



## **Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals**

Tuesday, June 14, 2022

**Moderated by Susan C. Winckler, RPh, Esq.,** Chief Executive Officer, *Reagan-Udall Foundation for the FDA*

Susan C. Winckler: [00:02:30] Hello and welcome to our webinar on Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals. [00:03:00] My name is Susan Winckler, and I have the privilege of serving as the Chief Executive Officer of the Reagan-Udall Foundation for the FDA. We are so pleased that you could join us today. I'm going to go through just a few items, background for our webinar, review the agenda, and then we will jump into our conversations. Just one note, the workshop is being recorded and we will post the recording along with the slide deck and a transcript on the Reagan-Udall Foundation website [00:03:30] a few days after this meeting. We welcome you to ask questions. To do so, please put them in the Zoom Q&A and we will address those as time allows. I will note however that attendee microphone and video will be off during the meeting. And as is typical with our events, speakers will not address any pending regulatory action in this discussion.

So if we want to talk about the agenda. So we will open with opening remarks from Dr. [00:04:00] Bill Flynn from FDA Center for Veterinary Medicine. And we so appreciate our partnership with CVM for this effort and particularly today's webinar. We will follow that with a panel discussion, exploring the value of collecting and analyzing antimicrobial use data in food-producing animals. We will then have a brief presentation about a roadmap to a public-private partnership based on a report that summarizes findings from the initial phase of this work. [00:04:30] A link to the report can be found in the webinar chat now. For those with public comments, we're going to have that at the very end of our public forum. Those of you who registered in advance to present public comment will be unmuted when it is your turn to speak. We will begin that public comment around 2:00 PM Eastern time.

We need you to check in with the meeting hosts via chat message by 1:30 PM Eastern. If you have not checked in by that time, [00:05:00] I will not call on you for public comment. And final note, public commenters will appear by voice only and no video will be transmitted. We will have a timer to allocate your two minutes per public comment. And then just a reminder that the public comment opportunity is provided for us to hear from you, but as it's also standard with our programs, we do not respond to that public comment. It is for us to hear your input. We also have [00:05:30] an opportunity for you to submit comments, not only today, but to provide feedback via the public docket. The information is noted on this slide here. And you may submit written comments about the report to that docket. A link to the federal register is in the webinar chat now.

And with that, we have finished with all of the housekeeping that needs to take place to start our public discussion. And I am going to turn [00:06:00] to Dr. Bill Flynn, who is the Deputy Director of Science Policy in FDA Center for Veterinary Medicine, a known leader in this space. And Dr. Flynn, I'm going to turn it over to you for your presentation.

## **Opening Remarks from the U.S. Food and Drug Administration**

**William T. Flynn, DVM, MS**

Deputy Director, Science Policy

*Center for Veterinary Medicine, FDA*

William T. Flynn:

Good afternoon. Thanks, Susan. Next slide, please. I do want to thank the Reagan-Udall Foundation for all their work in [00:06:30] coordinating this webinar. And also, I certainly want to thank our panelists and all that are participating in today's webinar. I think the input that you provide us is really important as we work to move forward with developing a strategy for collecting antimicrobial use data. Next slide, please. Just for context, FDA CVM has been working under a five [00:07:00] year antimicrobial resistance action plan that is primarily focused on the idea of Supporting Antimicrobial Stewardship in Veterinary Settings. And as you know, I mean, stewardship is really focused on how antimicrobials are being used. And so it's really critical that we have the data that we need that is reflective of how antimicrobials are being used [00:07:30] as a way of informing and guiding efforts with regarding to support antimicrobial stewardship. Next slide, please.

And we currently have for a number of years been collecting and reporting out data on the volume of antimicrobial sold and distributed for use in food-producing animals. And certainly that is helpful and [00:08:00] valuable information to track. But as you know, it does represent sort of volume of drugs distributed, but not necessarily the volume of drugs used nor does it really provide any real detail in terms of the reason for use or more specifics around what particular species or specifics in terms of how those products are being used. [00:08:30] So clearly a challenge for us is getting access to better data that is more reflective of actual use at the farm or animal level. And further

challenge by the fact that there's very limited or existing infrastructure to enable the collection of such information. And so that's really the focus of why we're here is sort of looking at [00:09:00] strategies by which we can try to fill that gap. Next slide, please.

So first off, why is. There's a number of reasons why we believe collecting antimicrobial use data is important and really critical for us in terms of having a better handle on information that's representative of how antimicrobials are being used [00:09:30] in animals and at the level of the farm or where these products are being used. First, I mean, certainly it provides us a better way of monitoring trends of use and a better understanding what the drivers are of resistance that may be emerging in connection with the use of those products. Again, sort of looping back to the point about [00:10:00] stewardship that this data is certainly is reflective of how drugs are being used and therefore informative and helpful in terms of us guiding our efforts in various veterinary settings related to antimicrobial stewardship and provides an important metric or feedback loop to help guide those initiatives. It also, from being an FDA and a regulatory agency, [00:10:30] having better data is really critical to us so that our decision making with regard to policies around antimicrobials are better informed by data that is more reflective of actual use.

And then lastly, certainly it helps to better improve upon transparency for all interested stakeholders in terms of how antimicrobials are being used in various veterinary settings. Next slide, please. [00:11:00] So we hope that, this is an issue that we've been discussing for a number of years where we believe that some of the steps and discussions we've had in the work we've done in the past and work that others have done sets some groundwork for us in terms of the efforts we're undergoing here to try to look at strategies we're putting in place, some form of potentially public-private partnership [00:11:30] for collecting this type of information. Going back to 2015, we worked collaboratively with our colleagues at USDA and CDC to host a public meeting related to collection of antimicrobial use data and looking at various metrics for assessing AMR and antimicrobial use. FDA has funded a number of cooperative agreements designed [00:12:00] to test out different methodologies for collecting this kind of information. And we believe that the data coming out of those pilot projects is important and provides important information to inform the activities here.

And so here we are in 2022, and I think this effort is a critical step forward in terms of us sort of learning from the past work and trying to develop a strategy where we can work collaboratively [00:12:30] for putting in place a sustainable mechanism for collecting this important information. Next slide, please. So finally, leading today's forum. Again, I want to thank everyone for their participation in today's webinar. Your input on this is really critical. I think the work that's been done so far is sort of setting the groundwork for more work that still needs [00:13:00] to happen in terms of developing a more fleshed out framework for how we can make data collection workable. As Susan mentioned at the beginning, we've also opened a public docket. So for those that wish to submit comments in writing, by all means, we encourage you to submit those

comments into the docket. Based on today's input and based on the information that we see or get the review from that docket, that information [00:13:30] is going to help us sort of inform what the next steps will be.

But again, we believe this is just the first step as we flesh out a more detailed plan and certainly expect to be looking for additional, identifying additional opportunities to engage critical stakeholders in the public as we develop a plan. So with that, again, I want to thank everyone for their participation today. And we look forward to a very productive discussion. [00:14:00] With that, I will turn it back to Susan. Thank you.

