Slide 1: Good day everyone and welcome to our webinar, “The U.S. and EU Animal Pharmaceutical Industries in the Age of Antibiotic Resistance.” My name is Kellie Burdette and I will be your host. As a reminder, this webinar is being recorded and will be posted on the ERS website next week. At any time during the webinar, you may type a question into the chat feature at the bottom left corner of your screen and our speaker will answer at the end of the presentation. Our speaker today is Stacy Sneeringer. Stacy is a senior economist in the Structure, Technology and Productivity branch, Resources and Rural Economics division of the USDA's Economic Research Service. Stacy joined ERS in February 2010, her research predominantly uses econometric methods to evaluate environmental and public health aspects of livestock agriculture in the United States. I believe we're ready to start, so Stacy you may now begin your presentation.

Hi, this is Stacy. Welcome everyone, and thanks for taking some time out of your day to hear about our recent ERS report. The title should be on your screen, "The U.S. and EU Animal Pharmaceutical Industries in the Age of Antibiotic Resistance." My email address is also right there, if at any point you would like to contact me directly.

Slide 2: As a way of introduction: the motivation for the entire goal of looking at the animal pharmaceutical industry, with respect to antibiotics, any use of antibiotics, be it in humans or animals, can encourage antibiotic resistance. That becomes, that means that the antibiotics that you're using become less effective. For example, if you had a bacterial infection and it could be treated by antibiotics A, B, and C, now we're at a point where we want to try A, A may not work to actually treat that bacteria. B may not work, then C may not work; so this is the real big worry, is that we get to a point where no antibiotics work to treat those bacterial infections. That of course can lead to both human and animal health problems. For humans this is much more, we're thinking of health issues, we're thinking of mortality, we're thinking of lost workdays for illness, lost productivity, and so forth. For animals we're really concerned about less growth, you have stunted animals, you have to perhaps have a higher chlorate, and it leads to productivity concerns for farmers and integrators. The methods that have been suggested to address the issue of antibiotic resistance: the first is just use fewer antibiotics. Now that's not to say don't use antibiotics at all, it's more the idea is that research has shown that both in humans and in animals, perhaps we are using antibiotics for problems that don't require antibiotics. For example, in human health there's been research suggesting that antibiotics are prescribed for a lot of viral infections, and they really don't need to be. However, we don't really have fast diagnostics to tell us necessarily whether you're seeing a bacterial or a viral infection, and a doctor may prescribe antibiotics which only treat bacterial infections when those aren't really going to be effective. It would be nice to be able to stop that kind of practice, perhaps through a better diagnostic. In the agricultural space, the idea is also to use the antibiotics more judiciously. Perhaps that would be involved with more diagnostic tests, or it could be through basically keeping disease off the farm. The idea is to use fewer antibiotics. This has been enacted in agriculture through government regulations, as well on agricultural use. Just recently, and I'll go into this a little bit more, we've had 2017 FDA policies that went into effect that limited the use of certain antibiotics for growth promotion in agriculture. There has also been a lot of campaigns for education to better use antibiotics, it's not bickering in both the human health and the veterinary spheres. And finally there's a, consumer demand is growing for products that are labeled as "raised without antibiotics," or you have large retailers will be wanting to market a line that is "has a lower use of antibiotics" in the process of raising the animals. These have been suggested both market and regulatory methods, and just an educational method of trying to reduce it antibiotics. Another idea is if you want to develop new products, so for humans this largely involves if antibiotics A, B, and C don't work then we really want an antibiotic D, so we want another antibiotic. And so the idea is to put more money into research and development of new products. For animals perhaps we would also like, perhaps a different

antibiotic D, not the same one that is used for humans, but perhaps we'd like something else that could be a substitute for antibiotic use in agriculture. These could be new antibiotics, they could be alternatives to antibiotics. Animal pharma is the industry that develops and markets products for animal health. So the question here is, what influences animal farmers investment decisions into new products?

