



Stewardship of Antimicrobial Drug Use in Food-Producing Animals



*A report of 12 regional
educational workshops*

January 2016

Farm Foundation, NFP, works as a catalyst for sound public policy by providing objective information to foster a deeper understanding of issues shaping the future for agriculture, food systems and rural regions. Since its founding in 1933, Farm Foundation has been a non-advocacy organization. The Foundation does not lobby or advocate positions. The Foundation's action comes in bringing industry leaders together to examine evolving issues that will shape the future, and identify options to address those issues.

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Executive Summary

Stewardship of antimicrobial drugs in food-producing animals is a complex issue with far-reaching implications for the nation's consumers, food industry and agricultural production sector. New policies of the U.S. Food and Drug Administration (FDA)—Guidance for Industry (GFI) #209 and #213, and a revised Veterinary Feed Directive (VFD) rule—are expected to change labels of medically-important antimicrobial drugs in feed and water to allow only therapeutic use (prevention, control or treatment of disease) of those drugs in food-producing animals. In addition, use of these drugs will require either a veterinarian's order or direct administration by the veterinarian. The necessary adjustments will require significant effort for some parts of the system, however, many changes are already underway.

Farm Foundation, NFP conducted 12 educational workshops across the nation to provide livestock producers, feed suppliers, veterinarians and support service organizations with comprehensive information on the new policies. These workshops were also an opportunity for the 530 participants to give feedback to officials of FDA and USDA's Animal and Plant Health Inspection Service regarding the management challenges to implementation. Here are key findings from the Farm Foundation workshops:

- While much progress has been made, lack of education on the new policies and the responsibilities of the respective stakeholders is seen as a critical barrier to implementation. There is a low level of awareness of the impending regulatory changes—particularly among livestock producers with small- to medium-sized operations. Many veterinarians are not aware of the impending changes. Less than half of workshop participants were clear about their responsibilities under the revised VFD rule. When asked to describe the impact of the GFIs and VFD rule on their day-to-day business, the second most frequently mentioned response of producers and veterinarians was a need for education (19%).
- Survey respondents listed improved public perception and better livestock management as the two top industry impacts of the new policies. These were followed by increased costs and concerns about animal health, including access to antibiotics and veterinary services. Among farmers and ranchers, increased costs and additional paperwork are seen as the greatest impacts.
- Changes in federal policy on the use of medically-important antibiotics in food animals are not occurring in a vacuum. The market has been driving changes as more restaurant chains and retailers have announced new policies on the use of antibiotics in their supply chains. Large integrated meat producers have also committed to the judicious use of antibiotics in their operations. These market-driven changes have already led many producers, especially those that are part of integrated production systems and supply chains, to eliminate the use of antibiotics for production enhancement purposes.
- Greater impacts will be experienced by the many farmers and ranchers—especially those raising beef cattle and small ruminants, such as sheep and goats—who operate independently from large integrated supply chains. Producers of small ruminant and other “minor species,” such as deer, elk, bison or honey bees, along with turkey producers, foresee that reduced access to antibiotics may have a potentially large impact to their operations.
- Many small producers lack an established relationship with a veterinarian and may struggle to establish a Veterinary Client Patient Relationship (VCPR). In some areas, there is a shortage of veterinary services due to an overall shortage of veterinarians, and fewer veterinarians treating food-producing animals. The problem may exist in remote locales as well as urban fringe areas.
- The requirement for a VCPR is likely to change and strengthen relationships between many producers and their veterinarians. Veterinarians are likely to play an increasing role in a broader range of animal health

decisions on farms and ranches. This will mean expanded business for veterinarians. At the same time, veterinarians will take on increased responsibility and liability as they will be required to maintain the original copy of each VFD. This may require investments in new record keeping systems and increased insurance costs for veterinary practices. Veterinarians will also need to better understand calculations for ration formulations, including the approximate number of animals treated by the VFD—a task that has generally been performed by the feed manufacturer, nutritionist or both.

- Another sector in need of education on the new policies is youth show exhibitors—specifically FFA and 4-H members and clubs. The show animal breeding and supplier segments are likely to have a VCPR, or have the resources to establish one. There is concern, however, about the youth segment of stock show exhibitors. This multi-species segment—whose show animals might include cattle, swine, goats or poultry—often rely on club leaders, agriculture teachers or Cooperative Extension Agents for direction on animal care and disease prevention/treatment. The FDA’s GFIs and VFD rule require the caretaker of the animal(s)—whether that be the club, school or individual owner—to establish and maintain a VCPR.
- While feed manufacturers and bulk distributors are already accustomed to VFDs under previous rules, changes in the rules and record keeping requirements will require adjustments. The increased number of products included under the revised VFD, combined with separate expiration dates for products and VFDs, will increase the complexity of managing inventories.
- Many small producers now purchase medicated feeds in bags from an agricultural retailer for whom feed is only one part of their business. If retailers decide that the costs of handling medicated feeds are too great, they may no longer carry these products. This could mean that small producers, who have relied on the local agricultural retailer, will have more difficulty accessing medicated feeds and water-soluble products.

Based on the findings from Farm Foundation’s 12 regional workshops, here are some immediate next steps that will help with implementation of the new policies, and build a framework to support the ongoing stewardship of antimicrobial drugs.

