interactions with the institute of infectious animal diseases and their pass through surveillance proposal on the table.

Man: Yes absolutely. We're actually headed down there next week to sit down with them and they are developing some other applications, software applications for collecting from enhanced pass surveillance as well as I would call it enhanced pass surveillance but other ways to collect surveillance information. The development of that was supported by the department of homeland security. They have been in communication with us all along on what it is they've been building now they're kind of at the point where we need to figure out how it can get incorporated or not based on what they have and what we need. We have conversations with them a couple times a month actually.

Man: Great.

((Crosstalk))

Man: Given (AR) and what we learned about that outbreak last year my understanding that - is that USDA is able to find that the large operations were hit harder than the smaller operations. And I guess my question here is at what point is it appropriate for the department to really start to weigh in more heavily on how they are doing other approaches to managing the livestock. What I'm saying here is we know the (unintelligible) kills the virus, the animals that were outside were less effective than the ones that were housed inside where they don't get the sun.

Man: Sure.

Man: And when in the department going to be responsible? Should the department have a position on that actually meets going forward that nature has a role in controlling the seasons and we'll take that away from nature. It means something.

Man: Well again I think we did a lot of (unintelligible) work, there's a lot more to do. We've identified some risk factors that we've shared with the industry. I don't think industry was necessarily surprised by some of those things that we found. But we also recognize that you know production in the United States has lots of different types and approaches that are all necessary that should all be supported by the USDA. I think you know conversations about size of operation or the way those operations necessarily determine for themselves how to work. We do have input with them, we've been sitting down with them, talking about bio-security practices, you know developing with the poultry industry while you know how do we start to do some bio-security assessments, how can we get that recorded, how do we help you guys get you know the highest level of bio-security.

As far as you know inserting ourselves into trying to tell the industry what's the most appropriate way to raise animals I'm not sure that's necessarily our role.

Man: (Unintelligible) USDA?

Man: Maybe from the research - research branch you know but not from the regulatory side.

Man: So I'm thinking (unintelligible) I mean a lot of USDA has been about helping to advise on production methods that things (unintelligible).

Man: Sure.

Man: Extension based on research.

Man: Yes I think that's right.

Man: That's what (unintelligible).

Man: Yes.

Man: Yes okay.

Woman: (Unintelligible) spend 15, 20 minutes here visiting about that. Let's put a large concept back on the screen.

((Crosstalk))

Woman: And one of the things I'd like to throw out is...

((Crosstalk))

Woman: We talk about (unintelligible) and we talk about the response from last year's recommendations and...

((Crosstalk))

Woman: And something very specifically - specific here. But want to recommend that the labs become able to electronically generate a message. The full (unintelligible) of diagnostic test results using what are called LOINC, logical, observation, identifier, names and codes. And HL7, health level seven message structure. So that ensures confidentiality in the security but also standardizes it so tests...

Woman: I'm having a bad moment. Let's (unintelligible) because I'm having trouble hearing you.

Woman: Okay sounds good. Sure. And I can just cut and paste. But - and I think you know (Belinda) from the laboratory I'd like to you know ask whether that meets what you think laboratory needs are for being able to not only generate these (unintelligible). You know I think the lab - the IT capability do it, it meets their needs. So one of the issues with this is that we have a (unintelligible) system and that deals with the catastrophic diseases and the emerging diseases. But then there's the whole rest of the laboratories in the United States that get very little recognition at state and regional laboratories that have done all the (glucoses) testing forever and that get you know little recognition and they're doing you know they're doing (unintelligible) test on horses and they're doing (unintelligible) and IBR test. And they're doing all the things that the industries have asked them to do. The (NPIP) lab that are serving (unintelligible).

So there's a whole bunch more diseases out there and most of those laboratories probably don't have the IT support. To get the messaging system up in place you know the (unintelligible) diagnostic lab and IT people help start the (unintelligible) system. And there results - there's a lot of personnel behind that university support. Some of these smaller labs it's tough to get that system functioning. So that's going to require you know if you want that from every lab in the country that doesn't have (unintelligible) that's going to be a lot of work, realistically.

So starting with the (unintelligible) system probably safe to go but that's going to leave out the (unintelligible) (endemic) reporting that might serve actually the producer group that are for our trade partners if we want to say how many samples we have (unintelligible) with zero. And it's great to be able to do that but we'd like all those to stay at the zero level. For our producers we really, for this, you know if we're going to call this comprehensive integrated I don't

know how surveillance we're really talking about the wide range of - but then you really have to incorporate more laboratories and think a little harder about that.

Woman: At this point you know maybe a recommendation that the first one you know provides (unintelligible) on the (unintelligible) and the second one assess the resources that would be necessary to bring to lighter network.

Woman: Yes that would be part of...

Woman: Focus on that work of state and...

Woman: That would be kind of part of number two for the various state and management investments that are (unintelligible) short and long term solution from management and animal health data. The labs have the data.

Woman: Right.

Woman: They're just limited in how they can share the data and it's not just whether anybody wants them to share it, it's literally the logistics of how you share it.

Man: One thing we didn't talk about was not (unintelligible) purview probably but you know who's paying for all these tests that we want to run, right? So we say we want to run (unintelligible) and stuff you know. And I know we have some programs and now it's divided into species more. You get the big pot you can do whatever you want with it kind of thing, or wherever the needs are right, wherever the priorities are. But this ongoing surveillance stuff if not free, it's a business of surveillance you know. So how do you think we should pay for all the surveillance we're wanting to do here?

Man: When you say all what do you mean? I mean if it's a new emerging disease I think that's on - I think I heard someone we determine otherwise. If it's a (unintelligible).

((Crosstalk))

Man: That's on us.

Man: Yes okay.

Man: But if it's something that's production related I mean you know that's probably on the (unintelligible).

((Crosstalk))

Man: Well it's like (unintelligible) influenza funding it's up and down, it's people you know we're stretching to make the - you know now we're doing 11 (unintelligible) which makes sense right? Because it is a business of surveillance, we need to be start about it you know.

Man: Right.

Man: But it's kind of hard to keep those streams going of course AI is a big deal now so you know now there's money for it. But if he's getting cut every year, you know what I mean it's hard to sustain that stuff is what I'm saying.

Man: It is and it's difficult to convince folks that it's worth money - putting money into surveillance as far as that prevention.

Man: Yes right.

Man: I mean we can get the billion dollars...

((Crosstalk))

Man: That's right.

Man: (Unintelligible) to respond.

Man: Right.

Man: But the frontend part sometimes is a little hard to system. But I think in general to answer your question I mean I think this may be a little bit conflicting but (unintelligible) it's program disease that's mostly on us.

Man: Right that's right.

Man: Right. And then if it's emerging disease to me that's on us until we decide well it's everywhere you know. And maybe a good example of that is (unintelligible) virus which is another swine disease virus that is this systemic or is it emerging or we were kind of showing we don't really know. So I think most of the testing for (unintelligible) fell on the industry because it was sort of a production sort of thing. But we covered some of it too, so.

Man: So the us that you're referring to do you have enough money in the pot to test what you want?

Man: We seem to...

Man: You seem to find it?

Man: We seem to (demand) it. I have been very careful standing in front of (unintelligible) talking anything about money.

Man: Yes.

Man: So - but we think we'd be able to manage but of course we have plans, we'd like to be able to make surveillance more robust for everybody. So yes I mean we probably don't have enough.

Woman: So how much of challenges with comprehensive surveillance is being able to access existing data in a laboratory so they're there anyway because of you know (unintelligible) animal diagnostics or whatever versus going out and finding samples.

Man: Yes so I can't give you a percentage but I mean obviously there's still issues in getting some issues is getting some data out of (unintelligible) into surveillance systems. I won't minimize that getting better all the time but for me there's still a big part of the surveillance where we have surveillance streams or populations that we would like (unintelligible) at certain levels that we don't either have access to them or we don't have ways yet to collect. And I won't say that's as big an issue as getting stuff out of the labs but it's right there.

Man: So I have a question as to how an industry might go about getting your ability or input in terms of tracking some diseases. I guess being from the west specifically I'm thinking about (unintelligible) which is not a program disease but for a lot of states it's a significant issue. And just - how do we go about trying to somehow get all the laboratory data you know accumulated and maybe even talk about things like (flouter) surveillance on (unintelligible) and

those types of things. To get a better handle on it - I think that would be - I think that's economically substantial important disease but yet it's not a program disease as far as...

Man: So that particular one that you're mentioning has come up and our cattle health staff has taken that one under his you know umbrella as to well how would we do this, what would this look like, and we're having our meetings over the next probably couple of months, we call them (unintelligible) where we had (unintelligible) culture I think last week (unintelligible) - service, I'm sorry service was last week. But the cattle health folks, the cattle industry folks will be in with our cattle health director and other members of our team here leadership team. We listen - (unintelligible) is one that the cattle industry says man this one is really kicking our butts and we'd really like some help in figuring out you know what we could do with you all, with states obviously have (tools). How do we standardize those, how do we make those harmonize, etcetera. I think we would be right there. The fact that we've already been talking about (unintelligible).

Woman: I have a question.

Woman: Yes go ahead.

Woman: As far as transport data, interstate, intrastate travel, is that also going to be captured and does that vary by state? And the reason I bring that up is a lot of the traceability cooperatives require a certain percentage of traits and if that data is manageable or if that data is able to be captured then that would help the states recover faster and meet their goals and incentives.

Man: Absolutely I agree with you. I think at least so far when we are talking about comprehensive (unintelligible) surveillance and the kind of data we want to

see in there we left sort of that (unintelligible) and moved it out. Because really I think the movement and understanding the movement is really important when we have an (outbreak). You know we need to know (unintelligible), right. For general surveillance maybe not quite as important and how - I say that understanding what the networks are you know how in general things certainly help us understand the transmission of the institution you know where we would want to put certain control measures in place, etcetera.

But I don't see you know the information that might be collected around traceability necessarily comes directly into it. Now part of traceability of course includes identification and premise identification is a big part of surveillance. Nothing like (unintelligible) the premised identification is huge for (unintelligible). That's the way we can be really efficient because we know where samples are being collected or animals are being tested in both in geography and in time and in what kind of production type we can really target and be more risk based and more efficient. So the premises are (unintelligible).

Woman: So (Belinda) earlier you had mentioned, we talked about whether the national list would tie into the comprehensive surveillance and whether reports should be made on any of those reportable diseases. And I've got it made available to all with a question mark because I guess I wasn't sure whether - where that extends as far as (sensitivity) or not.