Slide 3: The policy context, there's been some policy suggestion proposing incentives for new animal pharma products. There's been, this is the title of a report from the President's Advisory Council for Combating Antibiotic Resistance Bacteria, this came out in September 2017. The idea here was talking about how to incentivize the development of new antibiotics for human health, but also thinking about incentivizing the development of new products for animal health, and specifically agricultural animals, which I'll call food animals. These PACCARB, that's the committee name, focused largely in this document on vaccines and diagnostics for animal health, but you could think of a range of different antibiotic substitutes that are certainly being considered and certainly kind of in the research and development stages. Why would we need to incentivize these things? The issue for human health is really that the human pharmaceutical sector seems to be moving away from developing new antibiotics, and they just don't see a market incentive to do so. And the question is, from the policymakers perspective, is what kind of instruments and what kind of levers do we have to push in order to get the things that we want from the human pharmaceutical industry? From the animal pharmaceutical industry this is not as common of a policy intervention, but it's something that's being proposed. The idea for this report really was to, for policy makers' perspective, is to basically understand the animal pharmaceutical industry better.

Slide 4: The questions for today are, what impacts animal farmers' investment decisions into new products? Well obviously, the first one will be the costs of research and development per drug, how much does it cost to get something onto the market? The second one would be demand for the products used in food producing animals, so if nobody wants something you certainly don't want to develop it. Third would be competition for R&D dollars, an individual company doesn't have a limitless supply of research and development dollars, they have to choose which one, which products are most likely to give the highest return on an investment. Therefore you have competition, even within an individual company, of where to put R&D dollars. The ones that I'm going to highlight are companion animal products, that would be things like flea collars for cats and dogs, and the other bit of competition would be, but I'm going to discuss, is for generic products. And finally what else impacts animal farmers' investments? It's the development of products for human use that can influence what gets developed for animals. Now I'll go into this a little bit more.

Slide 5: Some background of the animal pharma industry, to just kind of set the stage.

Slide 6: The size and research intensity: human pharma is much larger than animal pharma. Animal pharma is not a small industry, but it is much smaller than human pharma. For example, in 2015 human pharma sales topped out around $1 trillion or $1000 billion, where animal pharma sales were only about $24 billion. The human pharma is about 42 times larger, that means sales are much larger, but also R&D budgets are much larger in the human pharma industry. Both animal pharma and human pharma are research intensive that means you're going to spend a large portion of your returns on R&D unlike, perhaps, other industries. For example, in human pharma the ratio of the amount spent on R&D to sales is about 13%, so that means of every dollar that comes in in revenue in human pharma, that you put 13 cents back into R&D. In animal pharma, that numbers around 8% and to just give you a general perspective for, if you look at the total U.S. R&D spending divided by the total gross domestic product,

that's around 3%. That's just trying to tell you that these are both research intensive industries. Both human pharma and animal pharma also extensively use patents and patent protections.

Slide 7: The location and end-user species of the animal pharma industry. Well, approximately 60% of the animal pharma market is in the U.S. and the EU, the European Union. I think all of the major firms are headquartered in the U.S. and the EU as well. Animal pharma, as I noted before, makes products for both food producing and companion animals, that means for both Bessie the cow who's not a pet, and for Fito your dog, and that's pertinent because the pet market is a larger and larger portion of, at least, the market in the U.S. What you see on this left circle, this is global sales by animal type. This is showing you this orange portion, which is about 36%, it goes to companion animals, where, while 64% goes to food animals. Now compare this to the U.S., you see that about 60% of sales in animal pharma are for companion animals and 40% are food animals. The reason for this is we have a growing interest in owning pets and also spending money on our pets, whereas in the rest of the world, perhaps you're using more products, so you have left pet ownership per capita, but you also perhaps use more drugs for food animals.