- 1) *Education and Outreach*: The online survey and workshops identified a lack of awareness of the changes required by the GFIs and the VFD, and the need for education as critical barriers to successful implementation. Despite significant efforts by farm, industry and professional organizations, federal and state agencies, Cooperative Extension Service and agricultural media, a significant awareness gap remains, especially among small and independent producers. All of the above stakeholders have a role to play in reaching small producers, but Cooperative Extension, with its responsibility for public education, and feed suppliers, who interact directly with farmers and ranchers on a daily basis, are especially important in closing the awareness gap and providing educational materials.
- 2) *Continuing Dialogue Between the Industry and State and Federal Regulators*: Participants identified as one of the most valuable elements of the workshop the direct interaction with FDA and USDA. One outcome of this interaction was the development of a list of unanswered questions for FDA (see Appendix E). FDA is working to address these questions, which will help lead to the resolution of many implementation issues. (See GFI #120, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>) A continuation of this kind of dialogue is critical not only to successful implementation of the GFIs and VFD, but to help support a continuing process of stewardship. The commitment of state and federal regulators to dialogue is clear, but their resources are limited. Ensuring that this dialogue continues will also require the commitment of private and non-profit sectors.
- 3) *Access to Veterinary Services and the Supply of Food-Animal Veterinarians*: In the near-term, state and federal officials need to work with colleges of veterinary medicine and professional veterinary organizations

to quickly develop options to provide access to veterinary services to small producers in underserved areas. Long-term, part of the solution will be efforts by colleges of veterinary medicine to increase the number of veterinarians with economically-sustainable food-animal veterinary practices. There may also be opportunities for other stakeholders—including feed suppliers, Cooperative Extension and state regulatory authorities—to explore new models of delivering veterinary services in underserved areas. Some of the most difficult challenges will be meeting the needs of producers raising other species, including small ruminants, deer, elk, bison, fish, honey bees and other so-called “minor species.” Few products are approved for use in these species, which risk becoming “orphan indications” due to the limited market size. FDA and the pharmaceutical industry along with industry groups will need to seek solutions to these challenges.

Forward & Acknowledgments

Farm Foundation - catalyst for a stronger future

Stewardship of antimicrobial drugs in food producing animals is a complex issue with far-reaching implications for the nation’s consumers, food industry and agricultural production sector. This issue has no geographic boundaries and affects every species of food-producing animals. Stewardship requires the coordination of livestock producers, feed suppliers, veterinarians, pharmaceutical manufacturers and government agencies.

So it was only fitting that Farm Foundation, NFP, an objective organization that works on issues that will shape the future of the nation’s food, agriculture and rural communities, should provide leadership to *Stewardship of Antimicrobial Drug Use in Food-Producing Animals*. Farm Foundation’s strength is its unique ability to bring diverse leaders together to share perspectives and identify options to address complex evolving issues.

Success in addressing the stewardship of antimicrobial drugs is critical to public health, food prices and the future viability of animal agriculture in the United States. Market forces are a major factor driving this issue, with many businesses along the entire food and agricultural value chain—production, supply and retail—taking action to reduce the use of antibiotics in food animal production. The U.S. Food and Drug Administration (FDA) has responded with Guidance for Industry (GFI) #152, #209 and #213, as well as a revised Veterinary Feed Directive (VFD) rule. These policies and rule have significant implications for veterinarians, feed suppliers and livestock producers and pharmaceutical manufacturers. (See GFI#152 at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>)

Early on, it became clear to Farm Foundation that successful implementation of these measures was an important opportunity to demonstrate agriculture’s commitment to good stewardship, as well as the effectiveness of voluntary programs. It was also clear that all stakeholders needed a clear understanding of their roles and responsibilities under the new policies.

Farm Foundation approached FDA with a proposal to host educational workshops across the nation. Involvement by USDA’s Animal and Plant Health Inspection Service (APHIS) was also sought, as APHIS is responsible for animal disease surveillance through the National Animal Health Monitoring System, as well as regulatory approval of vaccines and diagnostics. This public-private partnership was well received and FDA and APHIS committed to participate in the workshops. This partnership was further enhanced by project support from individuals, producer groups, agribusinesses and educational institutions.

Each workshop had two objectives: to help veterinarians, feed suppliers and livestock producers broaden their understanding of the new policies, and to help FDA and APHIS broaden their understanding of the management

challenges the policies create. Twelve workshops were completed between August and October 2015. An additional workshop took place Jan. 16, 2016, as part of the National Western Stock Show in Denver.

As you will see in this report, Farm Foundation's leadership on *Stewardship of Antimicrobial Drug Use in Food-Producing Animals* generated significant impacts while bringing much-needed attention to this important issue.

- The open exchange of information promoted at all the workshops provided producers, feed suppliers and veterinarians with more knowledge of what is required of them. It also provided FDA officials with boots-on-the-ground input on issues that need to be addressed to insure successful implementation.
- The 530 people attending the workshops directly influence the animal health decisions of more than 3,000 producers and 2.6 million animals. In addition, one of the 12 workshops was webcast, drawing 300 viewers.
- Farm Foundation set a cornerstone for future public-private partnerships.

With this project, Farm Foundation again demonstrated its strength—being the catalytic agent that helps public and private decision makers explore options to address industry-wide issues shaping the future.

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Irsik Farms
JBS United
Jennie-O Turkey Store
J.R. Simplot Company
Kautz Farms
Kentucky Veterinary Medical Association
National Pork Board
National Pork Producers Council
National Turkey Federation
National Western Stock Show
North American Meat Institute
North Carolina Farm Bureau
Pew Charitable Trusts
Rose Acre Farms
Texas A&M AgriLife Research
Texas Cattle Feeders Association
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SECTION I – Introduction

The use of antimicrobial drugs in humans and animals has been under increasing scrutiny worldwide as bacteria continue to develop resistance to important drugs. While issues exist in both human and animal health arenas, livestock production has come under fire for use of antibiotics, including drugs that are also used for humans.

Market forces are also at work. Responding to consumer concerns, some retailers and restaurant chains are promoting products produced from animals that are raised without the use of antibiotics. U.S. livestock producers have begun to shift management practices in response to both market demands and recognition of the value of having antimicrobial drugs available to combat disease outbreaks.

Management changes are also resulting from policy changes initiated by the U.S. Food and Drug Administration (FDA) on the use of medically-important antimicrobial drugs in food-producing animals—specifically Guidance for Industry (GFI) #209 and #213, and a revised Veterinary Feed Directive (VFD) rule. With these actions, labels for medically-important antimicrobial drugs will be changed to allow only therapeutic uses, and use of the drugs will require a veterinarian’s order, or direct administration by a veterinarian.

All the veterinary pharmaceutical manufacturers have agreed to the label changes, which are to be completed by Dec. 31, 2016. The revised VFD rule took effect in October 2015, but to date it only applies to a limited number of products—i.e. those that were VFD drugs prior to revision of the VFD rule. Beginning Jan. 1, 2017, the revised VFD rule will apply to all medically-important antimicrobial drugs used in feed. Written authorization from a veterinarian is required before VFD drugs can be purchased and fed to livestock. These changes mean livestock producers will need to have an established relationship with a licensed veterinarian—referred to as a Veterinary Client Patient Relationship (VCPR)—something that is challenging in locales where large-animal veterinarians are in short supply.