Susan C. Winckler: Fabulous. Thanks so much, Dr. Flynn, for joining us today and providing that kind of stage setting of the work that the center has been doing to get us to this point, as well as the expectations for the rest of our conversation to continue to gather input on this important initiative. With that, let's turn to the next segment of our meeting, where we will explore various perspectives on the value [00:14:30] of generating, collecting and analyzing antimicrobial use data in feed-producing animals. We have garnered the participation of a distinguished set of panelists to guide our discussion. And I want to welcome them to our virtual stage. We will be hearing from Mike Murphy, who is the Director of the Division of Animal and Public Health at the American Veterinarian Medical Association. Also, from Dr. Paul Plummer, a Professor and Anderson Chair of Veterinary Science [00:15:00] in the Department of Veterinary Diagnostic and Production Animal Medicine at Iowa State University.

Dr. Randy Singer is a Professor of Epidemiology in the Department of Veterinary and Biomedical Sciences in the College of Veterinary Medicine at the University of Minnesota. And Dr. David Wallinga is a Senior Health Officer in the People and Communities Program at the Natural Resources Defense Council. Welcome to each of you. We so appreciate you joining us today. And I'll note as a Midwesterner, [00:15:30] I have to applaud the strong presence of our Midwesterners on the panel. I want to open by turning to you, Dr. Wallinga. Help us, ground us in the public health importance of collecting antimicrobial use data and how might those data support broader antimicrobial stewardship efforts. Would you pick up the microphone first, please?

## **The Value of Data**

*Panelists:*

**Mike Murphy, DVM, JD, PhD**

Director of the Division of Animal and Public Health  
*American Veterinarian Association*

**Paul Plummer, DVM, PhD**

Professor and Anderson Chair of Veterinary Science, Department of Veterinary Diagnostic and

Production Animal Medicine  
*Iowa State University*

**Randall S. Singer, DVM, MPVM, PhD**

Professor of Epidemiology, Department of Veterinary and Biomedical Sciences, College of  
Veterinary Medicine  
*University of Minnesota*

**David Wallinga, MD, MPA**

Senior Health Officer, People and Communities Program  
*Natural Resources Defense Council*

David Wallinga: Pick up the microphone. Can you hear me okay?

Susan C. Winckler: We [00:16:00] can.

David Wallinga: Fantastic. Yeah. So thank you for the opportunity to talk. I actually wanted to say that this kind of my mandate to lay out more of a public health context is something I felt like was more could have been used in the report. And so I want take a step back and just talk about where we're at in terms of the bleak future that the experts are predicting from the spread [00:16:30] of antibiotic resistance. I track the literature pretty closely and what's often repeated now is the idea that unless we change something pretty drastically in terms of how we track and respond to antibiotic overuse, that by 2050, there could be up to 10 million people a year dying of resistant infections. And just [00:17:00] earlier this year in The Lancet, it published some estimates that basically we're about halfway there.

There's about 1.3 million deaths annually worldwide from resistant bacteria and about three times as many deaths where it's a contributing factor. In the US, similarly, directly maybe 35,000 deaths a year, but up to 160,000 [00:17:30] plus deaths if you include sort of indirect causes. So that leaves me with a couple of major points. One is that, basically in a generation, by the time our babies have their own babies, drug-resistant bacteria could be the biggest cause in death worldwide, unless there's a big change in the course that we've taken. And behind that is just the notion that this urgent health threat is being driven by [00:18:00] antibiotic use wherever it happens, and especially overuse, which is hastening the spread. Now we know that the spread of resistance crosses all kinds of borders very easily, whether they're national borders or kind of artificial distinctions between farms and hospitals or clinics or other environments. And so selection processors a matter of numbers. Also, and the US is among the world's biggest users of antibiotics and it also has [00:18:30] one of the biggest combinations of population of humans and animals.

So what that means is that all those individual organisms that are getting antibiotics means a lot of bacteria being exposed to the antibiotics and a lot of driver for the evolution and spread of resistant bacteria. Next slide, please. Next slide. Sorry. Back one. [00:19:00] My bad. Great. So the way that the report structure in the discussion today is a little bit narrow from my perspective. It's around the question of basically around how the public-private partnership around data collection would be structured, but from a public health perspective, my perspective, maybe the more important question is, what public [00:19:30] health outcome is the data collection supposed to be helping us get to? And clearly, I think the science says that it's antibiotic use. We need to know where, why, how, all the details about antibiotic use wherever it occurs, human and animal settings. And the goal of that, as Bill said, is not only to help identify [00:20:00] patterns of overuse and to inform stewardship, but there's another component that I want to mention, which is super important, and that's accountability. Just like in human medicine, there for many decades was kind of a lack of accountability.

Now in hospital settings, there's antibiotic stewardship programs. And oftentimes both in human and animal settings, there's a recognition that over-prescribers, over-users are [00:20:30] disproportionate driver of the overuse problem. So we have to identify where and why the overuse is happening. And the only way to do that is to actually collect information. So one puzzle I have is why reinvent the wheel. In Europe, across the region, they've been collecting comprehensive data on use for at least 12 years. [00:21:00] Basically they started collecting sales information about 2010 Europe wide, but very quickly the European authorities started moving to collect more granular data as well. So the FDA is just collecting sales data since 2010. And then I have another caution too [00:21:30] around the FDA stated goal to support tracking and monitoring of antimicrobial use. And I'm not exactly sure what support means.

It seems to undercut kind of the give and take role that FDA needs to play. We not only need to collect data, but there has to be verification by FDA that the data's robust, that it's accurate and transparent. And then there has to be some analysis to, [00:22:00] as he alluded to, to inform regulatory decision making. So in other words, there's got to be a translation of this some critical data on use and then identify ways to reduce use. Because if you have stewardship, but it doesn't actually reduce the overall use of antibiotics, if it doesn't eliminate overuse, it really is kind of besides the point. You're not achieving the public health outcome that you need in order to address antibiotic resistance [00:22:30] and its spread. So that's why the accountability piece is key. So I would say, FDA's role can't just be education. In other words, providing information to support what's basically a voluntary campaign to get people to prescribe more wisely. We've got a whole history of public health lessons where simply education information is [00:23:00] not sufficient to bring about the change that's needed to...

PART 1 OF 4 ENDS [00:23:04]

David Wallinga:

... not sufficient to bring about the change that's needed to protect public health. So you think about smoking indoors, there were years, if not decades of education, didn't work. You think about people watering their lawns during a severe drought, just giving education doesn't work. There's got to be some combination of information plus action.

Next slide please. And then, [00:23:30] I mentioned the European example, I want to return to it a little bit because there's simply more years of experience there. I'm surprised that the interviews with stakeholders and the forum that was held didn't seem to have representation of people who've actually been doing the work in Europe to collect antimicrobial use [00:24:00] at the farm level. I think that would be super valuable. As I said, EMA, like the FDA, began collecting and reporting on antibiotic use around 2010. The EMA, European Medicines Association, like the FDA, started with collecting sales, which is the easiest to collect. So, that makes sense, right? Easier is good.