Slide 8: There's significant attrition of new pharmaceutical products in the path from discovery to market, so it takes a really long time to start syncing up a new drug, going through testing, and then finally getting it on the market. We've seen estimates, and we've stylized it here that it takes about 10 years to get something from initial discovery, all the way to the drug approved for sale. We kind of make this as a cone, as a cornucopia; you have lots of different kinds of ideas here, but a lot of them fail, so you have high failure rates around each of these stages. We also have some overlap for human and animal pharma research in the initial stages of research - the idea there is that, perhaps something works on a bacteria in a petri dish, now that bacteria may be a problem for both humans and animals, and so therefore you could develop a drug that would be useful for humans and animals. It starts to separate later down the line when you start thinking of, perhaps, safety issues or, for example, something that is effective in treating the bacteria, but kills your liver quickly. This isn't something that you want to use in human health perhaps, but it might be something that you might consider for animal health. Specifically, when you're thinking of food animal production and it doesn't have any kind of residual other effects that you're worried about.

Slide 9: The percentage of animal pharma sales by product type, this is showing you for 2017. Animal pharma markets three general kinds of products, that's how they've divided them: first, the "pharmaceuticals", that's another word for just drugs, 58% of their sales are for pharma, and this is for global sales by the way. 30% would be in "biologicals", biologicals are largely vaccines; biologicals just means, things that are derived from something that was either previously living or living now, so that's what we're thinking of with vaccines for example. Then finally, another 12% of sales are a "medicinal feed additives," that would be pharmaceuticals added to animal feed, for food animals. Antibiotics are portions of the medicinal feed additives and the pharmaceuticals, I don't have more of a breakdown as to where antibiotics are in each of these. What I can say is, there's estimates that, in about 2017, antibiotic sales in animal pharma were about $5 billion globally, so that constitutes in 2017 about 19% of global sales, so antibiotics are a large revenue stream for the animal pharma industry.

Slide 10: Let's move on to R&D costs per new animal drug approval.

Slide 11: What we see here, this is titled "U.S. R&D Spending on Animal Pharmaceuticals and Numbers of New Animal Drug Approvals, by Type of Approval, between 1989 and 2013." What you're seeing is three different lines, and they're on two separate axes. Let me describe a little bit about what we're seeing; what we're seeing is this on the horizontal axis, this is just showing you time, and on the left-hand axis, you're seeing, this is the number of new animal pharmaceutical approvals. Right now we're just excluding all

generics from this table, from this chart. This blue line is showing you all of the new animal drugs that have been approved, and they're approved by the FDA, and what you see over time is this number is really falling, this number is declining over time. A second measure of new animal pharmaceutical approvals is the ones with an original ingredient that is a term that we have coined, "the original." Original, to us, as we suggested, just means that there's a chemical in that drug that has not been an ingredient in a previously approved animal pharmaceutical drug. That's our way of providing a second, more narrow notion of innovation in the animal pharmaceutical space. You can see this yellow line is sort of maintaining over time, but you also have, this is only about five per year, you're getting basically five new animal drugs, completely original animal drugs. This red line is mapped on the right axis, and this is showing you the millions of dollars that are spent in animal R&D that's going up over time. You can sort of start to see that if the number of drugs approved is going down, but the amount of spending is going up, means on this next slide.

Slide 12: That the spending per new animal drug approval is increasing. This is showing you these two different measures of animal drug approvals. This is R&D dollars per new animal pharmaceutical approval with an original ingredient, that's the yellow line here, as you can see that's increasing over time, and the blue line is showing you the R&D approvals per new animal drug, and these are all non-generics again. And again you see this is going up, it looks like it's becoming more and more expensive to develop a new animal drug. What we see is over this time period between 1989 and 2013, the average for a new animal drug with an original ingredient is $173 million, it's growing at 2.4% per year, and for any drug that is a non-generic it's about $51 million per year or it's growing at 6.3% per year.

Slide 13: That gives us a sense that it's becoming more costly to develop new drugs. It gives us a suggestion that the animal pharma companies really need to invest wisely. What's happening with demand for antibiotics for food producing animals? Here the question is, should an individual or should an animal pharmaceutical firm put its money into a new animal antibiotics?