To successfully meet the specifications of the revised VFD requires all stakeholders to understand their respective roles and responsibilities. Many large-scale operations may have a veterinarian on staff and be well prepared to adapt to the changes. Smaller producers, however, may not have a VCPR, or understand the management changes that will be required.

Farm Foundation’s leadership

For 83 years, Farm Foundation has served agriculture, the food system and rural communities as a catalyst—an agent of change. The Foundation does not lobby or advocate. The Foundation’s action is its ability to convene diverse stakeholders to identify options to address the complex issues that are and will shape the future of the industry. Farm Foundation addresses issues that impact the entire industry, regardless of locale, species or crop. Equipped with comprehensive, objective information, public and private decision makers can make informed decisions for the future.

This project resulted from concern by the Farm Foundation Board of Trustees that livestock producers, feed suppliers and veterinarians needed access to objective information if they are to successfully adapt to the new FDA policies. Successful adaptation to the policy changes is important to public and animal health. It will help ensure consumer confidence in the food safety, as well as the future viability of animal agriculture in the United States.

As an objective convener, Farm Foundation was well positioned to bring the respective stakeholders together for civil discussions to expand understanding of the issues surrounding the new policies and the management challenges for implementation.

Working with FDA and USDA, Farm Foundation, NFP organized a series of workshops across the nation with two key objectives:

- To provide producers, veterinarians and feed suppliers with comprehensive information about FDA policy changes, and
- To provide federal and state regulators, policymakers and other key stakeholders with information on the management challenges farmers, ranchers, feed suppliers and veterinarians must address to successfully implement the changes.

Twelve workshops took place between August and October 2015. (The National Western Stock Show also invited Farm Foundation to present a workshop as part of the January 2016 Stock Show in Denver on Jan. 16.) This report summarizes the discussions of the 12 workshops, presents findings of a stakeholder survey, and offers next steps needed as the industry continues its work on the stewardship of medically-important antimicrobial drugs in food-producing animals.

SECTION II - Background

In spite of past efforts to reduce the overuse and misuse of these drugs in both humans and animals, antimicrobials usage continues to be a critical problem. In December 2012, FDA issued Guidance for Industry (GFI) #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*. Based on FDA's review of the scientific literature, GFI #209 provided a framework "...for the voluntary adoption of practices to ensure the appropriate or judicious use of medically important (those used in human medicine) antimicrobial drugs in food-producing animals."

In December 2013, FDA issued GFI #213, which laid out a three-year timeline for phasing in the GFI provisions. This guidance provided recommendations for drug manufacturers to voluntarily align product use labels with the framework laid out in GFI #209. All the manufacturers of the specified drugs voluntarily agreed to make the specified changes. Once manufacturers complete these label changes, medically-important antimicrobial drugs can no longer be used for production purposes, and their use in feed or water to treat, control or prevent disease in food animals will require approval from a licensed veterinarian. Compliance with these rules is not voluntary for farmers and ranchers, veterinarians or feed companies.

In addition to the two GFIs, FDA revised its Veterinary Feed Directive (VFD) rule, which outlines the process for authorizing drug use in animal feed. The revised VFD rule now provides veterinarians with a framework for authorizing the use of medically-important antimicrobials administered in livestock feed. Taken as a whole, the actions by FDA and drug manufacturers will:

1. Eliminate the use of medically-important antimicrobial drugs in food-producing animals to enhance growth or to improve feed efficiency;
2. Change the marketing status from a) over-the-counter to VFD for drugs administered through feed, or b) to prescription (Rx) status for drugs administered through water; and
3. Require veterinarians to issue all VFDs within the context of a Veterinarian-Client-Patient-Relationship (VCPR).

FDA and the veterinary pharmaceutical industry are now two years into the three-year process to phase out the use of antibiotics to promote growth and to more closely regulate therapeutic uses. Full implementation of FDA's GFIs and VFD rule by December 2016 will significantly change the way medically-important antibiotics are used in animal agriculture. Once the changes are fully implemented, it will be illegal to use these medically-important antibiotics for production enhancement purposes, and farmers and ranchers will need to obtain authorization from a licensed veterinarian to use the drugs in feed for prevention, control or treatment of a specifically-identified disease.

The success of this effort, for both public health and the economic health of animal agriculture, hinges on the capacity of veterinarians to provide the additional oversight, and on the ability of producers and feed suppliers to develop the relationships and access the information they need to adjust their respective management practices. The goal of Farm Foundation's Project, *Stewardship of Antimicrobial Drug Use in Food-Producing Animals*, is to help provide the comprehensive, objective information producers, feed suppliers and veterinarians need to implement the policy changes, and to help federal regulators, Extension specialists, researchers at Land Grant universities, faculty at colleges of veterinary medicine, farm organizations and state veterinary regulators to understand the management challenges required. The measure of success is smooth implementation of the new drug use policies, leading to improved public health with a minimum of disruption to the food and agricultural value chain.

SECTION III - Farm Foundation Approach and Methodology

Use of regional workshops

The first goal of the project was to provide detailed information to livestock producers, feed suppliers and veterinarians on new policies from the U.S. Food and Drug Administration (FDA), regarding use of medically-important antimicrobial drugs in food-producing animals. Specifically, those policies are FDA's Guidance for Industry (GFI) #209 and #213 and the revised Veterinary Feed Directive (VFD) rule, as well as the role of the USDA's Animal Plant Health Protection Service (APHIS) in addressing antimicrobial resistance.

A second goal was to provide stakeholders who have important roles in implementing these policy changes with feedback on management challenges that face farmers, ranchers, veterinarians and feed companies. These stakeholders include not only officials of FDA and APHIS, but Extension specialists and researchers in the Land Grant university system, colleges of veterinary medicine, farm organizations, the feed supply industry and state veterinary regulators, as well as animal producers.