(Belinda Thompson): Well certainly some of the report will have to be reported but (unintelligible) and some changes state status as the free or not free of certain diseases and come with regulatory actions. Presumably those regulatory actions you could take it any way. You know so there might be rules that apply to when those things get shared but yes, if we're transparent with our

trading partners and each other in our state which I believe we are from a reportable (unintelligible) standpoint then they're eventually going to get shared. So you might have a time sensitive need for those perhaps.

You're not aware of (unintelligible) all the (unintelligible) reportable diseases that would change the state status. Eventually those come to life you know there may be a delay in everybody knowing that California has (unintelligible) for (unintelligible) but...

Man: I think any program diseases that are reportable diseases, one of the challenges that we currently (unintelligible) and depending on where labs are there have been occasions where samples tested outside of New Hampshire result in (unintelligible) but that has not been reported (unintelligible).

Woman: So (Belinda) the other one that I was going to ask you about where we talked about messaging and you talked about (unintelligible) reporting back to the state - is that something that fits in here you consider (unintelligible) more...

(Belinda Thompson): I was using (unintelligible) in kind of the general you know the lab packets go into a system and they have access (unintelligible) and presumably all those systems could at some point talk to each other. And having - people have to pick up farms or compose - remember to compose an email to report on top of that we've told for things to fall into the cracks. So it seems like it's one system and it can do everything.

Man: I think (Belinda) what you're trying to say in a perfect world all diagnostic labs would be sort of on the same operating system.

(Belinda Thompson): Certainly in the (unintelligible) system.

Man: Right.

(Belinda Thompson): The goal is for us all to be able to report our stuff with electronic reporting but I still have to call the state animal health official, I have to call the systems district director and in some cases I have to call the (unintelligible) director if I know they also have samples for the same animal and this is Friday night at 9 o'clock, there isn't going to be anybody to answer the call. And then I've got to call the number at (unintelligible) and I've got to remember to do all those. If I forget and leave somebody out somebody important maybe doesn't get that message.

And I called federal people and they've said you know it's Friday night at nine and your sample is negative, why are you calling me? Because you're in my phone tree and I'm told I should call you.

Woman: There's got to be a better way.

(Belinda Thompson): So I find that system a little scary when we're talking about (unintelligible) diseases, that's all. And so it just seems like we're developing electronic messaging. That could also dissipate out. If it's New York it goes to the district one, system district director and you can (unintelligible) New Hampshire animal or you know.

Woman: So we've got - (unintelligible) is supposed to show up in five minutes to talk about (unintelligible) resistance I think. We've captured some big topics here, we can - we have a really busy afternoon tomorrow afternoon. We'll capture some more on this. But unless there's something super urgent let's just take five or ten minutes and come back and be back for Dr. (Nelly).

((Crosstalk))

Woman: Hello?

Coordinator: Yes I'm here ma'am.

Woman: Hi we have - we're picking up a little interference just now and I wanted to know if there was a way to mute speakers from the speaker line. Like I can hear it now a little too. It's either someone joining through like their computer or they're not muted.

Coordinator: Okay unfortunately there's only one speaker line it's all coming from the one line in the conference.

Woman: Oh it's coming from our line?

Coordinator: Correct.

Woman: Because this is the first time we've had it and it's almost always just from another source.

Coordinator: Well I mean it could very well be from one of the lines but everything is connected through one main line feed here on our side. That there isn't anything that we can do unfortunately.

Woman: So we have a listen only line and then we have a speaker's line.

Coordinator: Correct.

Woman: Can you say whose on the speaker's line now? Is there anybody...

Coordinator: On the speaker's line there's just the one that we have connected for the main feed.

Woman: And that's this one?

Coordinator: Correct and that's the only one that can speak out.

Woman: Okay I'm just hoping we can get through the afternoon without the interference. Again we've been doing fine and then all of a sudden maybe it's coming from the air I have no idea. Okay we're going on a little break now so you can shut everybody down and we'll be back in ten.

Coordinator: Sure can just a moment.

Woman: Okay, alright thanks.

Woman: Dr. (Nelly) do we have you on the phone again?

Dr. (Joe Nelly): Hi there.

Woman: Hi (Unintelligible). We are ready to hear from you on (unintelligible) resistance activities.

Dr. (Joe Nelly): Okay at least I had a whole lot more to say.

Woman: (Unintelligible) are you calling through your computer or are you on the line? You're sounding a little muffled. Do you need to call on the bridge line?

Dr. (Joe Nelly): I am on the bridge line.

Man: RJ it looks like you've got him under there twice under presenters, is he both.

Dr. (Joe Nelly): I just muted my microphone on my (unintelligible) does that...

Woman: That's better.

Dr. (Joe Nelly): Okay.

Woman: We're ready to go.

Dr. (Joe Nelly): Okay we're going to talk primarily about priorities for two things today. One is global health security and the other is antimicrobial resistance. So let me, even though I've talked a little bit about global health security before let me mention it a little bit here. One of the reasons we need to ask these folks about priorities is that ordinarily businesses and even you know our personal priority are established by our budget. So we generally make our priorities and put our resources to what our priorities are. The challenge here, global health security agenda was started by the Obama administration by combining a series of Bush administration initiatives, international initiatives for malaria, aids, neglected tropical diseases, tuberculosis particularly antibiotic resistant TB in humans. And there was about 12 different programs that were significantly funded.

But the way that the Bush administration managed the influence was a much more traditional approach. The US had money and they partnered with what they called donor nations - nations that they would give money to, to assist them in their projects on any one of these diseases. Whether it be malaria, aids and so forth.

The problem that the Obama administration saw looking at that is that it was exclusively a bilateral range between US and that country. And many times either ignored or at least fell short of coordinating its assistance with the assistance of other donor nations. Japan, Australia, European Union, etcetera. So the first thing they wanted to do was create something that they called the global health initiative. And the global health initiative was intended to take an all of government approach and listen to that phrase carefully, all of government approach to work these unique projects in a way that USDA and - no wait let me leave USDA out for a minute because they did. CDC and USAID and the department of state and other health related entities through the government administration, etcetera.

And they were calling that an all of government approach. And what we were able to do was point out that agriculture feed you know some of those basics were left out when they started talking about whole of government. And we did get them to add USDA to the working groups that were looking at global health, the global health initiatives at the time. They also then recognized that there was another segment of the US government that's working with countries and that was the department of defense. And the department of defense had a slightly different sort of security approach to what they were doing.

So when they worked with a laboratory their concern wasn't necessarily the laboratories capability for diagnosing (Brucella), or tuberculosis or aids or anything else. Their concern was more the ability of the laboratory to secure biological specimens so that they either didn't get into the wrong hands or that the laboratory itself wasn't sort of seeing something in this area with these agents and using them for biological weapons.

So that led to the emergence of something called the global health security agenda. So we've now got global health which was the traditional stuff, we've got the security side which was the traditional stuff and now because we've gotten USDA and through it other parts of CDC and so on the global health security agenda talked a lot about One Health. And it talks about doing things in a multi-disciplinary approach. Throughout the documents there's a smothering of these words that it's still not really in practice even though they're in the document. And I made sort of a snide comment about most of us set our priorities based on our budgets. What happened within this global health security agenda is all the different agencies were brought together and said we want you to (unintelligible).

Develop the global health security agenda but we have no new money to do it. So we want you to take funds that you previously had and sort of repackage it into a global health security agenda. So that was easy for the state department and the department of defense and CDC and the rest of health and human services because they had programs like malaria, aids, (unintelligible), polio and so on for something that they you know (unintelligible) and the other military groups had funds and could just say oh okay well now we're going to continue to do the malaria initiative but we're going to put it under global health security and we're going to look at it in a couple of different directions.

The reason I point that out is it leads us to the question of priorities. It's a priority for the white house, it's a priority for the president. There was no funds for this previously within USDA so what is the priority to USDA? We have the ability to contribute. In fact we're in many ways a cornerstone for much of what would be done. In fact I said to one group at health and human services just last week, these were positions that were part of their medical (unintelligible) groups that all of the embassy's that we are the root cause of all of their problems.

And in the funding went to spend the tide of these diseases in the animal population we would never have to be talking about (unintelligible) diseases that spill over into the human population. And they sort of got it but nobody wanted to share their budget. But that's kind of where we are is given no money, yet the critical component of what we do being part of global health security and in a minute I'll show why I'm talking about it and anti-microbial resistance at the same time. What should we be doing that would both make a difference but at the same time demonstrate the value of intersessions at the animal level that could actually save money on the human health side. Save lives and money on the human health side.

Alright the next slide that I put up here says that the priorities that the global health security agenda follows were priorities we would see in animal diseases as well. Prevent, detect and respond are the three critical components here. Another critical component is that it is a (unintelligible) government approach, it's working not only with the agriculture organization, the international organization of the UN but the (unintelligible) for the world animal health association and the world health organization. So we've got human health and animal health working together within this global health security agenda. And the goal here is to prevent or mitigate avoidable outbreak.

And to work with vulnerable countries assuming that many of these diseases may emerge in those countries, lack of surveillance, lack of diagnostic capability that's been allowed to spread among the animal and human population. And with care transport the way it is as we saw in the US with Ebola people are only a short airline ride away from bringing these diseases to the US. Another critical part of this global health security agenda was to help

countries meet the WHO requirements for the international health guidelines or international health regulation.

So let me go to the next slide that shows you the - so those are the overarching three things, prevent, detect and respond. Specifically there was 11 action packages that were developed as the standard for global health. So not only are we a country now that's providing support but we are a country that are also subject to the same requirements. So if we've put together an action package that says anti-microbial resistance. That there will be certain surveillance type activities, that there will be the capability to detect and diagnose a certain list of diseases. Not only are we saying that those other countries must do that but we're saying we also need to meet that standard. So while this is an international activity at the same time as these standards are developed there's an expectation on the part of the world that the United States and everyone else will meet these standards just like Nigeria might be - or whatever other country might want to meet.

The challenge with that is I believe that domestically we meet a lot if not all of these standards and that's fine. But at the same time because we do we have a lot to offer to the rest of the world to help them meet these as well. And the only thing we're lacking is the resources to do that. In many cases we are partnering with CDC or (unintelligible) and they are funding our activities to be involved. So let me just quickly go through what these 11 action packages are.