But the difference though... Oh, sorry. [00:24:30] Skipped ahead. The third similarity between the European Medicines Agency and the FDA is their conclusion that sales data when adjusted by weight, by the weight of the animal population receiving the antibiotics is superior just reporting volume or raw sales data. So the FDA's own words in 2017 are that weight-adjusted sales "would provide insight into broad shifts [00:25:00] in the amount of antibiotics sold for use in food producing animals and give the agency a more nuanced view of why sales increase or decrease over time."

So I realized that the Reagan-Udall report's not about sales, but here's a key body of information that FDA already has and they've indicated that it is superior to just reporting raw sales. The EMA reached the same conclusion, the difference is that the EMA started reporting weight-adjusted [00:25:30] sales almost immediately and the FDA hasn't ever done so.

So the other difference is that the EMA is very clear that it considers weight-adjusted sales to be a perfectly fine proxy for on-farm use, and that it's appropriate, if there's not better information, to use the sales information as that proxy and the US could be doing the same. Now, does that mean don't [00:26:00] collect information on farms or at the farm level on use? No, absolutely not. Collecting more information is good, but it could take quite a while. And in the interim, we want to be using the best information we have on hand, sales information, and reporting it in a very transparent way, weight-adjusted, so that it gives us as much utility as it could.

I think I just mentioned that [00:26:30] the Center for Disease Dynamics, Economics and Policy, with whom NRDC's partnered, they similarly have been publishing a series of papers since 2017 that use sales as a basis for estimating consumption at the global level of antibiotics, both in human settings and in animal settings. So again, both Europe and the Center use sales as a proxy for [00:27:00] use, but then they call it consumption. So that can be a little confusing.

So the take home, if you look at the graph on the right, up above, is that using this measure, Europe has seen a 43% decline in weight-adjusted sales as a proxy for use just from 2011 to 2020. Now in my own analysis, [00:27:30] because we don't have weight-adjusted sales for the US, I just looked at just raw sales. And actually, raw sales are not a bad indicator for weight-adjusted sales. If you look at raw sales for Europe, again, you find about a 43% decline over the same time period. It's a little bit different, but not much. The US raw sales have only declined 27% [00:28:00] over the same time period.

One big caveat though, to finish off my comments, is that in the US, almost all the decline, in fact, all the decline took place between 2015 and 2017 as growth promotion was being phased out. Now in Europe, that phase-out of growth promotion happened years earlier, it happened in 2006. So all the 43% decline in Europe in weight-adjusted [00:28:30] sales has been after the decline of growth promotion. And in the US, as you see from the graph from the right, since 2017 when that growth promotion ban took effect, there's actually been a slight increase in sales. So will collecting data at the farm level help us give us some indication for why that is? Yes, absolutely. But we already know from existing [00:29:00] weight-adjusted sales data that we're not seeing much change in stewardship since 2017 in the US. Thank you and appreciate your patience and the opportunity to kick off this discussion.

Susan C. Winckler: Great. Thank you, Dr. Wallinga. To recapping just a couple of things, giving us that compelling narrative for why it is that we want to improve antimicrobial stewardship and [00:29:30] suggesting strengthening the public health goal and the report, as well as applying more from the European model. And then, I think I'd capture your last components of advocating for more action based on the existing information.

I want to open it up to our fellow panelists, any thoughts and reaction to Dr. Wallinga's contributions? I see no one reaching [00:30:00] for the unmute button so I will take us to our next question, unless I move too quickly for you. All right. Dr. Murphy, as we talk about the use of antimicrobials in the veterinary community, would love to hear from you on how real-world data about antimicrobial use informs veterinary practice and supports opportunities for education among your members, [00:30:30] among other veterinarians. Would you pick up that question?

Mike Murphy: Sure. Thanks very much to Reagan-Udall for providing AVMA an opportunity to comment. I'll try and take just a very few minutes to focus on real-world and veterinary practice and then education. But at the outset, I wanted to let folks know that the American Veterinary Medical Association has a committee on antimicrobials with representation from public health, all major and several minor food [00:31:00] producing animal species, which developed a policy regarding collection of medically important antimicrobial use data for antimicrobial stewardship. This policy has been passed by AVMA's board of directors and house of delegates. And I want to thank Reagan-Udall for providing a link to that policy as we go forward.



Now, turning to your question about the real-world, as in human healthcare, veterinarians authorize the use of antimicrobials to treat, [00:31:30] control and prevent bacterial diseases in animals. In food animal medicine, antimicrobials are necessary tools, not only for the health and welfare of the animals under our care to minimize their pain and suffering, but also to maintain our nation's food supply and food security. Collecting and analyzing antimicrobial use data in an integrated manner over time can help us understand what works and what doesn't work in real-world situations. [00:32:00] The goal, of course, is to maintain the effectiveness and availability of medically important antimicrobials and to minimize antimicrobial resistance in both human and veterinary medicine and appropriate use.

I will mention very few of the challenges that exist in the real-world. This is a Herculean undertaking requiring engagement of all folks that are actually involved in animal antimicrobial [00:32:30] use. The public infrastructure investment made in human medicine has not yet been made in this area, but any methods of data collection must preserve confidentiality of both the veterinarian and the client, include data anonymization and allow data input from a very wide variety of record keeping systems that exist. Dr. Singer and Plummer may discuss in more depth, [00:33:00] from AVMA's perspective, an array of objective, reproducible and interoperable methods of collecting, evaluating, analyzing, and then sharing medically important antimicrobial drug use data as encouraged.

If we turn to your question about veterinary practice, the veterinarian client-patient relationship defined in both state and federal regulations has been further strengthened [00:33:30] by bringing medically important antimicrobials under veterinary oversight.

With respect to any changes to current veterinary practice, those will turn largely on the specific facts in each of these individual veterinary client-patient relationships that exist across the United States.

With respect to education, the approach of education before regulation has been a very [00:34:00] successful strategy fostering the stewardship of medically important antimicrobials. This education has resulted in widespread implementation of antimicrobial stewardship by veterinarians and our client producers as has been born out by both FDA inspections and other [inaudible 00:34:19]. The need for education will be ongoing, of course, in part, to demonstrate to consumers the breadth and depth of appropriate [00:34:30] antimicrobial stewardship practiced in the United States.

And in closing, I encourage those interested in more depth on this topic, because we have limited time today, to read the Viewpoint article that was published by AVMA's committee on antimicrobials in the March 8th, 2022 edition of the Journal of the American Veterinary Medical Association. So with that, I turn it back over to you Miss Winckler. Thank you very much again for the opportunity.

Susan C. Winckler: Great. [00:35:00] Thanks so much, Dr. Murphy. And I just have to ask, can folks access that AVMA article online?

Mike Murphy: I will get a link to you.

Susan C. Winckler: Okay.

Mike Murphy: Sorry, I didn't think of doing that before.

Susan C. Winckler: Nope, that's all right. It's one of those, I didn't know if we all needed to renew our subscription to the AVMA journal or if indeed we could view that online. I wanted to call out a few things that I heard from you as well and then invite our other panelists to respond, [00:35:30] but reminding us as well the important role that antimicrobials play in animal health, obviously, in helping to improve animal health. And then, a couple of kind of keywords, if I think about things that I heard you say, was preserving the confidentiality or having the information anonymized, and then the idea of reproducible and interoperable efforts so that we're not trying to get everyone who generates this information [00:36:00] to change what they're doing, but rather, to gather the information from their system. So just kind of thinking through some of the insight you shared there. I'll want to give the opportunity. Dr. Wallinga, I see that unmuted, do you want to provide a quick response?