For this project, Farm Foundation used a regional workshop model, conducting 12 events across the nation. (Farm Foundation previously used this workshop methodology in the collection of stakeholder input on conservation policies.) Regional workshop audiences were diverse in both locales and production characteristics, i.e. size or type of operation, access to veterinary services or access to other support systems.

The target audiences for the workshops were livestock producers, veterinarians and feed suppliers. Also targeted were the staff of state and federal agencies, colleges of veterinary medicine, state departments of agriculture, and Cooperative Extension, who through their participation could gain insights into the changes needed to meet the new policies.

Each program featured a senior staff person from FDA to explain the specifics of the new policies, and a senior staff person from APHIS to discuss the role of USDA in surveillance, research and outreach. Local stakeholders—a livestock producer, a veterinarian and a feed supplier—then provided regional perspectives on implementation of the

new policies. Breakout groups were designed for workshop participants to drill into specific issues. The workshops concluded with discussion with the federal agency representatives and participants.

A total of 530 people attended the workshops. The 12 locations were Raleigh, NC; Dover, DE; Cobleskill, NY; Hanceville, AL; Ames, IA; Mesa, AZ; Denver, CO; Amarillo, TX; Twin Falls, ID; Rapid City, SD; Davis, CA; and Lexington, KY. The Denver workshop was webcast live and archived for later viewing; to date 300 people have viewed the webcast.