The first one is anti-microbial resistance, the second one is a zoonotic disease action package, the third is bio-safety and bio-security. Now in the agriculture community when we think bio-security we think of you know perimeter fences and you know somehow shower in, shower out facilities. Here was they're really talking about is more in a bio-defense posture where laboratories

are security from escape of you know for example (unintelligible) has now been eradicated worldwide. The only place (unintelligible) exists is in some of these laboratories in third world nations and the concern here is that we provide enough funding to ensure that these things are under lock and key and can't escape accidentally or intentionally.

The ones that are (unintelligible) are the ones that really apply to agriculture, the ones that are not - are more likely exclusively human. But even there the immunization action package really refers to specific human vaccinations. However, I think earlier today you just heard about (unintelligible) disease and the vaccine bank and what we need to make it whole while we can't certainly do that worldwide but there are certainly immunization actions that we can be looking at, at home, like you just did. National laboratory systems, there is of course the recognition that a national lab system must be linked between human health and animal health and some of the specifics within this action package talk about that. We've got our NAHLN laboratories, national animal health laboratory networks. And then there's the (LRN) network that's the human health, public health side of that and there are discussions occurring to link those things better together. Here on a national scale we are trying to work with the human health lab systems that are trying to develop this in third world countries and at least countries that have not had this before are the public health or animal health are actually starting off in a better place than we are because they can build it collectively as opposed to us trying to make it fit together sort of retrospectively.

Real time surveillance, the only way you're going to be able to respond is if you can accurately and rapidly detect something. There's a reporting action package that just talks about reporting and in this case they're mostly talking about the international health regulation you know for example China did not report SARS immediately and there was a lot of secrecy around you know

what they actually had, what was actually going on. So the international health regulations are designed to open that up a bit more in terms of reporting and from the animal health perspective that reporting was more along the lines of the OIE reports.

Workforce development, this is a critical one for us. As we move forward in doing One Health work we need to develop a workforce that doesn't think in terms of silos. That think in terms of agriculture is also a public health entity. That you know we collectively are responsible for providing faith, hope and affordable food supply to the US and the world. That's a public health issue, that's a nutrition issue as well as anything else. So we need to be developing you know veterinarians, animal health technicians and others who think more in a system approach and not I'm the only one who knows this and I have to do it alone because it's my responsibility as opposed to who else can work on this with me and let's put together a team of appropriate experts to go forward.

Another piece of response is emergency operation centers. It's already done at USDA through the H5N1 (unintelligible) you know international issue which we helped the (unintelligible) culture organization develop an operation center so that they could deploy resources worldwide to address any animal health issue. And then the last two were not highlighted for us but they could be. Linkages and multi-sector rapid response action and medical counter measures. So those are the 11 action packages that not only the US needs to meet and we are currently undergoing a baseline self-assessment. And that will be conducted in April or May I believe but we are pulling the data together for that now. And US is committed to assisting 30 countries with these 11 different action packages.

So let's talk more specifically now about anti-microbial resistance. And I'm intentionally using the global health security agenda as a way of framing the

anti-microbial resistance. They were both getting developed at about the same time. I was working with the white house on developing the global health security agenda and one of those packages with anti-microbial resistance and it's becomes apparent that the anti-microbial resistance one was so big that it actually needed its own white house led, they're called interagency policy groups where all the different federal agencies get together and discuss what the plan would be.

(Belinda Thompson): So...

Dr. (Joe Nelly): Yes?

(Belinda Thompson): Can I interrupt? This is (Belinda Thompson).

Dr. (Joe Nelly): Yes.

(Belinda Thompson): When you say we are committed, the US is committed, what was the format of that commitment? Is this a treaty? Is this something congress has endorsed? How are these promises made?

Dr. (Joe Nelly): Okay good question, let me also explain the organizational structure of the global health security agenda because that will help some. While the US has started this idea, the US recognized that this bilateral activity where we work with one country to do something just really wasn't getting us very far. So what the US did was partner with many countries that we ordinarily call the donor nations like Japan, Finland, the European Union, the United Kingdom. And created basically a steering committee towards the global health security agenda and Finland was actually the first chair of that organization. So the US may have created it but we sold it as a loose agreement between countries. It is not a treaty, it does not even contain memorandums of agreement. There are

principles that all these countries say they will adhere to but it is very much a verbal sort of commitment.

Below the steering committee group there are these 11 action packages and different countries lead different action packages. The anti-microbial resistance action package is led by two of the European countries. The zoonotic disease action package is led by Vietnam and Indonesia. Now again that's a loose commitment that they will lead this. The hard commitment that was committing the US to working with 30 countries was a commitment made by the white house in association with health and human services, USAID, state department and the department of defense that they would apply resources that they already had to these 30 countries over the next five years to help them try and meet the goals of these 11 action packages. So helping 30 countries was a hard commitment out of the white house, no dollar figures assigned to it but the whole thing overall is a sort of very loose commitment among dedicated countries to accomplishing these goals. Does that help?

(Belinda Thompson): Yes.

Dr. (Joe Nelly): Okay. While this global health security agenda thing is starting to be formed the white house recognized that anti-microbial resistance was a bigger deal than that and they created something called CARB, countering antibiotic resistance bacteria. And CARB was a multi-sectoral approach to developing a US government wide strategic plan for how we would address anti-microbial resistance. While that was going on, actually before that even started, USDA put together a group across USDA made up of like (NIPPA) that provides extra research funding, (ARF) that does our internal research, (ASIS), FSIS, economic research service.

And we developed a USDA anti-microbial resistance plan which is available on the internet. We were kind of held back a little bit in actually publishing that or moving forward with it because they didn't want us getting ahead of the white house in case the CARB plan had some different approaches and we had ours, we wanted to make sure that they were harmonious as we moved forward and so on.

So we do have now this CARB plan which is now public, we have the USDA plan which is also public, and then we have a subset of that with some veterinary services baseline studies that we believe need to be done to be able to address some of the concerns and quite frankly some of the criticisms that are at agriculture on the use of antibiotics and how it impacts any anti-microbial resistance organisms. So many times other groups want to point to agriculture saying that there is an indiscriminant use of antibiotics within agriculture, that there's an overuse of antibiotics within the agriculture sector and none of these statements really have the science behind them to back them up and demonstrate there's a cause and effect relationship here to what antibiotics are used in agriculture compared to what gets used in humans and where the emergence of anti-microbial resistance comes from.

I think much to (Tom Freeman)'s credit I have heard him press on that issue and he has been outstanding in not blaming agriculture for the anti-microbial resistance issue. He says agriculture will take care of agriculture. He's concerned about human health and he goes right into (unintelligible) infections and the hospitals and the use and abuse of antibiotics within that category. So the goal there is to try and develop some baseline studies so that once statements are made against agriculture we've got some science to be able to either defend it when appropriate but also I mean the reality here is if there are antibiotic uses that are in livestock that create antibiotic resistant organisms whether that's to the detriment of human health or animal health,

there should be some things done about that use, whatever that sort of inappropriate use might be. So those are the things that we are looking at in developing these...

(Michael Blackwell): (Joe)?

Dr. (Joe Nelly): Yes?

(Michael Blackwell): This is (Michael Blackwell).

Dr. (Joe Nelly): Hi (Michael).

(Michael Blackwell): I've been dealing with this issue since the late '70's off and on. And it's amazing that the question has been turned, the missing science is how can you use antibiotics at sub-therapeutic levels and not get resistance, that's the question where it's lacking. We have settle science that any time you use an anti-microbial you're likely to get resistance to develop. So many of us have been concerned about the sub-therapeutic non-lethal level uses of these agents on a large scale in agriculture and the lack of science that says that's safe. Now could you address that as far as the lack of science? I mean where is the science lacking?

Dr. (Joe Nelly): I think part of where the science is lacking there is in the evidence of the development of antibiotic resistance within the livestock population. Yes there are some but like you said if there is that significant amount of sub-therapeutic levels you would have expected many more antibiotic resistant organisms to be developed and in fact livestock themselves. And that isn't as large spread as one would expect.

(Michael Blackwell): Well I think in going forward I would strongly encourage veterinary services to take another look at where the missing science is. I think minimum inhibitor concentration and the whole science behind testing is very settle that if you don't get to a therapeutic level you're going to have resistance. When the drugs being used and fed water and most of the agents excreted through feces and urine unchanged we know that we are creating an environment that's loaded with sub-therapeutic levels of anti-microbial. And the microbes we know by settle science will change - will mutate in order to not be harmed going forward. I think it's a distraction and especially from a federal agency that speaks as though we don't have settle science around this.

Again what's not clear is how can an agriculture operation defy the laws of nature. That no one has exclaimed yet. How do you defy the laws of nature by putting these materials into the environment and not get resistance. So maybe you guys can figure that one out.

Man: But (Michael) do you know that sub-therapeutic use (unintelligible) this year by the FDA.

(Michael Blackwell): I know there's a voluntary...

((Crosstalk))

(Michael Blackwell): Listen I have 20 years at FDA, this is in policy, it's not in law.

((Crosstalk))

Woman: (Unintelligible) requires that there's no extra label use as additives. The voluntary part was for the sponsors to agree to change of labels - they've all agreed to change their labels. Once the labels have changed it will be against

the law for (unintelligible) or give to a producer to see at a level that is not on the label.

(Michael Blackwell): But that's still not addressing the sub-therapeutic.

Woman: Yes it is.

((Crosstalk))

(Michael Blackwell): All the sub-therapeutics are gone?

((Crosstalk))

Man: Except for (unintelligible) and those types of drugs.

(Michael Blackwell): Well I'm not a believer until I see it only because this is in a guidance document and guidance documents are not law, that's just the facts. They're not law. They have the weight of law but they're not law. And so if I choose to go another way I can go to court and defend my actions because FDA guidance document does not convert prescription drugs to (BFD)'s or whatever. You guys can cooperate but you can also choose not to.

Man: The labels going to change, for example...

((Crosstalk))

Man: Yes all the sponsors have said they're changing. So Virginia (unintelligible) below 20 grams a ton is sub-therapeutic, so all the claims below 20 grams a ton for Virginia (unintelligible) and poultry are going to be gone on January 1.

(Michael Blackwell): So why are you doing that? If there's no science.

Man: We're not using it below 20 now. It's illegal to use it below 20 starting in January.