David Wallinga: I just talked for quite a while, so I want to give others a chance, but yeah, I've got a question and comment.

Susan C. Winckler: Go ahead.

David Wallinga: [00:36:30] I think the interesting thing about antibiotics is that unlike a lot of what we do in veterinary or medical practice, there are common good. And the definition, in economic terms, of common goods or public goods are that the more any individual uses them, the more it erodes their benefit to the rest of the population. And so,

I think that in human [00:37:00] medicine, the problem has been if you have a patient come in and they say, "Gee, I realize I have the flu, but I really want an antibiotic, it worked for me last time," well, too often, I think, and this has been validated by science, that kind of short-term interest of that clinic provider trying to keep their client happy often has outweighed the public [00:37:30] health imperative to just say, "I'm really sorry, but they're not helpful and in fact, they're going to undercut the effectiveness of these drugs long-term."

So that's where I think that, to more, as the resistance crisis gets worse and worse, I think we're going to be challenged to reframe the idea of sort of the doctor and the veterinarian being sort of the king of their domain and [00:38:00] having purview over all the decisions because of this bad trade-off and this balance between the public good and the private benefit. So...

Susan C. Winckler: Helpful framing and kind of thinking about that tension. I guess it's consistent a bit with some of what we heard too about the need and we recognize that effort to address antimicrobial resistance. Can't just focus on the use in animals, [00:38:30] we also have to look very much so at human use and those stewardship efforts as well. So thank you for chiming in there. Dr. Murphy, do you want to respond to that? Okay. That means I'm just going to have to call on one of you to unmute, which I'm happy to do. With that, I'm going to turn to one of our panelists who has direct experience in collecting and analyzing the antimicrobial use data. Dr. Singer, [00:39:00] would you speak to us about this concept as well as the operational considerations to keep in mind for things like data governance, interoperability, picking up on a word from Dr. Murphy, and standardization?

Randall S. Singer: Yeah. Let me just start by thanking you for the opportunity to participate in this project and to speak in today's meeting. So I'm currently leading an effort in the US to collect on-farm antimicrobial [00:39:30] use data from the poultry industry, which includes broiler chickens, turkeys and table egg layer chickens. And so, some of the examples I'll provide are going to be specific to that project. But we have worked together, these two pilot projects that Dr. Flynn mentioned earlier through the different commodities. And so, some of the ideas will be relevant for all of the different commodities.

Let me also just start by saying that, personally, I believe it's important to provide transparency [00:40:00] regarding how antimicrobials are used in all sectors, and that includes human and veterinary medicine. I will say that I do not believe that sales data provide that transparency regarding how antimicrobials are actually being used. I disagree with some of Dr. Wallinga's conclusions that the sales data might indicate whether stewardship is going in the right direction, without context, which I know that Dr. Plummer's going to talk about, I don't know how you would ever evaluate whether disease incidences are changing and whether [00:40:30] there is a need for more or less antimicrobial use.

Within any of the commodities that we're discussing, it needs to be emphasized that this is a massive undertaking, and I know that Dr. Murphy already expressed that. So from an operational standpoint, a first decision that must be addressed, and assuming that you are going to engage in this activity, is whether the study would be in the form of a census, meaning that you're going to collect data from all of the [00:41:00] national production in a commodity, or whether your study is more going to be like a representative survey of that animal species.

If the study is meant to be like a survey, then an extreme amount of care is taken to ensure that the participants in your survey are representative of national production. Now, because our efforts at this point are voluntary, one of the things you'll have to address are whether those that agree to participate are similar to those who are not enrolled who may not have agreed to participate. And that's [00:41:30] not necessarily easy to do. USDA FAS has a considerable

amount of experience in those types of surveys and evaluating those biases and representation.

So we treated the poultry project, this poultry effort, more as a census where we attempted to enroll all of the major companies involved in chicken, turkey and egg production, but the reality is, that's probably unobtainable for some of the other commodities like dairy and beef, and maybe a representative survey would be more appropriate.

[00:42:00] Second, to get producers, the companies, the veterinarians to voluntarily agree to participate, it is essential that the data can be protected and the confidentiality of those data guaranteed. So in the request for applications that FDA published in 2016, which Dr. Flynn referenced, where they funded two initial projects in this area, it actually was stated very clearly in that RFA, and this was a quote, "to incorporate strategies for protecting farm and producer identity [00:42:30] and other confidential information." If you can't guarantee that, then, in many respects, this is a non-starter. So, that really is a key piece.

The example that I'm going to provide now is about the program that we created in the poultry industry, which we had been doing as a pilot even before FDA announced that RFA. But what we have established, I think, is an actual public-private partnership. So for poultry, funding is being provided by both US Poultry and Egg Association [00:43:00] and by the FDA. So we have this type of an informal public-private partnership. And what that does is it allows the raw, detailed data to be owned by US Poultry and Egg Association and the companies that provided it, while the funding from FDA supports data management, analysis and reporting. And that has, through the system that we've put in place, it ensures that protection and the confidentiality of the data.

So underneath [00:43:30] that first, that highest level of the partnership where we have the US Poultry and Egg Association and the FDA, we also then have the contributions of the various commodity groups like the National Chicken Council, the National Turkey Federation and the United Egg Producers. And so, from the very outset, they helped evaluate the system that we were going to implement for data collection and for data protection and then they helped encourage their members to voluntarily participate in the project. So that system really allowed us, [00:44:00] I think, to succeed in the incredibly high participation rate that we demonstrated in our first report that was put out in 2020.

To make this massive effort sustainable, but also trusted by the diversity of stakeholders who have an interest in the data, I think it's really important that we reach out to the multiple different stakeholder groups, and that will include like public health and civil society, to inform them of the project, to describe how the data will be collected and reported, [00:44:30] to discuss how the data will be validated. And so, I know for the poultry effort, we spent a considerable amount of time, even before we began the study, with these various stakeholder groups. I know that all of the commodity groups that were part of

these projects, we collaborated very closely with USDA FAS at all stages, including the data validation process. So I know that Dr. Wallinga brought up that issue of the trust in the data, we felt that A FAS was an ideal partner for helping with the validation [00:45:00] of the data, and going forward in these partnerships, I think, probably should play a major role given their experience with on-farm studies and surveys.

So the results from the various US projects, again, we released in 2020 in a peer reviewed special issue that Dr. Flynn mentioned. I believe the URL is provided in the chat. All those articles are free to download. Those pilot projects helped identify some key data fields that needed to be captured that we might not have been thinking about at [00:45:30] the outset, but if you're going to accurately and adequately reflect on-farm antimicrobial use, you're going to find that many of the fields that you need are going to differ by species. There really isn't a single approach that will cover all of the animal commodities. We can talk about the need for interoperability, for standardization, but the reality, in my opinion, is that first, each animal's species has different data collection systems in place. I don't think it's realistic to expect [00:46:00] that a single data platform is going to work for all species.