Slide 14: Well, what are the factors impacting demand for antibiotics in food producing animals? And food producing means you're talking about meat, milk, and eggs. What's going to affect it, let's start on the right-hand side. You're looking at total antibiotic use in food producing animals is going to be a function of the production of those livestock products, or you can think of it as the number of animals, and then antibiotic use per unit of production, so you're thinking about antibiotic use per animal. What's going to impact production of livestock products? Well, majorly, it's going to be domestic demand and export demand. In the U.S., I'm just going to describe that, the U.S. is a major producer of meat in the world, as is the EU. We are, I think, the U.S. and EU are second and third behind China, which produces about a quarter of the global meat supply. Domestic demand in the U.S. and EU is not growing very quickly. The reason that it's not growing very quickly is because we don't have very quickly growing populations, and the per capita demand for meat isn't really increasing, it's not like everybody's wanting to eat more and more meat every day. Certainly there is growth there, but it's not nearly to the extent of say, you're thinking about a country that's going from very low income to even a middle income, and then you have much higher increase in per capita consumption. In the U.S. and the EU, domestic demand for meat and food animal products is really not increasing very steadily, however, meat production in the U.S. and EU is, and they're both growing. The reason for that is largely because of export demand. If we have demand from other countries, largely for the U.S. and the EU, these are Asian countries, the U.S. also exports to Mexico and Canada, and that's really the source of a lot of the growth of the meat industry right now. That is going to be tempered by trade agreements though, and we've seen a lot of talk about this on the national stage so if you can't, maybe, bring your product into a certain market then that's going to put a damper on that export

demand. Moving down here: antibiotic use per unit of the production, that's also going to impact the total use of antibiotics in food producing animals. Well what impacts use per animal? Well there's regulations on antibiotic use, if you can't use antibiotics for certain purposes then, of course, that cuts down. Perhaps that can cut down on the use per animal. This is consumer preferences for food products raised with fewer antibiotics, I'll talk a little bit more about that in a second, and also disease pressures on animals - I'll go into that a little bit more. Let's talk first about these three drivers of antibiotic use per animal.

Slide 15: Regulations, as I said before, there were recent FDA policies that went fully into effect in 2017, they ended the use of what's called medically important antibiotics for production purposes. What does that mean? Medically important refers to antibiotics that are also pertinent for human disease treatment. There are other kinds of antibiotics that are not used for human disease treatment, the primary one is ionophores. Those kinds of antibiotics would be called 'not medically important' or 'not currently medically important antibiotics.' What are production purposes? Production purposes are how FDA refers to uses for growth promotion or feed efficiency. If you are trying to get an animal to grow to its market weight faster, what has been found, starting in about 1946, was that if you feed them very low doses of antibiotics that they would grow faster. Feed efficiency purposes meant that you could give, you could get a chicken to market weight with say six units of corn instead of seven for example, that's an increase in feed efficiency. The FDA policies ended the use, effectively ended the uses of antibiotics for those purposes, and they also moved all other uses of medically important antibiotics under the purview of veterinarians so you can no longer get medically important antibiotics over the counter, which was true before that time. European policies restricting antibiotic use in agriculture began in 1986 in certain countries. The EU in 2006 adopted basically what the US did in 2017, which was ending the use of antibiotics for growth promotion.

Slide 16: Other factors impacting use in animals; well there's consumer demand for products raised with fewer antibiotics. The label that has basically been settled upon over several years is "raised without antibiotics" or RWA. What that means is that antibiotics have not been used at all in that animal, not even ionophores for its whole life, and it's labeled as raised without antibiotics. I get this question quite a bit, which is, does that mean, you know, animals that are sick don't get treated? No, it doesn't mean that. It generally means that animals that become sick are treated, but they're moved to a different product line. They are treated, they're just not labeled as raised without antibiotics, they're sold in the conventional market for example. Now the RWA broiler that means chickens that you eat for meat, production was about 44% of production in 2017. That's not the portion that was on the market that way, that's much smaller, but what you see is that this is a not just a niche market for broilers, and I think it's even like half of the market in 2018. It's much smaller for beef and pork for a variety of reasons. You have this consumer demand saying we want fewer antibiotics used in our meat production, so that suggests that there's a downward pressure on demand for antibiotics per animal, disease pressures as well. Modernized farming practices really focus on biosecurity and basically keeping disease out, it's not just bacterial infections that you want to keep out, it's all sorts of things that would stress an animal and make it grow less fast, make it produce less well. There are lots of methods for reducing disease on farms that would be about biosecurity that would lessen the disease pressures and also lessen demand for antibiotics. Another issue is this concern that is a low probability, but high damage scenario, which would be the global spread of livestock diseases. If you have something that we haven't seen, for example, in the United States before that required antibiotics, that might drive up demand for antibiotics in food producing animals.