(Michael Blackwell): Why would that be though? If we hear a federal official say there's questionable science around it on what basis then are you making the change?

((Crosstalk))

Woman: You just said you want it change - it is changed and you don't accept the fact that it's changed. I'm confused as to what you're asking.

(Michael Blackwell): I'm not asking anything, I'm making the point that what we have is a voluntary program.

Woman: It's not voluntary. I'm a producer; I cannot get (unintelligible).

((Crosstalk))

Man: Once the label changes that's it.

((Crosstalk))

(Michael Blackwell): Well let me put it in another way. Okay we can talk offline I think we're debating the technical language that's found in law which we find in food and drug cosmetic act and what guidance documents represent and they're not the law.

Woman: I don't think any of us questions that the guidance document is not a law.

(Michael Blackwell): But that's where this all comes from.

Woman: But once the sponsor agrees to change the label, the label is changed to a regulatory approval mechanism at FDA. Because of the law (unintelligible) for producers of veterinarians it will be illegal to use it in any way other than what's on the label.

Man: When a label removes a sub-therapeutic dosage which they've all agreed it will by the end of this year...

(Michael Blackwell): No they agreed they wouldn't have fee deficiency and growth (unintelligible) that's different.

Man: No, that's not true.

(Michael Blackwell): Yes it is.

((Crosstalk))

Woman: Let's move on please.

((Crosstalk))

Woman: Yes.

(Michael Blackwell): Alright well I just want to - I came here thinking we would talk about antibiotic resistance and these are issues that are important to some of the constituents who pay taxes in this country.

Woman: Well I want to address the issue of the scientific gap but I'll do it after (Joe) finishes his thoughts.

(Michael Blackwell): Well I raised one and I think we should have a response to that.

Dr. (Joe Nelly): And (Michael) you know you're right there are challenges here and there are some that are based on perception and others that are based on science. And I think what we're looking to do here with these baseline studies is to help sort out those differences. One of the other things that's already moved forward was taking those antibiotics that are medically important in human health and removing them from use for animals - animals except in specific treatment and even moving in the direction where these are going to be done under the supervision of a veterinarian. And in our case we're thinking that would be an accredited veterinarian.

And then we are working with FDA in various collaborations primarily to look at antibiotic use. Right now FDA is collecting data on antibiotic use on a bulk scale so they know how much antibiotic might be sold but they don't really know how it's being used at the farm level. And we would be working with them to help collect that sort of data. The challenge with that is the producers look at that being done in Denmark and what Denmark did was they first did the study to find out what the sort of baseline use of antibiotics were and then they passed the law that said that baseline is now the maximum and have created a new baseline and it seems obvious that the intent there is to keep reducing that until the use of antibiotics and animal production is eliminated entirely.

So I don't know as a you know agent of the federal government whether that's appropriate or not. I don't see the data that supports it necessarily, there is both a public opinion that says under a - on an abundance of caution we should

reduce the use of these antibiotics and then there is the counter balance to that that says the production of food should be safe for human consumption and should not create antibiotic resistant organisms that should infect people. But at the same time we want those to be affordable and abundant. So how do we balance an increasing global population and need for food with the reduction of growth promote and activities.

So just like a great deal of money is going to (Barta) which is the group within health and human services that looks at the development of new technology, a great deal of money is going into looking at new anti-microbial agents. We're not looking at new growth promotants that would not be antibiotic resistance creating sorts of organisms. So we are participating FDA. In fact there's an anti-microbial resistant group that's established - that's co-chaired by (Don Clifford) and I assume that will switch over to (Jack Sheer) shortly. But by us and by FDA.

So just to give you a sense of where some of these things are coming from and the pressures that are going to be put on animal agriculture to comply with some of these requirements, global health security agenda has been aimed on (unintelligible), the world health organization has a global action plan for anti-microbial resistance, there is a national action plan for combatting antibiotic resistance bacteria - that's the par plan. There's a USDA plan that looks at surveillance, research and development, education, extension and outreach. So as the new feed rule is implemented we're working to educate practitioners on what's the judicious use of antibiotics and things like that. So those are the things that we should be doing to help educate producers and practitioners on appropriate use of antibiotics and what the science is demonstrating and what the new laws are saying they should be doing.

And we are doing some of that but we did request $10 million that we did not get to do any of that. So we're doing it with what funds we do have available but that does make it a challenge. And the even bigger challenge and certainly (Michael) for all the time that you've spent looking at this, this is only probably half of the complexity of the anti-microbial resistance problem. So trying to get a handle on that, trying to balance the need for certain uses in agriculture that don't generate antibiotic resistance or have no impact on human health like the (unintelligible) are not - this is something poultry industry is very concerned about.

(Unintelligible) are used routinely in poultry health and flock management but it's not used in human health at all. So they have thrown and someone in the room here might be able to correct me if this has been changed, they have thrown (unintelligible) into the same basket as antibiotics and that puts the same restrictions on them even though they would have no impact on human health or the use in humans.

Man: Who are they?

Dr. (Joe Nelly): Excuse me?

Man: You said they have placed the (unintelligible) in the same basket. Who are they that you're referring to?

Dr. (Joe Nelly): FDA.

Man: Well in that document that lays out those drugs that are important to human health I don't think that's true. They have specifically left (unintelligible) off of that list and talked strictly about those that are important to human health. That's in writing.

Dr. (Joe Nelly): And is that the same in reducing the use of (unintelligible) as well? Not just that list of medically ones.

Man: (Unintelligible) usually get brought up again as a distraction. We're talking about those drugs that are important to human health, that means (unintelligible) is off the table, (unintelligible) that discussion.

Dr. (Joe Nelly): Okay.

Man: Yes.

Dr. (Joe Nelly): That was a concern at one time that was getting lumped in with antibiotics in general in reduction.

Man: No.

Dr. (Joe Nelly): Okay.

Woman: Recorded for sale there's an antibiotics but it's not part of the guidance 213.

Man: Exactly, exactly.

Man: I think that's the confusion often is they're part of what's recorded, right.

Woman: Yes.

((Crosstalk))

Man: So it really does need to be viewed as a distraction and we focus in up on those that are used at sub-therapeutic levels that are important to human health.

Dr. (Joe Nelly): Okay good, was there another comment or question?

Man: Yes just one question. On the draft that we're looking at right now where you have different compartments. Are the size of the compartments in any way, shape or form related to volume, or...

((Crosstalk))

Man: I'm just curious.

Dr. (Joe Nelly): No they're not.

Man: Okay.

Dr. (Joe Nelly): But that is a good question because we have had, and (Liz) can probably expand on this, we have had issues with CDC in graphics like this where it sure makes us look like the agriculture sector is exclusively responsible to the emergence of antibiotic resistance organisms. And they really don't show the human side of that to give kind of a balance of how this applies.

In fact one of the figures that gets thrown around a lot that bothers me is the poundage, the tonnage of antibiotics that are used in the animal health sector versus the tonnage of antibiotics that are used in human health. And I did a quick sort of back of the envelope (unintelligible) about the body mass of the entire livestock population of the US versus the body mass of the entire human population of the US. And if you compare those the use of antibiotics

in humans is quadruple or more times what would be the sort of recommended dose to be used.

So some of the science is really questionable as to what people are going to use to demonstrate their point. And that's something that we would like to do is develop the data necessary to either support those statements where appropriate or refuse them where they're not. And I'm going to go onto the last slide because it's really the discussion slide now about the sorts of questions that we would like you to address for us.

The national strategy looks at slowing the emergent or preventing the spread of resistant bacteria, strengthening national efforts to identify and report resistant bacteria, to advance the development and the use of rapid diagnostic tests, to accelerate basic and applied research, new or alternative to antibiotics. Improve international collaboration you know I think if we're concerned about emergent we might certainly be looking at countries where antibiotics are treated as an over the counter product and one can buy it indiscriminately either for yourself or your livestock.

And then the next one here gives you a little more food for thought on this. FDA is finalizing their guidance on use of anti-microbial only when necessary. (VS) has worked on some antibiotic use - kind of judicious use of antibiotics for veterinarians to understand. And to say that the (VS) does not support just the broad elimination of antibiotics but certainly scientifically based reduction as appropriate. So the judicious use guidelines here are things that veterinarians just need to understand is changing the way veterinary practice is conducted on the farm. And both committee deliberations then with all those things in mind, all of the pressures being put on use and appropriate use or judicious use what is the importance of both global health security and anti-microbial resistance to USDA.

We have no funding for global health security. We're getting money from others where we can but seeing very little as a result. And on the anti-microbial resistance the Obama administration put funding in but congress removed it. Both houses of congress removed it. So while they approved billions of dollars on the human health side they would not approve $10 million on the animal health side. Is this important to the agriculture community? And it's a double edge sword you know if I was a producer and you were saying we need more money to work on the use of antibiotics, it could threaten your livelihood. I'm like we did not support you getting those funding - that funding. But on the other hand FDA is getting the funding, FDA is moving forward with regulations that are driving down the use of anti-microbial.

And the data I believe is lacking in many areas to do that. It's much more the precautionary principle in if you don't need it don't use it. And the question whether that's just the money hungry producer versus the producer who's trying to provide an affordable nutrition source for the American public is really an issue that needs to be discussed here and what the role of government, whether that be state, local or federal government in assessing the user of anti-microbial on the farm and helping to make scientific needs to valid decisions on what they should be.

The second part of that is with those multiple action plans what you might suggest that we do to obtain resources if - and it goes back to the first presentation, what are those non-traditional partners. Should we be reaching out to non-traditional partners that might support getting those resources? How does that impact the typical production agriculture sector that has almost sort of skipped the schizophrenic, I'm sorry (Liz) you and I are good friends. The schizophrenic attitude about we could really use your help but we don't

want to give you the information that you might use against us. So how do we get through that and develop a trust relationship where - I've worked for USDA now for 30 years and I've honestly said that my goal is to say I'm from the government and I'm here to help and to have people say thank you. So I won't retire until that happens.

Woman: You might be...

Man: You'll be on board a long time.

Dr. (Joe Nelly): But yes so there's that question of okay so then how - you know what is appropriate for us to do and if that is appropriate how do we fund it? And then lacking the support stakeholders, the traditional stakeholders, should we be considering regulatory approaches to this? You know certainly (unintelligible) may have spent more of their time on the public health side of this and FDA might say yes. Traditionally in (ASIS) we have been like I said yesterday you know education rather than regulation. As long as we accomplish the goal the means to get there is less important.