PART 2 OF 4 ENDS [00:46:04]

Randall S. Singer: ... That a single data platform is going to work for all species. I also think it's unrealistic and perhaps unfair to believe that the veterinarians and/or producers are going to have time to reenter their antimicrobial use data into an entirely separate data management system. So for instance, in the poultry project, we worked with the data formats that were being used already; we provided feedback about how data recording could be improved to ease the process of data aggregation on a national scale.

[00:46:30] And I also think it's unrealistic to expect that this entire process can, or even should, be automated. We're going to need dedicated personnel who know those animal species to assist with some of the manual curation of the data. For example, there are going to always be data entry errors, there'll be data outliers. How will you know if it's an error or an outlier? Who's doing the quality control? So if you find things that look like an outlier, what's the response? Do you just accept the outliers and keep them in the dataset? [00:47:00] Do you throw them out? Or do you spend the time to follow up with the veterinarian and the producer who actually entered that information? Which is what we did on the poultry project, but it is an extremely time consuming effort, so you are going to need a considerable number of personnel dedicated to this kind of a program.

So in the end, the ability to collect representative data of antimicrobial use, I think is going to vary by species. And although many are going to be tempted to compare the usage data across species and perhaps place [00:47:30] judgment regarding which species is doing better, which needs improvement, I think we need to discourage those types of interspecies comparisons. If we pit the

species against each other, voluntary participation will suffer. But more importantly, I think that the data across species aren't even comparable. For example, you have different diseases in each species and you have a different incidence of the diseases across the species, you have different antimicrobials approved for each of the different species. And because of [00:48:00] those differences, there's different routes of administration, different potencies. When we do standardization, I think what you're doing is allowing yourself to aggregate the data within the species, but it's not as if all of a sudden we can magically enable interspecies comparisons.

My hope is that when we have national data sets by species, it can help show the diseases that are resulting in the majority of the antimicrobial use in that species, and, optimistically, that would result in hopefully federal funds being directed towards [00:48:30] research of interventions for those key diseases, so that we can reduce the need for the antimicrobial in the first place. And with that, I, again, thank you for the opportunity to speak.

Susan C. Winckler: Thanks so much, Dr. Singer, and I was struck first... Helpful to have just a different perspective on the utility of the sales data. And then the comparison on a survey versus census, helpful to think about where [00:49:00] a survey might be appropriate versus the census approach. And then the value of champions, and then the last piece that I wrote down, I think I'm making up this phrase, but species specificity. I'm probably using two words that shouldn't be used together, but I think is helpful in that kind of contextual piece.

I want to again offer the opportunity to any of the other panelists who wanted to unmute and respond to that. Dr. Wallinga, [00:49:30] go ahead. Nope? Okay. I was responding to an unmute, not just assuming that you would want to chime in. But helpful, so let's get to maybe a better word than species specificity, maybe our easier word there is context. Dr. Plummer, could you talk to us? We've heard it a lot in the interviews and in our discussions leading up to the preparation of the report about the need for context. Help [00:50:00] ground us more in the importance of providing context when both analyzing antimicrobial use data and when utilizing reports about that data, would you pick up the context flag?

Paul Plummer: Sure, and I appreciate this opportunity to participate in this discussion and the work that Reagan-Udall has done on this important topic, and appreciate the comments from my fellow panelists. As you pointed out, antimicrobial use data [00:50:30] is extremely complex and varied. And Dr. Singer just alluded to this a couple of minutes ago, we're looking at multiple different species that have entirely different context, not only, as he pointed out, in disease processes as well as the approved antimicrobials, but also in their entire production system. So some of those are heavily integrated and animals stay on a single farm [00:51:00] for the majority of their life, whereas others of our systems, as he alluded to on the beef side, perhaps, or on the dairy, those animals move multiple times during their life and live for a longer period of time, so the context becomes very difficult.

At each of those stages, there's differences in disease outbreaks, what diseases are most relevant, and what treatments we have available. There also is a significant complexity around [00:51:30] farm sizes, and so variation in those farm sizes, and as it's been pointed out multiple times today, the record keeping systems. And so, quite honestly, we have everything from highly automated and integrated record keeping systems that exist in some of our vertically integrated systems to paper sheets in barns where farms are keeping quite detailed information, [00:52:00] but in a non-automated fashion; particularly, when we consider that we have a diversity of farmers, a number of which, for various reasons, do not use computer or electric record keeping systems, and so that adds, an increased complexity to that process.

So as we think about all of these different contexts and we aggregate this data back in, or collect this data from these different sources, it becomes important to recognize where there's [00:52:30] potential downfalls in the contextual understanding of what that data details. And so I think it's helpful, at least to me, and perhaps, I hope, to you all as well, to think about this somewhat in the context of even the human side as we come out of the COVID pandemic. And when we look at how antimicrobials use changed, obviously, there's been some significant changes.

For a period of time, when [00:53:00] we had significant lockdowns and we weren't able to do our routine hospital visits or our routine doctor checkup visits, prescribing of some of those routine antimicrobials that would've occurred in those outpatient visits declined and changed, and that resulted in changes in not only prescription, but also some changes in most common class, or those types of changes. I don't think any of us would look at that characteristic [00:53:30] and say that was all because of stewardship. It was not a decline or a change in antimicrobial prescribing because of stewardship, but because of an outside contextual issue, the lack of ability to go visit your physician.

Likewise, we had a disease outbreak with COVID that influenced prescribing behaviors in human ICUs. And again, yes, we could get into the fine details, and secondary [00:54:00] bacterial infections were not a huge component of COVID, nonetheless, the changes in prescribing behavior under appropriate stewardship protocols that were in place in those human hospitals resulted in increases in some forms of antimicrobials. The same holds true when we see disease outbreaks in our animal systems. And so to expect that as we decline antimicrobial use numbers, that those will always be a continuous [00:54:30] decline in the absence of understanding context around, we have a disease outbreak, or in this particular system, this disease...

And in many cases, that may still fall under good stewardship. We were using good biosecurity, we were using good vaccination strategies, but just like with COVID and its ability to mutate and evade, some of our vaccine strategies, as we have these disease evolve, they [00:55:00] may get around stewardship components of good healthcare vaccinology and biosecurity and still cause a

disease outbreak that influences antimicrobial use. So I think it's important to think about these contexts, and I really agree that as we start aggregating this data down, it becomes much more complex because we remove much of that context as we do that, and that really [00:55:30] opens us up to an increased risk of misinterpretation or at least over interpretation.

I also would like to, in the context of... Well, in the topic of context, if you will, the context of context, address, again, this principle that I think we need to be cautious considering antimicrobial use as a key performance indicator of overall stewardship programs. When we think about [00:56:00] stewardship programs, these programs are designed to balance prevention of disease processes, continuous analysis of our antibiotic use and success of that use, prevention through vaccinology, biosecurity, and then making the best appropriate treatment decisions given the clinical case that we face.