The workshops were facilitated by the Adayana Agribusiness Group. In advance of each workshop, a press release was sent to an exhaustive list of associations, organizations, universities, producers, and news outlets. Both the press release and the online workshop registration routed registrants to a pre-meeting online survey with questions designed to gauge their awareness, perceptions and the actions they have already taken to prepare for these changes. Then, a brief overview of the changes was presented, and participants were asked to outline any concerns, unmet needs, or challenges they had in being compliant.

This online survey was open to all interested stakeholders, whether or not they attended the workshops. Between July 30, 2015, and Oct. 22, 2015, a total of 340 surveys were initiated and 264 were 100% completed. Veterinarians comprised 25% of respondents followed by 19% producers, 18% university/extension, 10% government health officials, 7% associations, 5% feed suppliers, 5% animal health suppliers, 3% nutritionists, and 8% others. (Chart 1) Nearly all species were represented in the survey, with cow/calf operations making up 30%, dairy 15%, pork 12%, feedlots 11%, poultry 9%, all species 9%, stocker/backgrounder 5%, other species 5%, small ruminants 3%, and aquaculture 1%.

Chart 1: Participants' and Areas of Interest

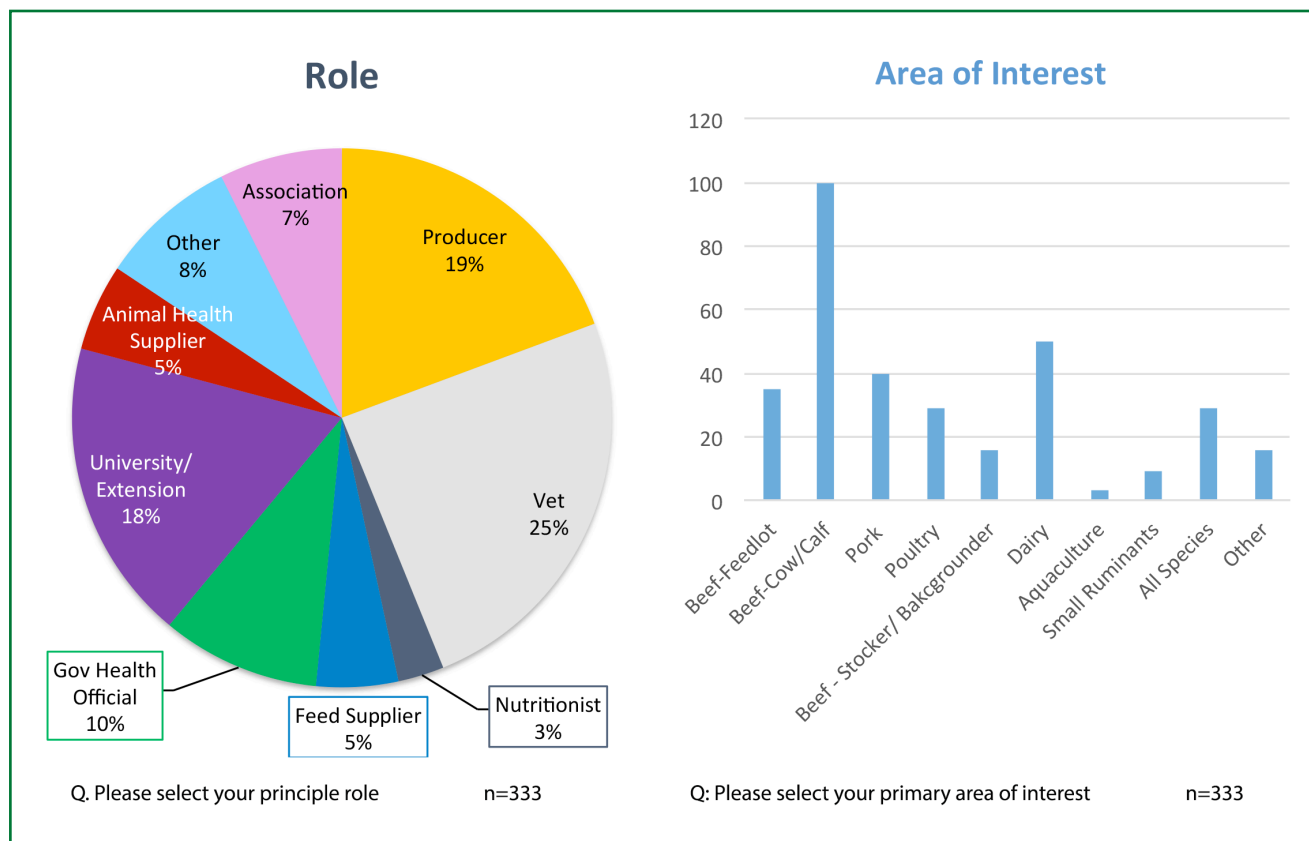
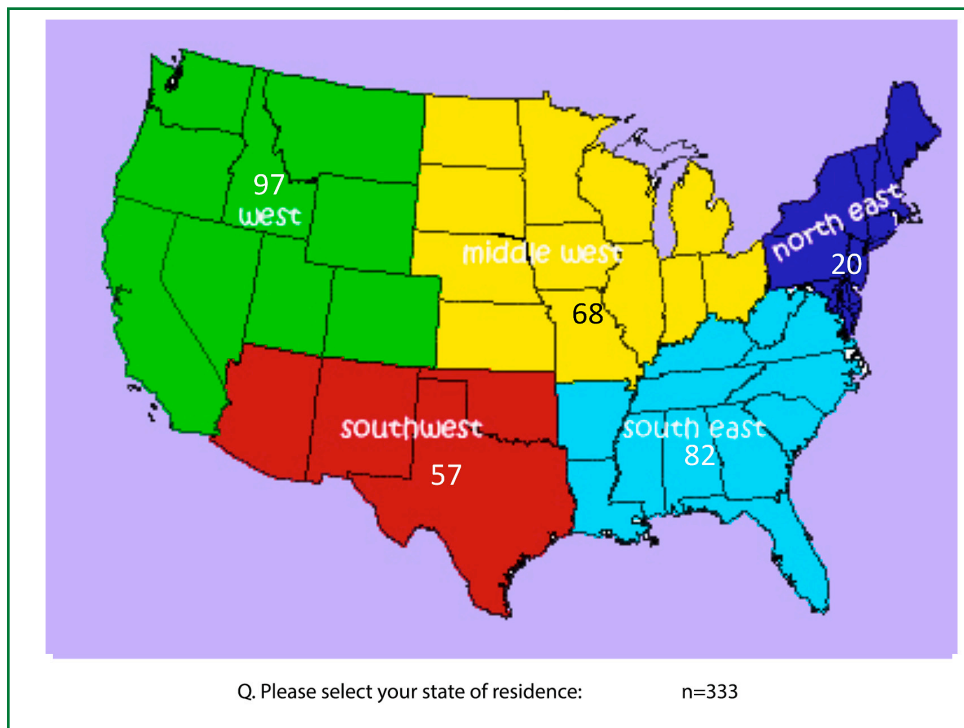