So then you know should there be regulatory approaches? How do we monitor these things under a voluntary program? Should it become part of the veterinary (unintelligible) program? And I have one more slide with a bunch of questions. Should the secretary consider asking congress for something like supplemental appropriation? If we didn't get it under the regular appropriation and it was in the secretaries and president's budget should we somehow go back to congress and say hey I know $10 million was a rounding error but it happens to be important here. If there was some specific reason you cut it out can we get it under a different sort of appropriation to help cover it?

And then this other one, request for $200,000 per state is far too honest to implement a USDA action plan on an accelerated schedule. What should USDA provide to gain stakeholder support for the additional continuing near of $100 million budget in support of lab diagnostics, (unintelligible), data gathering, data quality assurance and so on. You know is this simply partnering with the agencies that did the (unintelligible) funding and work on them collaboratively? Or is there a way to approach funding for this because in my opinion industry will likely get hurt if only the public health sector is looking at this and the agriculture sector is not.

And then the last one is should USDA shift its stakeholder support base to a more consumer oriented human health concern and have it more food safety focused on anti-microbial resistance? So we're kind of opening ourselves up in a wide range of things with these questions but I think they need to be discussed and I think this may be the right mix of folks to help us address some of the answers to those troubling questions.

(Liz) I'm getting an awful feedback.

((Crosstalk))

Man: It's a leaf blower.

((Crosstalk))

Woman: Sorry about this. As this discussion I'm sure will be lively one thing I'd like is just going to mention (unintelligible) that when you talked about funding is we've looked at funding across all of the (unintelligible) panel. The only agencies that really got much for funding was CDC and NIH, department of defense was zeroed out, Medicare was zeroed out, I don't think (Barta) got

much. So NIH and CDC were the only agencies that got funding. So while USDA took it - has taken zero, many of the human health agencies did as well. So I think just to put that into perspective might be a bit of a fund information.

((Crosstalk))

(Judith): I just have a question and (unintelligible) I don't know if you or someone else around the table to answer this. But would the new restrictions on antibiotic use and leaving aside enforceable or not enforceable, just trying to understand the scope of them. What I'm hearing, what I've understood with that is based on you know on dosage you know how much per pound, are there any associated timelines however as to how long they can continue being used to see through. Or how frequently they can be reused.

Dr. (Joe Nelly): I am not familiar enough with the new bill to know. I believe FDA did not have hard deadlines for implementation because they do recognize the challenges that agriculture has in moving that forward. So there is not yet as far as I know deadlines on those things and (Liz) and others that maybe follow that more closely would know what FDA is planning to do. But I think they've been a little bit flexible at least initially.

Woman: So to answer your question (unintelligible), labels must be changed by January 1 of twenty-seventeen. So that is you know there may be some as far as actual enforcement consideration or easy enough for the first few months but the labels must be changed.

What (Judith) is asking is whether there are restrictions in how many days say an animal can be treated in like an entire lifetime.

(Judith): Or how frequently.

Woman: Or how frequently it could be.

Dr. (Joe Nelly): Oh.

Woman: So you will, if you look at labels most labels will have a duration on them. There are certain labels that do not have a duration on them that FDA has clearly signaled that they are concerned about those and that they are working with the sponsors to try to build separation on the labels. That is I would say their next priority. And then for you know there are refills of the (VFD)'s but the veterinarians could write a subsequent (VFD) though it was in their professional opinion that needed to be written. I don't know if (Marianne) and (unintelligible)...

Man: No I agree it's all going to be label based so as veterinarians we have to follow (unintelligible), there's no alternative.

((Crosstalk))

Man: And the problem there is...

((Crosstalk))

Man: The off label - the laws of off label use is going to severely affect the small remnant industry because very few things are labeled for small remnant. There are no toxicity stats for example that are available for small remnants. The only one that would be labeled at all and I just had to look it up is (unintelligible) and that's only for goats raised in confinement. So if you have animals out on pasture and they have toxicosis you have an alternative.

Man: (Unintelligible).

Man: Well no I don't think that's what they mean by confinement. And so you're going to run into, particularly in the small remnant industry, you're going to run into a real animal welfare issue where there's nothing available to treat disease because most things are off label because small remnant are such a small species that companies are unwilling to undergo the expense of having something approved for use in small remnants, they're not going to recovery the expense. And so that kind of gets back to your support for the stakeholders as well. You're not going to get a lot of support from small remnant producers because they don't have any alternatives now to use. And they're really scrambling for that.

So perhaps one of the things that you might consider supporting research for are some alternatives, preventive methods that would be useful from integrated test management or integrated disease management standpoint that the small remnants producers might have some sort of opportunity to reduce the incidents of disease and help to control the outbreak of disease on their operation when they do occur.

((Crosstalk))

Woman: Go ahead.

Man: That was the point that I wanted to make.

Man: I bet you did and I wanted to jump in before you did.

Woman: I just wanted to emphasis and I mean (unintelligible) have all seen it but you know this study that came out not too long ago on the use of essential oils as a an anti-microbial (unintelligible) operation. You know we know there's work out there, a lot has been done in the organics and sustainable ag community about looking for preventive. I will say from personal experience from you know in that community it's got to be part of the preventive system, if it waits for an outbreak these methods are not as effective as antibiotics. They need to be things that are done on preventive.

And so getting support from USDA on identifying these effective methods, how they can be implemented on an ongoing basis and preventive basis and then getting the education back out and spreading the word beyond sort of the hard core organic sustainable groups that have been developing these which is very helpful.

Woman: I think that's important of producers of all sizes and you know we talk about reducing antibiotic use, I would rather say let's reduce the need to use antibiotics and what we do in our production systems and our preventive medicine and whatever whether it's better vaccine development, whether it's better (unintelligible) flow or facility design or whatever to reduce that we need to use. And I think that is something USDA with the money they're getting (unintelligible) could really look at those. Yes I know there's an approach to alternative of antibiotics and I don't want them to think you know we need something that makes our animals grow faster, let's talk about how we keep our animals healthier. So we don't need a necessarily a foo-foo dust that's going to add a you know little bit of gain. What we need is something to help us reduce the need to use antibiotics.

And then we also need to look at what are the potential anti-microbial resistance implications to those alternative products and I know

(unintelligible) when everything moved to (unintelligible) full screening because they weren't using antibiotics at those screens, all of the MRSA that they're finding in large animals begin (unintelligible) increases this. And it's while they're sensitive all of their staff is both sensitive and resistant are they all resistant to (unintelligible). But the (unintelligible) seems to be linked with (unintelligible). And so I think some of those very you know - those substitutions may also have public health implications.

So that's exactly one of the points I wanted to make in the science gap so there are significant science gaps and our understanding of anti-microbial resistance and particularly understanding how the - and whether anti-microbial resistant organisms that develop an animal effect people and people effect animals. And in some cases assumptions are being made that they do because for example resistant e-coli will be found in most populations but now that we have sequencing tools people around the world are starting to sequence these agents, they're finding separate pools of organisms and some of the assumptions are not holding true.

So the national strategic anti-microbial resistance plan includes a significant part of surveillance both on the animal and human side try to close these gaps because they recognize that those science gaps are there. And the issues you know there are a lot of alternative products that have been - (unintelligible) alternative products that might have anti-microbial in them but because there's no science behind them we don't know the answer to that. And then there are other products like (unintelligible) that's a disinfectant that's now been shown to link to anti-microbial resistant and possibly even potentiate that. So there are some very, very significant gaps and the science knowledge behind the epidemiology is (unintelligible) that really needs to be closed in order to answer some of these questions.

Because if we can make changes based on assumptions that are going in the wrong direction I would have to agree that anything we can do to prevent illness that otherwise would require anti-microbial going in the right direction because prevention is part of (unintelligible) anti-microbial. But we also have to look carefully to see whether if we eliminate an anti-microbial that's used for prevention what the outcome of that will be.

There were some cases in Europe where preventive anti-microbial were eliminated and that resulted in a greater use of therapeutic anti-microbial and total anti-microbial use went up.

Man: For what?

Woman: For what, yes.

Man: And then it corrected itself.

Woman: Yes.

Man: Because they learned that you've got to give these animals adequate space, you've got to do a good job with waste management and therefore therapeutic uses went down. Let me just say folks the science around anti-microbial resistance is not as missing as I think some would have you believe. As early as the '50's it was clear that the use of anti-microbial and livestock could contribute to resistance, that's science.

Woman: No one's arguing that it contributes to resistance. The question is what's the impact on human health of that.

Man: Well...

((Crosstalk))

Man: Let me finish I'm going to answer that.

Woman: Actually the resistance exists before the anti-microbial are even used.

Man: Well...

Woman: (Unintelligible) anti-microbial.

Man: So then...

Woman: Archives of bacteria that pre-date anti-microbial have the genes for anti-microbial resistance. We're just collecting for them.

Man: Let me just finish what I was going to say it won't take long. When we took steps in 1977 to ban the use of (unintelligible) and Penicillin in livestock especially for growth promotion and feed efficiency. Congress stopped that action and they were able to do it because FDA gets a budget from the ag committee and the ag committee will not fund that agency to do anything that is believed to disadvantage agriculture, understandable. FDA struggled with what do we do, what do we do? I was there also when we decided we needed a third class of drugs. Before the '90's we only had prescription drugs and over the counter. And it's the over the counter drugs available to (unintelligible) person that were considered a huge problem because we felt that veterinarians we were making different types of decisions in many cases. But at any rate we didn't know what veterinarians were doing with the drugs.

And so we came up with the veterinarian speed directive. And (unintelligible) was intended to address the fact that there are minor uses that are out there that are off label. And before we ruled down (unintelligible) it was illegal for veterinarians to go off label ever even though it wasn't be enforced. So the idea was to correct that federal law in order to protect the interest of veterinarians who chose to make a professional decision, (unintelligible) judgement about using a drug.

I want to just hasten to say this there are multiple studies that show you can go to any one of these retail stores and pull meat out of the case and you're going to find resistant organisms on a huge percentage of the product. Now you ask yourself where does that come from? Did it get contaminated in the truck that transported it? Did it get contaminated only at the slaughter facility? Wherever you go back in time you're still dealing with the fact that animal products provide a source of resistance micros to the public.

Back to the volume and (Joe) I hope you're still on the line...

Dr. (Joe Nelly): I am.