In the case of using use as a primary outcome, we do risk, [00:56:30] in some cases, potentially altering that stewardship because the diversity of antibiotics that are out there, the potency, the amount of drug that we have to use to have a regimen treatment, we can adjust use or change use, perhaps, in some cases, by changing antimicrobials, and those may not always be the best public health outcomes that we want. In changing to a more potent antimicrobial [00:57:00] that reduces our use, we may actually be selecting a drug that either is extra label or is more medically important, so I think we need to consider the context of use as a primary key performance indicator.

Now, I think we all appreciate that reducing use on an overall scale is a goal. We want to make sure that we're using antimicrobials [00:57:30] and not overusing them, and so I think in that context it's appropriate, but I think we just need to caution ourselves that a use metric can fully demonstrate a successful or a well-designed stewardship program. And I think if we look at the human example, going back to COVID, those hospitals all had well-developed, highly successful stewardship programs, but [00:58:00] we still see prescribing and use changes. And so again, the measure of use is not always linked to stewardship success or failure with the understanding that, overall, we like to continue to see reduced use.

Susan C. Winckler: Dr. Plummer, I think you gave us three different areas to be thinking about context. One in the context of the animal, [00:58:30] their life cycle, and then where they are in the... I was going to say sophistication, I don't mean that pejoratively, but just kind of where we are in record keeping, all of those things about the animal. Then the external contextual issues, so what else is it that's going on in the environment that might affect that in this context that we need to consider? And then the third being, [00:59:00] when it's used for an infection, what is that discrete animal health context? Did I capture the three correctly?

Paul Plummer: Yes, I think that's a good summary, and all of those are important as we think about this contextual issue.



Susan C. Winckler: Yeah, yeah, okay. Well, that brings me to the end of the questions that I had to ask, but we have a little bit, I want to just offer our [00:59:30] panelists, do any of you want to offer a final thought here before we turn to Dr. Bhat who's going to talk a bit about the report, and then move to our public commenters? Anyone want to unmute and speak up? Go ahead.

David Wallinga: I have one last thought. I find the framing around stewardship to be lacking in some respects, and it's not unlike in the human [01:00:00] setting, but, ultimately, the public health goal is different. The public health goal is, how do we reduce selection pressure that drives the evolution of resistance in the spread across the globe? And that could happen regardless of the determination of how stewardship is taking place in any one place. So at some level, the public health goal [01:00:30] has to be predicated on the question of whether overall usage becomes lower over time, however you get there. It could be that you get there through a huge investment in vaccines, it could be that you get there by other public health or safety and hygiene measures that reduce disease so that you don't have to think about using antibiotics in the first place, [01:01:00] it could be all of the above. But I really do think there's a somewhat different question and that you can't presume that the question around stewardship is automatically going to address the public health concerns.

Susan C. Winckler: Hmm, okay. So stewardship is one component, but the public health piece is broader than that as well.

David Wallinga: Stewardship is a question, ultimately, it's about [01:01:30] the values and the practices of the individual who's making the decision, whether it's a doc in a clinic or a vet on the farm. And the societal goal to reduce selection pressure is really something that takes place at a much broader level, at an ecological level. It comes out of our understanding of what drives the evolution of resistance and bacteria to take up resistance genes in the first place.

Susan C. Winckler: Mm-hmm, mm-hmm. [01:02:00] Another helpful component for us to think about, so thank you for chiming in with that piece. With that, I'm going to thank our panelists for joining us today, underscoring interoperability, opportunities to do things better, species specificity, which I will probably not ever say again, but I will practice. And then underscoring, again, the imperative for why we want to [01:02:30] have a better understanding of and improve the stewardship here as well as to address antimicrobial resistance. So with that, I will thank you all for joining us, really appreciate you investing your time, and we will turn to the next segment of our meeting.

So thanks again to Doctors Murphy, Plummer, Singer, and Wallinga. Our next segment is going to be led with a presentation from Dr. [01:03:00] Amar Bhat, who serves as the Chief Operating Officer at the Reagan-Udall Foundation for the FDA. And Dr. Bhat, we've challenged you to speak to us about some of the key learnings from the report issued late last month, and I believe you have some slides to help guide your remarks, so would you pick up the microphone and review some of that report with us?

## A Roadmap to a Public-Private Partnership

**Amar Bhat, PhD**

Chief Operating Officer

*Reagan-Udall Foundation for the FDA*

Amar Bhat:

Sure, certainly, thank you, Susan. And thank you, panelists, for [01:03:30] a great discussion. It was really good, set a great context, to use a word we've heard a lot, for our report. And I also want to thank CVM, the Center for Veterinary Medicine, and our colleagues there for sponsoring this activity. You've been great to work with, we have learned a lot in the last six months and we look forward to continuing our work together.

All right, why can't I... Oh, here we go. So [01:04:00] as Susan said, I serve as the Chief Operating Officer for the Reagan-Udall Foundation for the FDA and a point of contact for this project within CVM. I'd like to provide a quick review of the goals of our work with the Center for Veterinary Medicine. Throughout my remarks, I will be referring to our interim report, which can be found in our website.

Our original request [01:04:30] from CVM was to explore the potential for a public private partnership with animal producers to collect and analyze data related to their antimicrobial use in food producing animals. On this slide, you will see our basic approach to this task. To accomplish this goal, we met with a large number of stakeholders. A list of those groups can be found in our report. And I want to thank all those stakeholders for their [01:05:00] generous time in spending with us, their input was extremely valuable and they provided a critical context and time to us for this report. Please know that your input was greatly appreciated.

In meeting with these groups, we came across a consistent set of themes amongst the groups. Some of those themes you have heard discussed in our last panel [01:05:30] discussion. You can see these on the screen, and also in our report, of course. I'll just read out a bit of this, antimicrobial sales and distribution data and antimicrobial use data are not the same. Context, which we've heard a lot about, is essential to understanding antimicrobial use in food producing animals. Collecting standardized data across species and roots of administration is challenging, I think Dr. Singer [01:06:00] voiced that pretty eloquently. Each food producing species or food commodity requires unique considerations and species data, and species data should not be directly compared to other species. And finally, a clear data access and privacy protection is important to build trust amongst the partners and also with the public.

We also held a small virtual round table with a few of the stakeholders, [01:06:30] primarily those who have or manage antimicrobial use data. Through

the course of this round table, and afterwards, we discussed and developed this key objective which you see here on the screen. In addition, we developed a set of draft principles, which can be found... There's numerous of them, I don't want to read them out, but you can read them in the report [01:07:00] there. And I still will emphasize that they are still in draft, we'll be continuing to work on these, but they kind of help understand what we're trying to achieve with this public private partnership.

While we have made great progress over the last six months, many questions are still yet unresolved. While the stakeholder groups are definitely open to the concept of a public private partnership, the exact governance [01:07:30] model is still under debate, it's not something that we have settled on. So we're considering a few different models.

In this first model, we have a single public private partnership, serving as a kind of a hub, and under which we have several different modules or spokes, if you prefer, each representing a different major species, and they will all operate under the [01:08:00] same governance model and also, to some degree, a similar financing mechanism. But the main thing is that they operate in the same governance model and they feed their data up to the central hub.