Chart 2: Residence of Respondents



During the workshop, live-feed, in-meeting polling was used to gather anonymous audience feedback. About half the workshop attendees participated in the in-workshop polling. Findings from the workshop discussions and the online survey are compiled in this report, summarizing producer concerns and needs, questions concerning policy interpretations and implementation, and future educational needs. This report will be highlighted at a national summit Jan. 20-21, 2016, in Washington, D.C. Policy, education and economic issues related to antimicrobial stewardship will be the focus of the summit, which is being presented in collaboration with the Association of Public and Land-grant Universities, the Association of American Veterinary Medicine Colleges and USDA's Economic Research Service.

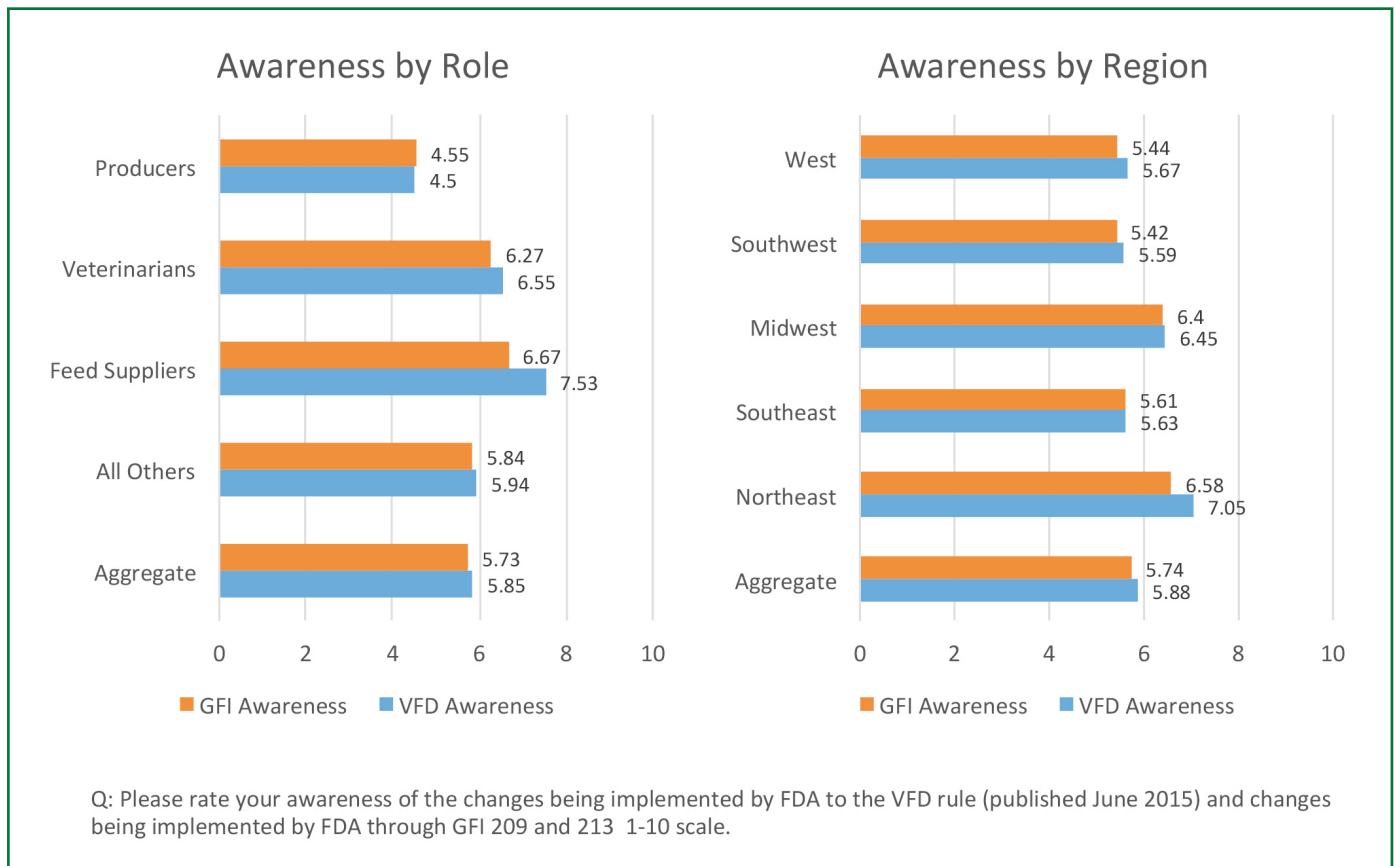
Section IV – FINDINGS

Discussions at the 12 regional workshops and the online survey results reveal the challenges that face farmers, ranchers, veterinarians and feed companies in implementing the policy changes in FDA's GFIs and VFD rule. Overall the findings suggest that while the necessary adjustments will require significant effort for some parts of the system, changes are already well underway, and FDA's goal of moving food animal production to more judicious use of antibiotics is an achievable one.

Awareness and Education

One of the most critical challenges for the successful implementation of the GFIs and VFD rule is the low level of awareness of the impending regulatory changes. The gap in awareness exists across value chain roles and regions. (Chart 3) Overall, survey respondents ranked their awareness of the GFI at 5.7 and VFD at 5.8 on a scale of 1 to 10. Individual rankings ranged from 1 to 10.

Chart 3: Level of Awareness



Feed suppliers are the most familiar with both the GFIs and the VFD, likely because they are already dealing with VFD feeds. The feed suppliers’ levels of awareness were 6.7 for the GFIs and 7.5 for the VFD, again on a scale of 1 to 10. The average level of awareness for producers was 4.55 out of 10; veterinarians rated their awareness as 6.27 out of 10. Regionally, awareness was highest in the Northeast at 6.58 for the GFIs and 7.05 for the revised VFD.

Evidence about understanding of the GFIs and VFD rule indicates the importance of information and education. Less than half of workshop participants were clear about their responsibilities under the VFD rule, however 80% of the online survey respondents indicated that they understood the GFIs after being provided with information about the content.

When asked to identify the greatest barriers to compliance, online survey participants ranked the lack of education at the top of the list. The most common source of information and education is the internet. (Chart 4) Although many producers see their veterinarian as a go-to resource, many veterinarians are not aware of the impending changes and have questions themselves. Discussion in the workshops pinpointed the lack of a responsible party delivering a clear, comprehensive and consistent educational message. When asked to describe the impact of GFIs and VFD rule on their day-to-day business, the second most frequently mentioned response of producers and veterinarians was a need for education (19%). (Chart 5)