Man: Yes the animal's bodies are much bigger but I would say the issue is how much product you're putting into the environment and it just so happens because these animals are big you're using a lot more product than a human would require. And the fact that (APR) the products are being used at a non-chilling level, non-lethal level from micros just meant scientifically that resistance was more likely to develop than if you were using at a lethal level. In human medicine they don't use sub-therapeutic use levels of (unintelligible).

Woman: Actually they do.

((Crosstalk))

Man: No, no that's a mistake. These pills are intended to be used strictly at a therapeutic lethal level. Now let's keep this straight, we're talking about the way they're labeled, the way they're intended to be used legally. People may not...

Woman: They're sold all over the world over the counter in countries that don't require...

((Crosstalk))

Man: Wait a minute we're talking - this is the United States and I just want to stay here right now, okay, because we don't have as much information. The reason we can't draw the lines to connect what goes on in the farm with what goes on in the community and gets back to transparency is because ag will not allow those kinds of studies to be conducted. And so if you...

((Crosstalk))

Man: Pardon?

Woman: I question that - as an example in the pork industry we volunteer to be part of a study called calves which is a collaboration for animal health and epidemiology. We found 48 (unintelligible) that allowed USDA's (unintelligible) employees on four times a year to collect environmental samples, pig samples, antibiotic used data. We asked them to follow those (unintelligible) and collect carcass swabs so that we could understand the - you know have a good logical study and understand it.

Now USDA ran out of funding, we went in (lobbied) for funding for that and so I'm trying to be calm but I think that gross generalities of lack of transparency are not recognizing that agriculture has come a long way in the last 20 years and going hell no it's not our issue to what...

Man: Fair enough.

Woman: (Unintelligible) and how can you address it.

Man: I appreciate that, fair enough, and I don't want to overstate it but you have to understand for a decade literally I've sat in these discussion where people start shooting off in other directions and all I'm saying is it's not as complex and complicated as it's meant to be. Even we...

Woman: (Unintelligible) has been providing not only the anti-microbial resistance but the actual organism to the national veterinary service lab which applies them to the (unintelligible) interface. We provide every single salmonella that we ever get. We've been providing respiratory pathogens to collaborate projects across the country. I would have to agree things have come a long way.

Man: Yes I mean (norms) is ongoing.

Man: Well I'll just be quiet then I think we're in a good place.

((Crosstalk))

Woman: As a producer...

Man: Pardon?

Woman: As a producer who is also - I'm semi-retired now but I was (unintelligible) nutritionist so I worked with a lot of people. We do not feed antibiotics randomly like you say we do.

Man: I did not say that ma'am.

Woman: That's...

Man: I did not say that.

Woman: Well that's what it sounds like.

((Crosstalk))

Man: Well I did not say that.

Woman: You said we don't want you on the farm, we can't understand what you could possibly find.

Man: Bingo.

Woman: Antibiotics unless something is sick. So where do you think we're using antibiotics incorrectly, I'm confused.

Man: I didn't say that either.

Woman: No I'm asking.

Man: I said that you cannot place sub-therapeutic levels of these drugs into the environment and not see resistance emerge. That's settled, fine.

Woman: I understand that.

Man: And if 80 - and that is a strong figure, 80% of what's sold each year in this country that we presume is going into the environment is in agriculture.

Woman: You're saying 80% is going into the environment.

Woman: 80% goes into animals - well here's the thing...

((Crosstalk))

Woman: On issue of transparency.

((Crosstalk))

Woman: Is we've had a lot of arguments and I've heard you know the arguments on both sides about 75% to 80% antibiotics sold in this country goes to agriculture use and then put back on the producers. But that doesn't actually say how much is gone into animals, and I agree you know if it's in the animals then it gets peed out, it gets pooped out you know it's going to go. And this is our problem with if you go back on the slides you know (unintelligible) human use up the sewage, guess what it goes into our sewage system and that creates a zone. Animals it doesn't go to the sewage system, it goes into the general environment.

And there's hunchback of like well just because X amount is sold doesn't mean it's actually animals but the agriculture industry isn't providing a basis of

knowing how much it is. I mean if the pushback is we're not using that much you know it's not really happening at that level how do we prove that?

Woman: Well that is going to change when (unintelligible).

Woman: Well I do think that one of the things that when USDA did not get the funding last year every one of the major commodity organizations, turkey council, turkey federation, beef, milk and pork have been working with USDA to say where can we help you get data, are we already collecting data that we can share with you whether it's accounting data, whether it's you know whether we can help get survey information out, whatever. So you know I expect that each one of the commodity groups over the next several years will spend millions of dollars collecting data to help share with USDA.

And so it's - we're ending up spending you know producer checkup dollars or other dollars that would otherwise be going to research or promotion of the product to help fill the gap for USDA lack of funding.

Woman: And perhaps that's something that needs to be stated or shared or you know publicized more. And I think that a change - honestly what I hear from around this table at this moment differs from what I heard six years ago when I joined the committee. I mean it's been that rapid of a change and (unintelligible). And at the same time it's recognizing that I think that there shouldn't be a shock if the rest of the world hasn't realized that there's been that shift in industry attitude. You know that's something that industry has to say hi. We get it now and here's where we are, we're trying to collect this data.

Dr. (Joe Nelly): If I could just interject a thought here, sort of a sobering thought that I had and came to recently. I've been trying to wrap my head around all the questions that we're discussing and then as I eat out whether that's a fast food restaurant

or a sit down restaurant I'm seeing in bold letters at the bottom of the menu somewhere you know antibiotic free you know whether it's beef or poultry or whatever. So I started looking at that thinking you know maybe this horse is out of the barn already. Maybe it doesn't matter if we develop the scientific information to make a decision one way or the other. It's the consumer and then right back on you know the food chain driving what the use of antibiotics are going to be based on what the consumers going to get.

So that's a whole different way of throw all of that science discussion we just had out the window and look at public perception and what we need to do collectively for producing you know low cost, safe, affordable food for the American public. You know can they afford what they've asked for.

Woman: Let me interject because we'll go into that point and then how about (Belinda) and then (Michael) how about that. But I did want to say (Belinda) I think you were using - I was using prevention in a different way than you were using prevention. I mean what I was saying that I'd like to see USDA try to research and then educate you know do that to get the outreach. It's the stuff before you ever would need antibiotic which is considered the preventive level. How do we keep animals from needing...

(Belinda Thompson): So I was including that in my...

((Crosstalk))

(Belinda Thompson): But I also was including some incidences where there are high risk settings where antibiotics are applied in a preventive way. And I was saving room for that as a potential option. But one of my concerns is if the USDA or whatever appropriate agencies our government chooses to include doesn't provide appropriate funding for the global health security alliances that it will

have a significant impact on the anti-microbial resistance issue because some of the worst resistance combinations and pan resistance that have come to the United States have come from overseas and they definitely did not develop in our human or our animal agriculture. They were imported to us and they were related to lack of judicious use of anti-microbial and the availability of anti-microbial over the counter around the world. And you know the traveler advisory don't go anywhere without having (unintelligible) in your suitcase.

And a lot of those other things. And this has to be an international effort if it's going to get anywhere because no matter how much we protect ourselves in our food supply and I think it's important to protect our food supply, if we just import the worst diseases and the worst anti-microbial resistance we're shooting ourselves in the food. So this has to be an international effort and at some point it would be good if this city or if all the commodity groups recognized that we need the funding to (unintelligible) in this global health security action effort address that anti-microbial resistance. And that if we're going to participate domestically we need to participate internationally as well.

(Michael Blackwell): The comments made that the FDA was funded fairly well for these projects.

((Crosstalk))

Woman: $18 million and they got $8.7 (unintelligible) so the money they had asked for, for (unintelligible) last year was not - this year (unintelligible) budget only included one million for (unintelligible). They wouldn't let them out for the other seven that they had originally asked for last year.

(Michael Blackwell): We have a culture at a federal level. On this issue we have a culture where one industry has been very successful in preventing certain things from happening. Now I'm not judging whether that was good or bad, I'm just saying that's what happened. It is considered politically incorrect to fund efforts that might hurt agriculture. And all you've got to do is go talk to those representatives on the (unintelligible), those congressional members, and you'll find there's a huge (unintelligible) of them that take care of agriculture. And FDA gets their budget from those same folks.

So I lived in a world where we were frustrated from a public health standpoint that we couldn't get done what needed to be done because of stress of our budget. And so the agency didn't do anything for a long time until we came up with (DFD)'s and that was because we were determined to not approve any more over the counter antibiotics. And none have been approved since then. We think the (unintelligible) in our profession really should be in control of those products.

And what I was trying to say earlier about guidance documents, guidance for industry are not law and we really shouldn't be spinning it that way, it's not law. It doesn't amend the act in any way and it's not a regulation. It's a guidance document that is strictly policy. Which means I by law don't have to follow it and you guys ought to know that. By law you're not required to follow a guidance document.

Man: Can - any way we can find that out?

(Michael Blackwell): Look it up.

Woman: He's not - (Michael)'s not incorrect. The (unintelligible) is totally voluntary for the sponsors to determine if there's any change to labels.

((Crosstalk))

Woman: Publically every sponsor has said they are going to change the label.

(Michael Blackwell): And they will.

Woman: And they will.

((Crosstalk))

(Michael Blackwell): It has to change, it is the law then, it's an indirect law. I mean I see your point that it's you know if sponsors go along with it you're right, nothing's going to happen. But once all the labels change it all happens, that's the theory.

((Crosstalk))

Woman: I would say our medicated feed is (unintelligible) we dealt with the (AFIA) and (NGSA) and others. They are not going to take a risk and mix anything that's...

((Crosstalk))

Man: They're not allowed to do any manufacturing of medicated feed on their own. You can't have a private feed mill with something with medication in it.

(Michael Blackwell): So the label change becomes law, is that correct?

Woman: Well so the label change has a legal effect on the businesses. Two holes, I do see a couple of holes (unintelligible) in the middle here. I see a couple of holes. One is label changes aren't necessarily permanent because it is a guidance document so things change, the label changes can happen again. The other hole is the one I was pointing out about timing which is I think there could be a lot of abuse still on label usage. It won't be the same but you know there's still that potential for abuse even within the on label.

((Crosstalk))

(Michael Blackwell): Let's take it one step further. If you look at the list of drugs you'll find that there's an overlap in the labels use such that so called preventive uses actually are at the same level as growth promotion and feed efficiency. So one can literally continue to use the drugs or whatever you want to call it as far as preventing diseases but you're literally using it in the same way it was being used for both growth. And therein is where a huge problem exists because these are still non-therapeutic, non-lethal level uses.