In the second model, we have multiple different public private partnerships, each feeding data to a single data repository or a partnership hub. Each partnership, whether it's representing, again, each major species, [01:08:30] will have their own governance model and their own financing mechanism and will decide how they will provide the data to the central repository. And so there is a subtle difference between the two and it's exemplified by the way the arrows or the lines are connecting the different groups together.

Let's see now. Oops. [01:09:00] So...

PART 3 OF 4 ENDS [01:09:04]

Amar Bhat:

We have made good progress over the last six months, but many more decisions are yet to be made. In our next stage of work, we'll be working to achieve consensus on which governance model to use, and working on commitments to participate by the different sectors. We'll be going from the theoretical, you might say, to the practical stage, which will uncover [01:09:30] many more questions, and I'm sure many more hours of debate amongst the partners before our partnership is fully and finally established. We look forward to continuing our work with the Center for Veterinary Medicine to making this public-private partnership, or partnerships, a reality. Now, I'd like to turn back to Susan who will moderate our public comment section. Thank you, everybody.

## Public Comment

Susan C. Winckler: [01:10:00] I'll note that... I apologize I am not able to turn my video on, but if one of my colleagues at the foundation wants to correct that, then I will, but I want to thank those of you who have participated in the public forum so far and your very helpful comments. Now, we will turn to the public [01:10:30] commenters. I will note that we had individuals who said that they would like to provide public comment, but we have not yet heard from them. I'm only going to be calling on those who registered for public comment and responded to our outreach during this webinar. We're going to call on commenters in alphabetical order by last name.

Each speaker will have two minutes to speak. There is a countdown clock that will display on screen displaying the time remaining. [01:11:00] If you have not begun speaking within 10 seconds of your name being called, we will move on to the next commenter. I'll note, again, this is our time to listen to you. And so, the foundation, FDA and [inaudible 01:11:13], none of us will be responding comments, but are rather actively gathering your input. With that, I will turn to the first public commenter who I have noted here, is both registered and is on the webinar. That is Jim [01:11:30] Ehrlich. Jim Ehrlich, would you unmute and provide your public comment?

Jim Ehrlich: I want to congratulate FDA and the Reagan-Udall Foundation for careful consideration of the problems in collecting detailed medical data while guaranteeing the privacy veterinarians need to hold the confidence of our clients. With support from USDA NIFA, [01:12:00] vcpr.org is developing internet-based tools for managing veterinary treatment protocols. We will have not only detailed information on what, when and where drugs are used, but also what animals are treated for what medical conditions at what doses and what the medical outcomes are.

Maintaining [01:12:30] the effectiveness of antibiotics is important to veterinarians and farms, and the data we collect for improving care of individual animals could be anonymized and shared. This would require informed consent from users and confidence that privacy will be maintained. Vcpr.org is operated by veterinarians for veterinarians, [01:13:00] because without active support from practitioners, it is hard to imagine change of the magnitude that is needed. Functional independence from both regulatory agencies and the pharmaceutical industry is necessary. Controlled sharing of data can benefit us all if there is scrupulous attention to boundaries. Thank you.

Susan C. Winckler: [01:13:30] Thank you so much, commenter Ehrlich. We'll now turn to our next commenter. If we could clear the countdown, our next commenter is Lindy Froebel. Lindy, if you would pick up the microphone and we will restart the clock.

Lindy Froebel: Hi, thank you for the opportunity to speak today. My name is Lindy Froebel, and I'm representing the National Turkey Federation, which represents nearly 100% of the [01:14:00] commercial turkey industry in the US. The health of turkeys is vital to NTF members. Just as in human medicine, the judicious use of antibiotics

is essential to protecting the health of turkeys. NTF and its members are strong supporters of judicious use guidelines established by the American Association of [inaudible 01:14:21] Pathologist and of the American Veterinary Medical Association. Like others present today, NTF continues [01:14:30] to be concerned about the misuse of information regarding antibiotic use in livestock and poultry. To help address some of that misinformation, NTF has been pleased to participate with the US Poultry and Egg Association in their FDA grant to collect antibiotic use in poultry products. Through that effort, Dr. Randy Singer analyzed the use of antibiotics across almost 70% of the turkey production over the last several years.

Dr. Singer's work has been effective in showing that antibiotic cells to livestock and poultry do [01:15:00] not equate the antibiotic use. Additionally, while our industry has long known that our use has gone down, Dr. Singer's work has been able to document it. We understand and appreciate how data collection can help provide value, information to producers and others. But in the wrong hands, the same data, especially raw numbers, could be detrimental. In putting together the project with Dr. Singer, we worked to ensure the information was blinded and data was not attributable to any specific company. [01:15:30] This was and is critical to the success of the program. The private-public partnership being discussed is unclear how the data will be handled, which is a significant concern for our members. We strongly encourage this issue to be addressed before further action is taken. Thank you.

Susan C. Winckler: Thank you, commenter Froebel. I want to confirm, I know that we were going to... Yes, I'm going [01:16:00] to turn next to Tim Herman. Tim, would you pick up and your time will start.

Tim Herman: Yes. This is Tim Herman. I'm a professor, state chemist and director of the office of the Texas State Chemist, part of Texas A&M AgriLife Research. I wanted to share briefly our experience with public-private partnerships, one in which I lead as a director of a regulatory agency, where we have [01:16:30] a shared responsibilities and mutual benefits involving the management of aflatoxin risk. Essentially, the shared responsibilities involve qualifying analyst using a common USDA-approved sampling and testing procedure. As a result, the mutual benefits allowed us to use a single test for [01:17:00] the purposes of trade regulation, as well as crop insurance indemnification. This public-private partnership cut across producers, grain handlers, regulatory agencies, crop indemnification, and crop insurance purposes.

That leads me to the comment about potential governance models. What we have is referred to as co-regulation, [01:17:30] where in fact, we rely heavily upon those participants who are part of the program. We rely on their data rather than the command and control type of regulatory process. We see public-private partnerships leading to a more enlightened form of governance, but I do think we need to emphasize the mutual benefits. I think a number of those issues [01:18:00] were raised by speakers from various trade associations. Thank you for the opportunity to comment.

Susan C. Winckler: Thank you, commenter Herman. We will now turn to our next commenter. Next on the list, I have James Kincheloe. James?

James Kincheloe: Thank you for providing the opportunity for public comment today. As FDA progresses towards developing the antimicrobial [01:18:30] usage monitoring system, they should prioritize a major challenge that the foundation identified in its research, having standardized data across each species. While collecting and aggregating the antimicrobial usage data at a regional and national level will certainly provide key benefits and form the creation of effective regulation and policies, the most impactful benefits of a uniform monitoring system may stem more from the individual farm level. With a standardized monitoring system, [01:19:00] farmers will be able to compare themselves to their peers and an inadequate animal health system will become more apparent.

Pressure to have better stewardship and decreased usage could then come from multiple angles. For example, the farmers themselves could feel pressure to change as unhealthy animals in antibiotics or costs that potentially could be avoided. Pressure could come from the herd veterinarians who are trained in antimicrobial stewardship and should be looking for ways to improve animal health and decrease usage where possible, [01:19:30] or processors and others higher up on the production chain who want their animal production facilities to meet certain standards would likely also add pressure to have better stewardship to the facilities that they purchase from. Many other aspects of animal health and production such as weight gain rates and bulk tank somatic cell counts, which indicate dairy herd health and milk quality, are measured across animal production systems.