Slide 17: All these features play on, they create changes in the demand for use for animal. What's going on with sales for antibiotics for food producing animals?

Slide 18: Well, this chart is showing you, this is the U.S. sales of antibiotics for food producing animals between 2009 and 2017. 2009 is the first year that we had these numbers available publicly, these are from the FDA's Animal Drug User Fee Amendment reports that's ADUFA, if that rings any bells for anybody. What I'm showing you is, the blue bars are the sales. This is the kilograms sold, so this is not a dollar value and it isn't necessarily, it's not like treatment per day, it's just the total amount in kilograms of active ingredient of antibiotics. The blue bars are medically important antibiotics sold, and the red bars are the not currently medically important. What you see here is that between 2009 and up to 2015, you really have an increase each year in sales of antibiotics. In 2016 however, that number starts to drop. It dropped about 10% between 2015 and 2016 for medically important antibiotics, that drop is smaller for non-medically important antibiotics, and then in 2017, which is the first year post those FDA regulations, you see a major drop. Between 2015 and 2017 you see a 43% decline in sales of medically important antibiotics for food producing animals. The drop for non-medically important is about 9%, it's smaller. This really suggests that antibiotics is not a growth market, at any rate, in the United States, and that perhaps those regulations were really having an impact on sales. There was some concerns that this would not be the case because there was a concern, perhaps, that producers would just switch their use of antibiotics from growth promotion to disease prevention, and that might be true in certain scenarios, but this certainly suggests that something happened.

Slide 19: When we compare this, now what I'm showing you here is percent changes in each year. This is 2009 to 2010, 2010 to 2011, etc. What this blue bar is showing you, this is the percent change in the kilograms of sales of all antibiotics for use in food producing animals, so what that's showing you, where my arrow is pointed, is saying that between 2009 and 2010 you had a 5% growth in sales. When any of these lines are above zero, that means you have growth in them. When they're below zero, that's a decline. What you're seeing is that you have growth in sales for antibiotics, in all of these years, and then between 2015 and 2016 you're first starting to see that 10% decline overall, and then you're also seeing a decline between 2016 and 2017. Now let's compare this to the meat production, this is the red line. This is the basically saying that between 2009 - 2010, you basically had, in the U.S., a growth in meat production of about 1%, okay. You see this is pretty much growing over time, but even in those periods where you see this big decline in antibiotic sales, meat production still grows. So between 2015 and 2016 meat production is growing at about 3% and the same is true for 2016 to 2017. The green line is showing you milk production as well, and that's, again, growing over time for the U.S. What this suggests, at the very least, is that animal antibiotic use for food producing animals per animal is declining. If you have just as much meat, or if that amount is growing, and you have fewer sales of antibiotics, it suggests that you're using less per animal.

Slide 20: The impacts of two things: first, the competition for R&D dollars, and also that fewer human antibiotics are being developed. Let's return and remind ourselves what we're talking about. Which is, really, what are the investment decisions for animal Pharma firms?