And (Marianne) just to go back to your question earlier about the environment, when the drugs go in...

(Marianne Kneeble): I understand.

(Michael Blackwell): Most of it comes out unchanged. I'm trying to...

(Marianne Kneeble): Not if it's injected, if it's fed...

(Michael Blackwell): If it's fed or due to water yes. I'm trying to think of a drug that currently is at a control preventive for treatment that was the same dosage as growth promotion.

Woman: There's a couple (NADA)'s that have a bunch of generic...

((Crosstalk))

Woman: Well yes but if you look at the - but if you look at them that's four compounds.

(Michael Blackwell): Right.

Woman: And all the generic.

(Michael Blackwell): But you understand why that's a problem. Because we learned in the '90's that one compound can cause genetic transformation and low and behold a bacteria exchanged genetic materials so that they don't have to be exposed to the other drugs, they can pick up resistance in the environment.

Woman: And I think that I would suggest that, I had actually recently read an actual systematic literature review looking at one of the potential public health (unintelligible) of not - sub-therapeutic and (unintelligible) uses versus therapeutic uses and whether there truly was literature suggesting that one had an impact - greater impact on public health than the other. First all the literature sucks, there's only like four papers that even meet any criteria from a systematic literature review. And of those criteria, of those papers it was no evidence that sub-therapeutic had any more public health impact than therapeutic.

So I think that brings us back to the point we talk about antibiotic resistance is how do you minimize the need to use antibiotic, how do you...

Woman: At any level.

Woman: At any level. How do we most carefully have veterinarian oversight and impact into preventive health programs using a variety of strategies and what is USDA's role in that. And so I think that nobody here is wanting to be able to use antibiotics like they did in 1960. You know I think now it's how do we refine, how do we do what's best for the animals and what's best for public health.

((Crosstalk))

Dr. (Joe Nelly): Sorry I was going to add one point to the discussion before about having to work on this internationally is significant because this will be developing elsewhere as well. Something that I mentioned sort of subtly and I'd like to just point out is that I had mentioned that the anti-microbial resistance action package is led by two European countries. Led by Germany and the Netherlands both of which have a zero antibiotic use policy in their own countries. And are driving those same sort of policies in the development of the guidelines for that AMR action package. So I guess the question is why should we be involved internationally if we don't have the funding and I've even said to people within the department let's just pull out of this entirely and not even waste our time if we don't have the resources to do anything.

But there's one of the arguments against that is if we're not engaged we'll be subject to what others impose as that international standard and then that's going to come around to bite us even if we have scientific proof not to, if it's already gained acceptance at WHO and elsewhere. So just wanted to point out that that's where that action packaged is being led from those anti antibiotic use government.

Woman: (Unintelligible).

Man: Well if we educate our producers - the producers in this country would like nothing better and (Marianne) back me up on this. The producers in this country would like nothing better than to give the public a site for a better food supply. And if you educate producers on how to do that they'll do it. So education is key here.

Woman: And I think (unintelligible) example on the (unintelligible) side. Of these are...

((Crosstalk))

Woman: (Unintelligible). But it was pointed out that there were lesions on the top (unintelligible) because that's the way (unintelligible) were designed, give shots within the butt. Realized that was a problem (unintelligible) brought that to light. We've always given shots that's due in the shoulder. And I mean that's all education and sharing things that need to change. So there are - have been great strides in doing things like that. But there's still a lot more to do and always will be.

(Dave): And again for those small remnant people there's still the need for therapeutic use that is not available to them now, they don't have an option. And so what there's - I mean I know that when March rolls around and we start getting wet in Arkansas I am going to have (unintelligible) on my plate. I usually have two, three cases a year. Now I have nothing now with which to treat those animals. So what do I do with them?

Woman: So is that a recommendation (Dave) that USDA should add the case with FDA to address the (unintelligible).

(Dave): There needs to be a minor use species...

Woman: Exception or?

(Dave): Addendum, I don't know if exception is quite the way to go but there needs to be an option available to veterinarians to prescribe for minor use species which we've had in the past.

Man: And I believe there are committee's kind of taking that action.

Woman: Yes in fact (unintelligible).

(Dave): Yes.

Woman: The order came through.

Woman: I wanted to go back specifically what (Joe) was saying about the international work and (Belinda) you know one of the ideas that occurred to me if you're looking for a way to try to get public support for what's going on and therefore generate maybe some support for funding is - and what (Max) said yesterday about imported foods. I mean I don't think that's - I mean you were referring to human use but I mean our folks keep looking and going look at how China uses antibiotics, look at how Vietnam uses antibiotics in their (aqua) culture.

Man: Yes.

Woman: I mean they're using stuff that we're not allowed to use now you know even under current systems. And I think - and there's a lot of public concern about that. I mean the public is worried about imported (unintelligible), the public worried about the standards in other countries. And so we can - I'm trying to think you know we can use that. I think that would be a message to help

generate public support for the idea that you, you know here in this country we need to be coming up with how do we address this on a global scale. People see it as a threat and it is.

Woman: So one of the things and my life is too wrapped up in this issue. But sitting on that advisory channel for the presidential initiatives it's divided into five areas. You've got stewardship surveillance, international collaboration, development of diagnostics and development of new product. And is it important for this body to - or advisory committee to say what should - how should the FDA either you know advocate for a part in those five areas. You know and an agriculture you know (unintelligible) because working groups and I don't know if (unintelligible) I think people still probably continue because it's the international collaboration one. But I mean do we want to in any way I don't even know where I'm going with this now, I'm walking around in circles.

You know advocate for further interactions or for us to take - for again to take some of our recommendations to the CARB advisory channel for the CARB's initiative as well as just within USDA. You know because they're - they truly have the whole gamma of all the agencies that's (unintelligible).

Woman: So I got feedback from some of the organization like (unintelligible) and others that want to see these veterinarians control these anti-microbial and want to see that effort continue. They want to see veterinary services and USDA be - play a significant role in educating veterinarians on the (unintelligible) use of anti-microbial and to take a lead on that. They don't want to see USDA to be in a regulatory role. For example the last question monitoring responsible use of the (VSD), they'd rather see that be the (FBA) that does that.

You know that's the direction they want the USDA to be - to play a big role in choosing best management practices for giving control in all different ways. The husbandry, the management, the density, the feed practices and nutrition and all of the things that go into minimizing the use of anti-microbial.

Woman: And I do think one of the things that I saw there which is part of the (unintelligible). So their (unintelligible) does not need to be accredited to write a prescription (unintelligible) I think they just need to be licensed. And so there is a disconnect of what USDA might actually interact with accreditation versus the practice of veterinary medicine that's regulated by the state pharmacy board.

Man: I believe that under the new anti-microbial use bill in California all veterinarians in California are required to have two hours of CE on judicious issues of anti-microbial for their licensure.

Man: And the California law has a reporting requirement also.

Woman: Yes (unintelligible) by any chance.

Man: I was involved with the California bill and here again working with veterinarians in the state of California and trying to simplify the whole matter of basically that law (SB27) governed assigned was intended to make clear that this is such a complex public health matter. First of all we need to look to licensed veterinarians in the state of California for any use in livestock. It's the food supply. Why wouldn't this country use best trained people to make such decisions. But the reporting requirement was intended to ensure that the public health folks, universities and so forth could gain access to better information so that we would make decisions - better decisions going forward.

Now some would say well we didn't need to do all that in California because FDA volunteer program would bring about the change. But when you start looking at reporting requirements that are in that new law you start to understand I think that it's way more robust of an approach to the size of this problem and the nation. And frankly I hope that other states will take up similar legislation. I don't know any veterinarian that would disagree - well there may be some but I don't know any that would disagree that veterinarians should have that legal oversight.

And for this nation to do only as much as give it voluntary treatment, that's just insane. When in fact it's one of the biggest public health issues based by the planet.

Woman: Would this committee support a recommendation that veterinarians should report you know usage...

Woman: Volume - not identities of buy-in.

((Crosstalk))

Man: No it's just that because they cooperate under the BFD. Basically the only difference between FDA's program and California's is this. In California it is law it's not suggested as a voluntary program, it's law that the veterinarian must do it. And the reporting is made a lot clearer about how that works. But the BFD, the three parts of the BFD, the veterinarian, the producer and the feed mill or whatever and that others could have under certain situations access to that information.

Man: And I guess one of the problems that I'm facing as well on the small remnant side is the shortage of veterinarians who are willing to work with small

remnant producers. For example in Arkansas we have four members of the small remnant practitioners group and three of them are located around (unintelligible), one of them is located in Little Rock and she's does practice. She's teaching at (unintelligible).

And so for a small animal that to be willing to even talk to me about prescribing something for me especially the off labeled is almost impossible. And maybe of them expect that - many of them don't understand what the veterinary client relationship has to be and some of them expect to have to come out every two weeks. And I understand that's not what the law says but what I'm saying is their understanding of that veterinary client relationship it varies by state. It's whatever the state's ruling happens to be. But they won't come out at all, they won't prescribe at all without having a bi-weekly or a monthly visit and it's $500 a trip. When I've got 25 ewe's that's four lambs everything that animal comes - everything the vet comes out. It's not going to take me long to run out of lambs to get a prescription.

And so we have a shortage of vets who are willing to work with small remnant people and the cost - and I understand the reason for the cost, you've got to pay for vet school, you've got to pay for that vet truck, you've got to pay for your technician, you've got to pay for the drugs. There are a lot of things that have to be paid for but that cost is beyond our ability. And you know in Arkansas we have four producers with more than 200, everybody else is under 50. And that kind of cost cannot be borne by those individuals to tell me that you just have to get out of business is not going to be acceptable.

So there is a problem that's going to have to be dealt with there as well. And so you know that kind of cuts backwards on my need to have that veterinary exception for small remnant producers and (unintelligible) species people, llamas, alpacas, there's nothing approved for them either. And you can't find

people willing to treat or even offer a prescription. So where does that leave us.

((Crosstalk))

Man: You talk about medically important antibiotics, you are caught up in the crisis. If you're talking about toxicity of that, that shouldn't be the same problem.

Man: They are not approved for use in small remnants.