This measuring has driven massive improvements in these categories in the United States. AI [01:20:00] microbial usage needs to be added to the list of always measured aspects of animal production. Like the others, improvement will come. Thus, as the FDA explores the means to collect antimicrobial usage data, it needs to prioritize that every form is a recording usage in a uniform manner for the species or production model, regardless of whether the data is collected for federal use each year. Thank you.

Susan C. Winckler: Thank you, commenter Kincheloe. We will now turn to [01:20:30] our next commenter who is Steve Roach. Steve?

Steven Roach: Thank you. I am the Safe and Healthy Food Program Director at Food Animal Concerns Trust. I've worked on antibiotic resistance policy for over 20 years. Over that time, antibiotic use data collection has always been an FDA priority, but never enough of a priority for a system to collect that data to be implemented. With respect to the report, FACT is disappointed that the report does not address or even mention the challenges to collecting data that [01:21:00] is representative. This is related to FACT's second concern that the report does not address to divergent needs of data users. Consumers, public health officials, drug makers, and livestock producers may have different needs. It is important to acknowledge and address a divergence of interest in creating a

public-private data collection system since public resources will be involved. There are real issues related to the control of data, how it is collected and how it is reported.

For example, the private interests may want [01:21:30] the program to be entirely voluntarily, which creates real challenges to getting representative data. If the on-farm use data are not representative, then they cannot be used to analyze trends or measure the impact of stewardship efforts on a national level. FACT is also concerned that the report denies that sales data are an appropriate proxy for antibiotic use. If the sales were not a valid proxy for use, then we would have to believe that the large drops in sales in 2017 actually did not reflect a reduction in use and that they were not [01:22:00] a reflection of the policies that FDA had put in place.

This is patently false, and no one actually treats the sales data this way. Sales data are a better proxy for national use than an unrepresented sample of producers that choose to participate in a voluntary program. Finally, the claim that species data should not be directly compared to other species versus [inaudible 01:22:22] perceptions of one potential set of users. Consumers may choose to select to purchase chicken instead of beef, because there [01:22:30] is less antibiotic used to produce that, and that's a valid choice of those consumers. Thank you.

Susan C. Winckler: Thank you, commenter Roach. We will now turn to commenter Phil Stayer. Phil? I don't see commenter Stayer. There we go. [01:23:00] Go ahead. Yes, please go ahead.

Phil Stayer: I'm Dr. Phil Stayer, corporate veterinarian for Sanderson Farms' Incorporated, the third largest integrated meat-chicken producing in the United States. Sanderson Farms' corporate veterinarian for over 20 years. I've helped oversee all antibiotic use during that time period, more recently with the help of three other licensed board certified corporate veterinarians. Since Sanderson Farms' is vertically integrated, which means all birds are owned by the company even if [inaudible 01:23:28] family owned contract farms, [01:23:30] flocks only receive antibiotic treatment after consultation with one of the Sanderson Farms' veterinarians. As Sanderson Farms' veterinarians, we are encouraged to treat both flocks with available efficacious antibiotics when we believe such antibiotic use is prudent, not to over treat or treat without diagnoses. Disease instances have waxed and waned over my 20 years, so antibiotic use has also gone up or down based upon flock health. [inaudible 01:23:56] everyone to prevent disease and minimize antibiotic use, [inaudible 01:23:59] animals will not grow as [01:24:00] well as healthy animals.

We do our best to prevent diseases. However, antibiotics are needed at times to treat illnesses. Sanderson Farms' has participated with Dr. Randy Singer's antibiotic use and commercial poultry data project, primarily to educate all consumers and potential customers about prudent antibiotic use in commercial poultry. Dr. Singer's survey places antibiotic use in context, that is, why

antibiotics are even needed, and also maintains anonymity for the participant. By the time Dr. Singer requests updated antibiotic information, [01:24:30] Sanderson Farmers' veterinarian team has already assessed any trans-antibiotic prescriptions, particularly prescriptions increase from previous experience. Our goal as Sanderson Farms' veterinarians is not to stop using antibiotics, but to try to prevent the disease that necessitate take the use of antibiotics, which will hopefully reduce the need of antibiotic use. As US-licensed veterinarians bound by veterinary oath, corporate veterinarians are committed to, and I quote, "Use our scientific knowledge and skills for the benefit of society through the protection of animal health, relief of animal suffering, [01:25:00] conservation of animal resources, promotion, public health, the advancement of medical knowledge, antibiotic stewardship of food animals." In this case, meat, chickens. [inaudible 01:25:10]

Susan C. Winckler: Thank you so much, Dr. Stayer. We'll now go to our final public commenter, and that is Liz Wagstrom. Liz, would you please begin? We'll restart the clock. [01:25:30] We will unmute you. My colleagues at the foundation, would you unmute Liz Wagstrom, please? My colleagues [01:26:00] at the foundation, would you unmute Liz Wagstrom, please?

Liz Wagstrom: Okay. Can you hear me now?

Susan C. Winckler: Yes. Now, let's [01:26:30] re-begin. Thank you.

Liz Wagstrom: Thank you. Defining the purpose of data collection, the uses of the data, and the plan for reporting prior to designing a system will be essential to success of a public-private partnership. We believe that the focus on improving stewardship at the local level, which is the farmer and the veterinarian, should be the primary driver of collecting antibiotic use data. Simplicity will be key. We must avoid duplication of efforts on data recording in our collection, but granularity such [01:27:00] as dose, indication, age or class will be what provides the most value. Just to give an example, the pork industry right now is very focused on preparedness for a potential foreign animal disease. We have several programs that we are encouraging farmers to participate in, but because of the multiple asks for similar data, there is frustration on farmers and veterinarians with those efforts. We need to avoid something similar with collection of antimicrobial use data.

While simplicity [01:27:30] is key, production systems themselves are complex. In the pig industry, I counted at least six different production classes that data could be collected from, and because of the complexity of different production systems and the differences in life cycles, not only is the comparison between commodities undesirable, standardization of the data collected between commodities may not provide value.

The references to regulatory and policy decisions need to be clarified [01:28:00] or voluntary participation in such a partnership could be stifled. We need to recognize that there is significant noise between the data collected by NARMS



and what happens on the farm. It will be difficult or perhaps impossible to draw conclusion from the NARMS human disease data on the on-farm use data. Developing reports that are factual and provide adequate context will be key to robust participation in a voluntary public-private partnership. While we know that [01:28:30] this data is eagerly awaited by many audiences, it's essential that trust is maintained with those who are providing the data. Thank you.

Susan C. Winckler:

Thank you. Thank you very much to all of our public commenters today. We greatly appreciate your participation. I will also remind you that you may submit comments to the public docket. Allow me also to extend a sincere thanks to all of our speakers and everyone who attended the meeting [01:29:00] today. As noted at the beginning of the event, we will post the recording on the website soon and add the event transcript within a few days. With that, we will close out our discussion. Thank you very much for joining us and take care.

PART 4 OF 4 ENDS [01:30:30]