Slide 21: This graph is showing you the number of veterinary drug approvals over time. This is showing you the generics and also the originals. The time scale is different than a previous one that I showed you, this is showing you 1971 up to 2015. This is all approvals inclusive of generics, and so what you're seeing is, this is all veterinarian drug approvals whether they be for companion animals or food animals, but that's declining over time, you can see that even in a longer time horizon. The first generic approval was allowed to come to market, that's when the first kinds of regulations allowed for a generic marketing of an animal drug, that happened in 1989, but the first one came on the market or was approved in 1992, so that's why you don't have a yellow line here. What you see is that since they've come onto the market, generics

make up about 50% of new animal drug approvals. They're really a competitor for R&D dollars in essence here is just, but maybe you don't want to spend money on a new drug if there is just an easy, cheaper way of putting something else on the market. What we were concerned with here is, this is the number of innovative new drugs, the drugs with the original ingredient, and we were concerned that perhaps when the generics come on, if this just goes to zero or this has a major change, that is certainly clear evidence that the generic drug approval really hurt innovation. We don't really see that however, but you're looking at really small sample sizes so we're starting to do more analysis on that.

Slide 22: This is showing you the share of new veterinary drug approval. This is 100% in each time period, right. By type of treated species, and here I'm just dividing by companion animals, which is just the yellow, and then food animals, which is all of the blue. What you're seeing is that over time the companion animals, and I haven't divided that up by type of drugs, they are basically constituting a larger and larger percentage of the drug approvals in the U.S. for food, for veterinary drug approvals. These, this light blue is showing you that non-antibiotic approval for food animals. That's sort of staying constant and perhaps growing a little bit, the rest of it is antibiotics. First of all, you see that antibiotics constitute a pretty significant share of drug approvals for food animals, but that percentage is declining over time. It's going from 62%, all the way, and then it basically goes down to 33%, you get a little bit of a bump up to 40%. Antibiotics do not seem to be where the animal pharmaceutical industry is necessarily wanting to go, it looks like companion animals is becoming more and more of a lucrative market. This is also showing you generics versus non-generics for the antibiotics, and so what you're seeing is you get a pretty large share of the new antibiotics are generics.

Slide 23: This is the second to the last slide. This is the number of food animal antibiotic approvals by medical importance and generic status. These red ones, these red bars, solid red and like a cross-hatched red, is showing you the non-medically important antibiotics. The cross-hatched is the generic, and the solid red is the non-generic. What you see is these don't constitute a large percentage of the new antibiotic approvals over time, it's becoming a smaller share of new antibiotic approvals versus, if you're looking at medically important antibiotics, what you're seeing is they constitute the largest share of new approvals - that doesn't seem to be changing, and more and more frequently it seems that a larger and larger amount of them are generics. If you're a policy maker who wants to incentivize something new, perhaps you wanted to see a new non-medically important antibiotic, you want to see these red bars growing, if you're the policy maker that wants a complete substitute for those antibiotics. That doesn't seem to be happening that might be because of economics that might be because of science - this graph gives no indication of that.

Slide 24: In conclusion, just try to wrap all of that together, what we're seeing is increasing costs of R&D per new animal drug approval means that firms must invest wisely. The antibiotic sales are dropping in the U.S. and the EU, this is likely due to regulations, it's likely due to consumer preferences, and it also is likely to due to modern methods of animal production that really focus on disease prevention. There's competition for R&D dollars, a growing share of new products, new veterinary products, or for companion animals. And what I didn't mention was that most products, when they're labeled and come on the market, very few of them are both for companion animals and food animals. They're either one or the other. You also have a significant share of approvals for generics, this is going to be important for innovation in that space. Finally, the new non-generic antibiotics for food producing animals, though they're still being developed, they still exist, they're still coming on to the market, but they're decreasing share of product approvals. That might be because, in part, a lot of products for the animal space are coming from the human market. Something that perhaps didn't work out in testing for the human pharma markets, might be then transferred over to the

animal market to see if it can make a return there. If the human space moves away from doing research into new antibiotics that has, perhaps, repercussions for the animal space. This decline in new animal antibiotics being approved might be, at least in part, a function of what you're seeing in the human space.

Slide 25: That is all I have today. I'm happy to take questions, either directly to me on my email. This is a link to the report page, and I can also take questions from you. I think Kellie will be reading them, is that correct?