Man: But I think you can - it was never the intent of FDA to present a veterinarian from prescribing or making available a drug that would help. And the BFD was written and such not that veterinarian client patient relationship thinking was based on if at least once a year that veterinarian came out and was familiar with the premises he or she could continue to provide BFD's over the phone even.

Man: That's an education issue for the veterinary community that they need to understand. But toxicity cannot be prescribed off label.

((Crosstalk))

Man: Or through the water and that's the way they're given is feed and water.

((Crosstalk))

Man: Yes and that's the way that I personally do it but that's as a treatment after these. It's not as a preventative going into you know going into the season we're going to have mud. There's not anything that I can do to avoid it. I've got plenty of pasture space, they can all wander around but there's going to be

mud and there's going to be toxicity, I can't prevent it, I can only treat it. And the treatments not very good.

Woman: So let's talk on this...

Man: Just one clarification question going back to earlier on. But of the - of the anti-microbial animals used that we record or we have in the United States on an annual basis how much of that is going to non-livestock species? Like dogs, cats, horses?

Woman: We have just total sales on reported but they don't...

Man: Yes.

((Crosstalk))

Man: There was - is it a significant amount or not a significant amount?

Man: It's not a significant amount because the ones that are most troubling are the products that are actually formulated for feed and water. And that's not dogs and cats generally, that's livestock.

Woman: I would actually have to...

((Crosstalk))

Man: I think I would tend to agree with you.

Woman: I agree with you on the products. But from a diagnostic lab perspective we see some very scary anti-microbial resistant organisms coming out of

(unintelligible). In humans - the human medical side is aware of that, they're worried about that (unintelligible). People are licking and kissing their dogs and cats and we know what dogs and cats do. And people are not sleeping - you know I know we eat meat but we cook meat you know we don't cook our dogs and cats mostly. And we do - the companion animals need to be addressed as part of the nation's initiatives. That may not be the USDA's purgative but it's in the plan, it's in the strategic plan to consider it.

Woman: It's interesting when you look at Denmark the majority of their animal uses were (unintelligible) and companion animals versus you know (unintelligible). So I don't think it's (unintelligible).

Woman: I wanted to say two things. One is a possible additional recommendation and then also you know procedural. Recommendation is I think some of us have brought up on the admin call that we'd like to have a topic on like the shortage of large animal vets and kind of defines (unintelligible) of this meeting. But it keeps coming up and I think it's of particular importance, it is directly relevant to this topic. I don't see how we deal for small scale underserve producers, small remnant producers without saying something about the fact that USDA has got to get in gear and getting serious about large animal vet shortages.

So I vote that we come up with some sort of recommendation on large animal vet shortages. The other thing is this is so not well phrased, so not well organized, I'm throwing it up here so that folks have a chance the next 15 minutes to say are we missing a big point and then I can do editing over tonight and come back to everybody with something more logical tomorrow.

Man: Should we ask about getting more (unintelligible)?

Woman: One of the things...

Man: I mean we are an animal health community.

Woman: The other thing that I would like to suggest is that whether - and I know it's something that we're struggling with from the industry is what is the right metric to report anti-microbial use? Is it days of therapy for large animals, is it count of use which if for count of use it means (unintelligible) the same as persons (unintelligible) which clearly is not. Is it some therapeutic index, is it define daily dose like they use in some of the hospitals? And can we remove some medically you know unimportant (unintelligible) from the total pounds (unintelligible) so that they're not rude.

Woman: Yes.

((Crosstalk))

Woman: Yes to me I think making a metric that allows us to benchmark and show progress in minimizing the (unintelligible) is somebody's very important antibiotics - it's a very important benchmark. And it's you know that whenever the sales report comes out whether it's 100 million pounds or 100 pounds. To both consumers that looks like a really big number. And so how do we put that in a usable context that allows us to benchmark and show progress? And I think that's the challenge. I don't know that this - I mean I think it's something that committee should suggest as USDA considers collecting anti-microbial use data. They work on developing a meaningful metric.

Man: I think we have it now. Not in companion animal medicine because there's always been reluctance to play reporting requirements on practitioners who are already over stressed. But the BFD is a three part record. And it's just a

matter now of starting to acquire that information - at least that's the way California is going to approach it.

Woman: I was going to say if they think the small animal vets are over stressed they...

((Crosstalk))

Woman: The small animal vets charge so much for their services compared to our large vets. I am perfectly comfortable telling a small animal vet.

((Crosstalk))

Woman: I'm sorry your BFD form there's an allowance in the law that a producer can ask the (unintelligible) BFD that may or may not be filled. The BFD's may have you know it's not unlike a prescription that you may take or not take to the drug store. And if you do take to the drug store you may only take ten pills instead of 20.

Man: Yes.

Woman: So but to me that's the quantity portion. But to me the metric is the how do you report that in a meaningful way so that you don't you know like I said if you report to the pound that suggests that every antibiotic is an equal focus and equal importance. And so do you go to that daily dose or some other metric that is more meaningful?

Man: Well my personal opinion is I don't think we're going to do better than an index. I don't think we'll ever have precise information without an undue burden on everybody in the system and it will cost way too much to get specific verifiable data. But if you go to a feed mill, a co-op that fills that BFD

then one can assume that the product - most of those products are going to end up being used because nobody's going to go buy that and not use it probably. And so that would be a pretty good index that wouldn't involve any more work than has already been done except to go in and acquire the record. That would be my concern is not placing any burden on any veterinarian with respect to new records or reporting and all of that. And produce it for that matter.

((Crosstalk))

Woman: It won't get you the quantity, it won't necessarily get you the numbers of animals treated, it won't get you the indication of why they're treated whether it's prevention control or treatment if there's any overlap (unintelligible). So that accrues (unintelligible) you know in my mind that's a (unintelligible) measurement and is there a way to you know if we're - we're looking to provide additional data, get additional data from producers that are willing to provide data. Is there a more meaningful metric that can be developed? And so I mean...

Woman: That might come straight from the industry.

Woman: Right.

Man: There's also some industry proposals to do that now.

Woman: Yes I mean we're looking at that and I don't know...

Man: Yes we're looking at it too and it's more confusing than you think it is and it's kind of a slippery slope a little bit. You know where's the data going, who's going to do what with it, anything times a million is a lot. You know there's

nine billion chickens raised in the United States. You know some of them need antibiotic, it's a big number. Same with the swine. So anyway but we are working towards that goal to provide some transparent numbers you know, but it's not mandated which I think is your point.

Man: It's not and so that's the one thing we tried to address in California is that the law should be available.

Man: Right.

Man: To the appropriate agencies. Then there's a route to getting to a different level of information so we won't have to guess as much.

Man: And I think the BFD's are available for review by FDA.

Woman: Yes.

Man: Oh yes.

((Crosstalk))

Man: They kind of look at them but is there any you know I don't know if they have any money to collect the data or do anything with it you know.

Woman: I think...

((Crosstalk))

Woman: Has done a pretty good job of telling (unintelligible) because so many of them are paper based to collect millions and millions of pieces of paper is a little overwhelming for most people involved.

Man: And I think that gets back to a lot of the data reporting stuff we've been talking about in some of the other areas is there's a way to streamline some data reporting and data storage. Because how many veterinarians want to buy another file cabinet to stick in their office, that's floor space that you're renting.

Man: That's right.

Man: You know or paying for, and it's time and it's a buyer and now what do you do about three years' worth of data that's gone. So there needs to be an electronic method of storying this information and there needs to be some kind of streamlining so that it's not different for poultry, swine, cattle, sheep and goat, llamas, alpacas, turkeys, ducks and geese.

Woman: (Unintelligible) emailing an electronic storage of (unintelligible). But it's still...

Man: Yes it's still paper form.

Woman: It's still paper.

Woman: Yes it's not a form that seals the data...

((Crosstalk))

Woman: Can I...

((Crosstalk))

Man: Up here are some of the questions that they're asking us to address. You know the one is what about obtaining resources to implement these AMR action plans.

Woman: Yes.

Man: And (DHSA) action plans. You know I kind of think that they should not - USDA should not be diverting their funds to try to cover the cost but they need to go and try to get funding if they're going to do it. Some places you just have to say no you can't do it, you don't have the resources.

Woman: Yes I would like to say that new mandate for actions on top of current activities needs to be accompanied by funding.

((Crosstalk))

Man: Correct me if I'm wrong, my understanding is we direct tell go get your money, they can't do that, they (unintelligible).

Man: Yes they can't, (unintelligible) to get your money (unintelligible). New money I think is perhaps the way but we need to figure out a different way than ask them for money, that's not going to help them I think.

Woman: We have five minutes left.

Man: That just build on that and say what I think might make the most sense - if money is on the human side...

Woman: (Unintelligible) public health authorities.

Man: Pardon?

Woman: I just said don't divert your (unintelligible) funds, seeking funding from the human health authorities.

Man: Yes but we can't ask them to just write a check. I think we're trying to get them to apply some of their resources and mission toward the ag side of things but that gets tricky and one has to think careful how you have to do it.

So (FDAR) cant transfer funds to USDA to do some work easily I don't think.

Woman: That's going to be I'm just going to say, again we've got like five minutes left. So I'm just going to say that's a (unintelligible) that maybe we can let USDA figure out. I mean our job is to tell them that we don't think they should be using their funds and they can negotiate with FDA about how exactly that fund change (unintelligible).

Man: Plenty of funds out there.

Woman: Yes.

Man: I think it's how they're being used - a company issue.

Woman: Joe do you have any last minute or you know presentation comments?

Dr. (Joe Nelly): No I don't other than to say that this is enough of a complex and ongoing issue. My goodness (Michael) I didn't realize you were involved for so long in

it. But it's certainly not going to get solved in this afternoon's discussion and I think that RJ said that you folks were going to meet you know another time at least this year. And I know in the past groups have had phone conversations. Perhaps this is one that you can give us some immediate feedback but also think it over, over the next couple of months and perhaps get on a phone call and see what suggestions you might have from your various contacts.

But thank you very much for listening to me. Yes it's all One Health related but it's also some very unique and difficult problems that we're trying to address. But thank you for thinking about it and adding your thoughts to the solution, appreciate it.

Woman: Thank you.

Man: Thank you.

Dr. (Joe Nelly): Thank you all very much, you guys have a good evening.

Man: Same to you.

Man: You too.

Woman: Verizon?

Coordinator: Yes I'm here.

Woman: We're at the end, we're adjourning. Thank you very much.

END