Chart 4: Primary Education Source

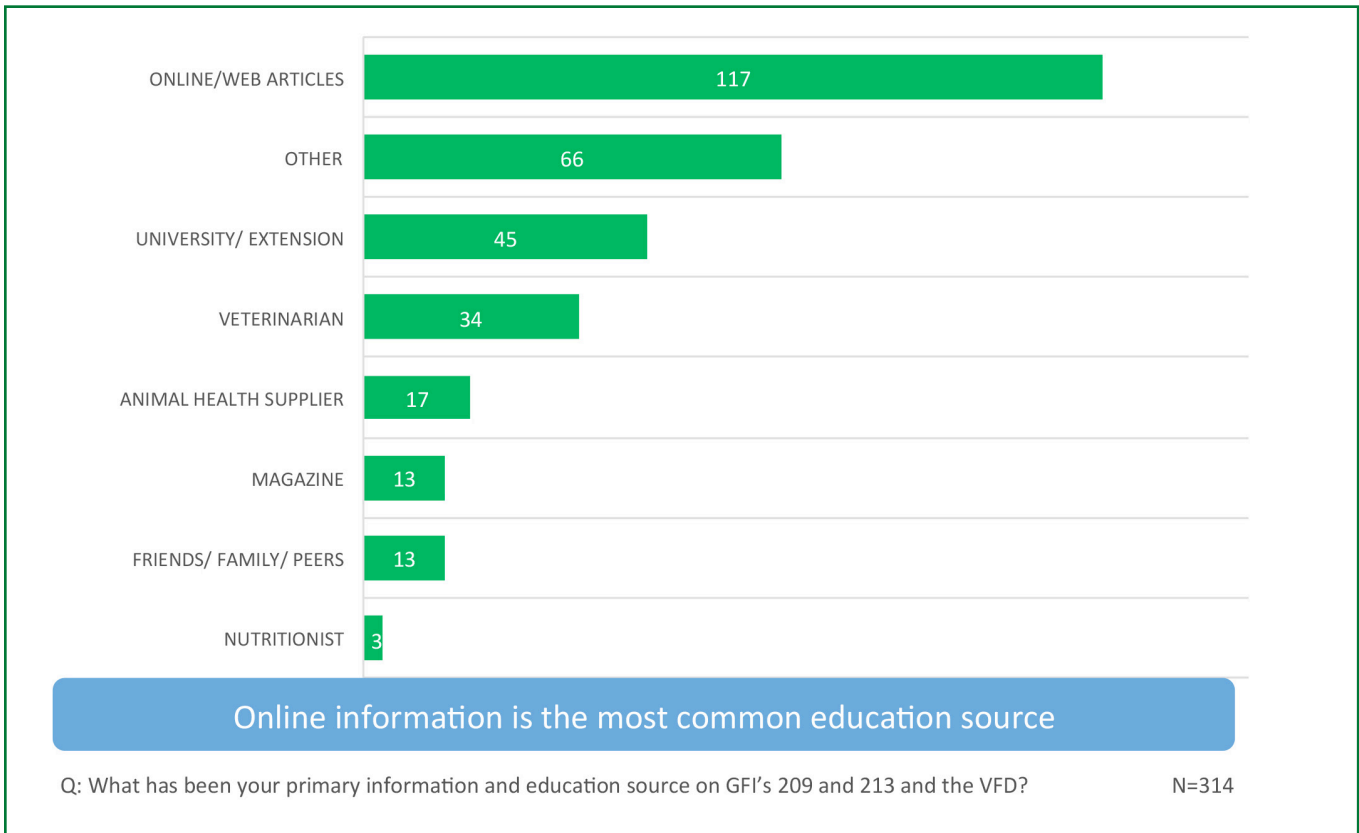
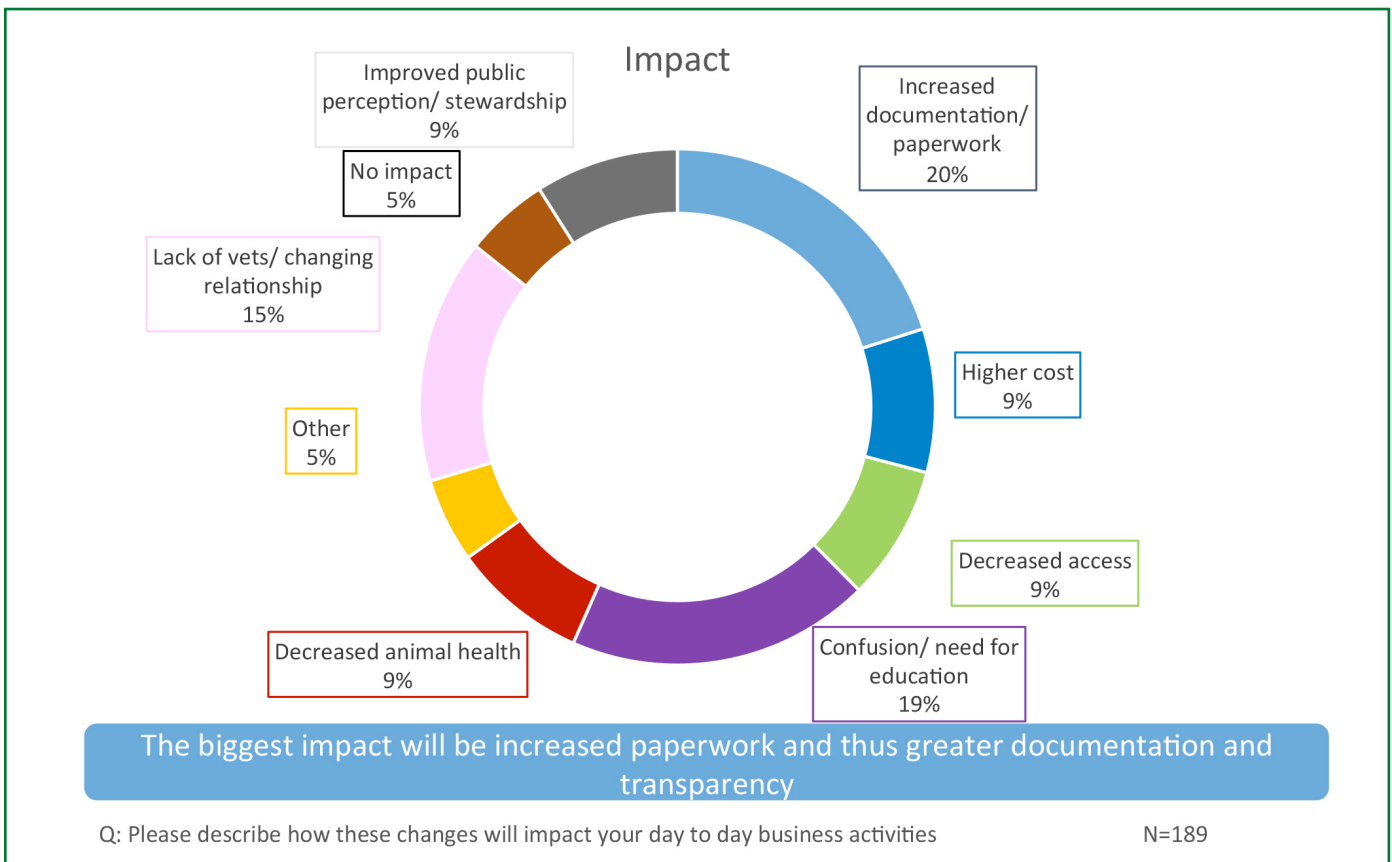


Chart 5: Impact on Day-to-Day Business Activities



Impacts on the Livestock Industry

When asked about the overall impact of the GFIs and VFD rule on the livestock industry, just under half of the online survey respondents anticipated a negative impact, while just over half expected either no impact or a positive one. (Chart 6) Regionally, respondents in the Northeast viewed impacts most positively, while respondents in the Southwest had the most negative view. When asked to describe industry impacts, survey respondents listed improved public perception and better livestock management as the top two impacts. (Chart 7) These were followed by increased costs and concerns about animal health, including access to antibiotics and veterinary services. Among farmers and ranchers, increased costs and additional paperwork are seen as the greatest impacts.