It is, thank you Stacy. And we do have some questions. We have one question, could you repeat your point about limitations of antibiotic use for growth in food animals?

Slide 15: Sure. This is talking about the FDA policies. That was, the idea was that they've removed from the labels of the drugs that you cannot use those drugs for purposes of, or production purposes, growth promotion or feed efficiency. They're limiting the use for those purposes by just removing that from the label. If anybody is using it for that purpose, it's technically illegal. That's what the limitation is there, so you're limiting certain uses for certain purposes in the United States. The EU has also done this; there are specific cases earlier than 2017 in the United States for very specific antibiotics, but this is for all medically important antibiotics for use for production purposes. I hope that answered that question.

Thanks. Here's another question, with human and animal drug makers becoming more separated, how likely is it that potential human antibiotics will be recognized and pursued by animal drug makers?

I didn't really go into this a whole lot. Most, I think about six of the largest seven animal pharma companies, are basically subsidiaries of human pharma companies, and then the seventh is just, was spun off not too long ago. You'd think that there would be a lot of business connections, research connections within those industries, but what you see is that you're having a decline in the number of human antibiotics being developed, and as I suggested is, that's because you're getting a lot of the research base from human pharma to animal pharma. If they're going away, if the human pharma R&D departments are going away from developing new antibiotics for humans, that suggests that there's, perhaps, fewer ideas, there are fewer things that didn't work out for human pharma that are coming into the animal pharma base.

Slide 23: And that is sort of what we're seeing here, you see a decline in the number of animal antibiotics being developed. This little bump up between 2013 and 2015 is potentially because of something that happened in the human pharma market, which was the GAIN act, which it's an acronym that I, right now, cannot remember, but basically what it said is that if you're trying to get an antibiotic, a new antibiotic through the approval process, you get to skip the line, and we're trying to do that more quickly because we want new antibiotics. This might be an artifact of that, we really have to go into the individual ingredients to understand that more, and we certainly have started doing that kind of research.

Good. Here's another question, what incentives do animal pharma firms have to develop new products that would lessen sales of some of their other products?

This is the other issue, is that, you know, when you take something off the market for a certain purpose, as the FDA did for growth promotion, there's definitely a space that the animal pharma sector could go into with a new product, right. But for growth promotion it's really easy to say, it'd be great if we could get something else that would be in there, and that would sell perhaps as much as the antibiotics for growth promotion did as long as it has similar pricing, etc. and so forth. But when you're looking at something and saying, okay, we want a product for disease prevention, so disease prevention is really, I'm going to treat animals for a disease that is likely to happen, it's a high likely this to happen. I don't necessarily have

evidence that the animal is actually diseased, but we're going to treat it, and that's largely because you have animals in pens and in large groups, it doesn't make sense to individually diagnose chickens because there's like 10,000 of them in a barn, so you might preventively treat those animals. The issue there is that you, perhaps from a policy makers perspective who wants to say, let's limit or let's reduce the use of antibiotics in agriculture by having something different, well, an animal pharma company is saying, you want me to develop something that would, for purpose A, right, and I already have a product, let's call it X, that treats purpose A. Now you want me to develop another product, Y, that also treats A. Well when I already have a market for that, for treating the disease, why would I try to put something into the market to compete with myself in essence, or my own product? The incentives really start becoming around those features, that starts becoming an issue of regulations provides the incentive, consumer preferences provide the incentive, and perhaps a program to incentivize certain things actually provides the incentives, but there doesn't, it's not like one that just righteously exists in the market.

Thanks. Here's another question, what is the practical value of the study?

The practical value of the study was to give the President's Advisory Council, if they're talking about incentivizing the animal pharmaceutical industry to do something other than what it's already doing, you don't want to put money as a federal agency into, you want to say, if you're already doing X, Y, Z, but I'd really like you to do X, Y, Z, here's some money to do X, Y, Z; Bob's already doing X, Y, Z, you didn't need to give Bob money to do X, Y, Z, alright. You really want to understand what the animal pharma industry is doing already, before you give them money to do something, right. That was a first purpose, was to better inform these kind of policies or kinds of incentivization policies that are certainly being discussed. When you're thinking from a producer perspective, this is pitched, it's sort of like what's going on the animal pharma market but from a producer, and producer I mean farmer or an integrator, you really want to know, okay, are we going to, you know, if we do have to move out of the using antibiotics for these other purposes, what's coming down the pipeline? What have they been doing? Because if you don't see, you know, any shift it becomes a question of what else can I do to satisfy these regulatory requirements? And since you have such long time horizons in the drug approval process, you might have to be planning ahead by like that many years, right, so that's another practical application for this report. And it's also that a lot of this information is not public. For example, these drug approval numbers that we pulled together, that was all of our own scraping of the FDA websites and some older documents to put together a data set, so that was the thing that we did as well.

All right. Another question, what happens to meat prices if antibiotics no longer work or can no longer be used in agriculture?

That is a concern of producers that you certainly seen some of the trade journals. If you can't use antibiotics, well you certainly hear producers very concerned about animal welfare. I think they all want to be able to treat sick animals. They do not want to see animals suffer and so they don't want all antibiotics to certainly be regulated away, and I don't think if consumers understood this that perhaps consumers would want that to happen either. And the question is, if they regulate it away or that maybe antibiotics become, you know, far down the line, you have antibiotics that just don't work in agriculture, and so you know, you have to come up with other ways to perhaps getting your animals health maintenance or in their rigidity of growth that you would like that satisfies markets. Conceivably you have increases in meat prices unless there are comparable substitutes for the antibiotics at the time.

All right. Here's a question, is current data available on antibiotic sales since the implementation of the 2017 legislation?

Slide 18: Yeah. The only real, the data sets we are showing you the ADUFA data, which is the Animal Drug User Fee Amendment data, which here. This is available publicly through the FDA; I would just Google ADUFA reports and you'll be able to find this. They report, so the 2017 data is the most recent data and that's deported in 2018, so in 2019, I think around December is when we usually get the ADUFA for reports, so that's the next time to look at it. But again, the policy really didn't just suddenly happen overnight in 2017. The policy really happened, I would say this is post-policy, and we sort of think that this, and from some case studies and some other trade press that we've read, was that this decline is perhaps producers preparing for the policy. They're starting to move away from the regulation or starting to move away from medically important use here anyway. I would say these are kind of both impacts of the policy. If you're asking about individual farm level uses of antibiotics and data on that, the USDA's Animal Plant Health Inspection Service has produced some reports on beef, I think cow-calf, you'd have to look at that webpage: the National Animal Health Monitoring Survey, I'm not certain whether that captures the post-regulatory environment. But beyond that there might be smaller scale surveys that have been done by individual, perhaps, extension specialists for example, or individual firms, but those wouldn't necessarily be nationally representative.

All right, Stacy. We have one final question, is antibiotic resistance lessening the efficacy of antibiotics in agriculture to an extent that it is noticeable to producers and integrators?

Right now, we've found some studies that have been showing increasing antibiotic resistance for the antibiotics used to treat BRD, which is Bovine Respiratory Disease, which is a major illness and a major loss of productivity in the beef sector. You see antibiotic resistance increasing, but it doesn't necessarily amount to a level that would be showing up to producers right now. Perhaps because things fluctuate over time and there's other things going on like drought and feed prices feed, prices and drought, or of course major things affecting the beef market, and antibiotics perhaps not so much. Or it's just that the impact of these regulations gets kind of drowned out or any kind impacts of resistance kind of gets drowned out by these much more, these much larger scale events. Right now there's certainly scientific evidence that antibiotic resistance is increasing in treatment of certain animal diseases, but is it a scale enough for producers to say, hey, I need to do something? No, it doesn't look like there's something that is reaching that level yet.

All right, thank you so much Stacy. That's all the questions we have, and this concludes our webinar. Thank you all for joining us and have a great day.

Thank you.