Chart 6: Regional Impacts on the Livestock Industry

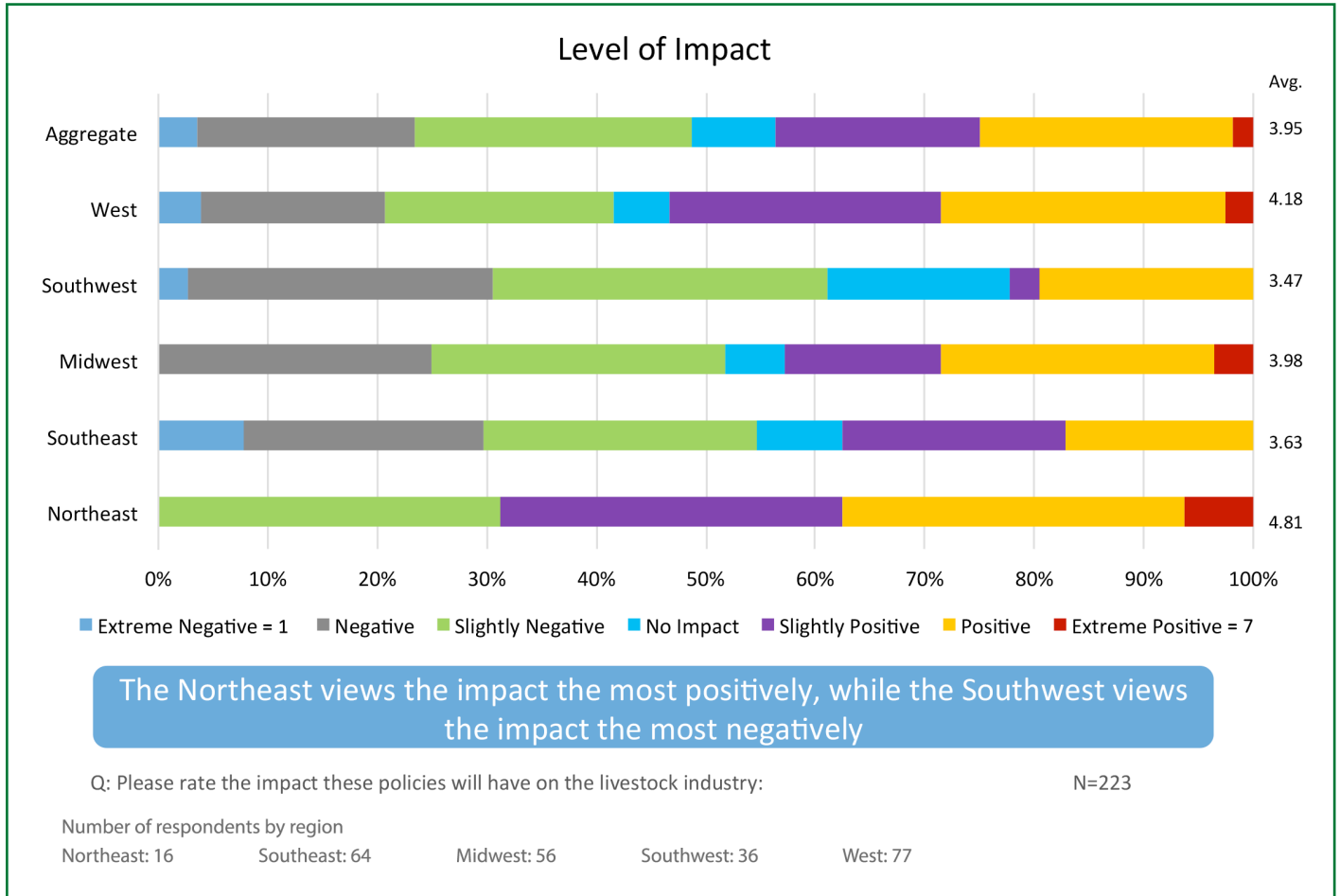
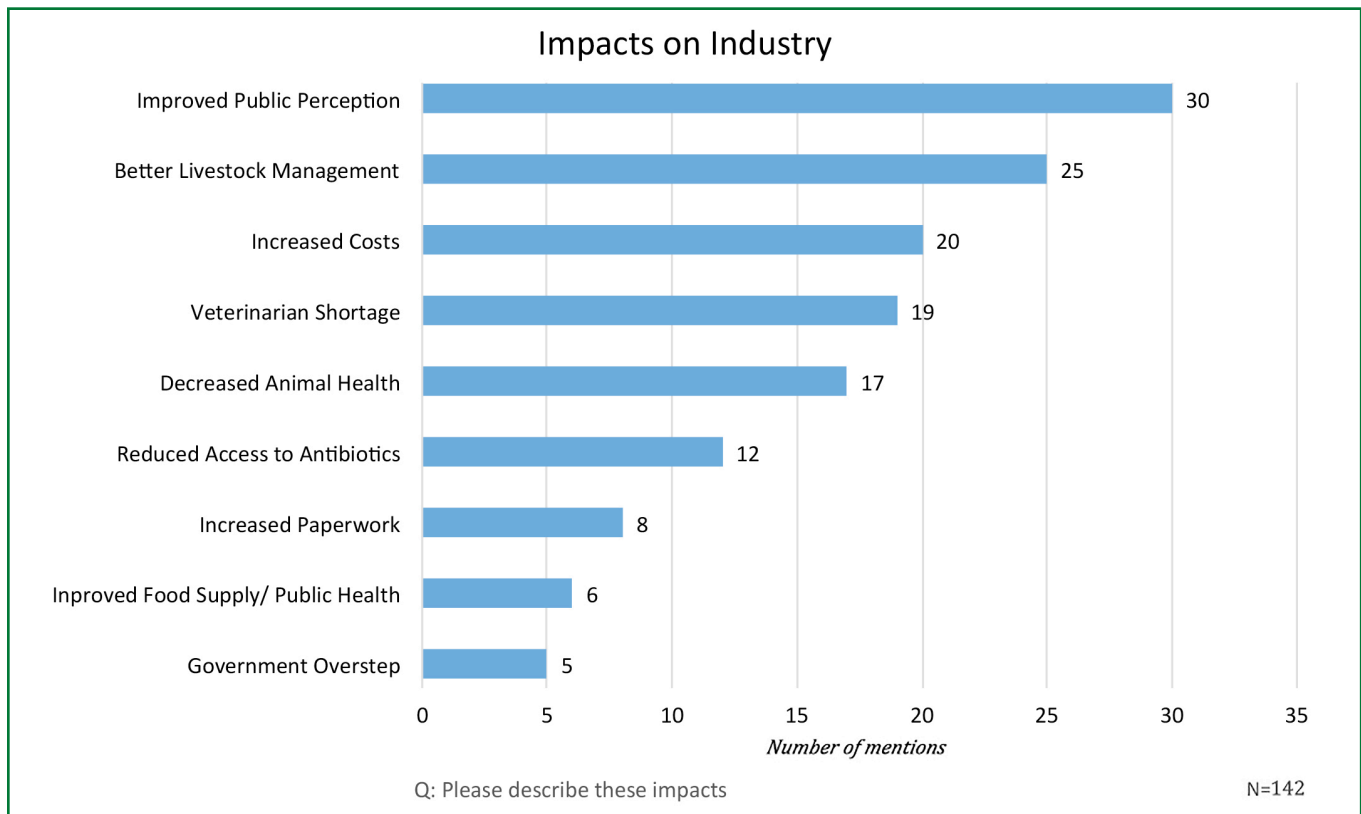


Chart 7: Impact on Livestock Industry



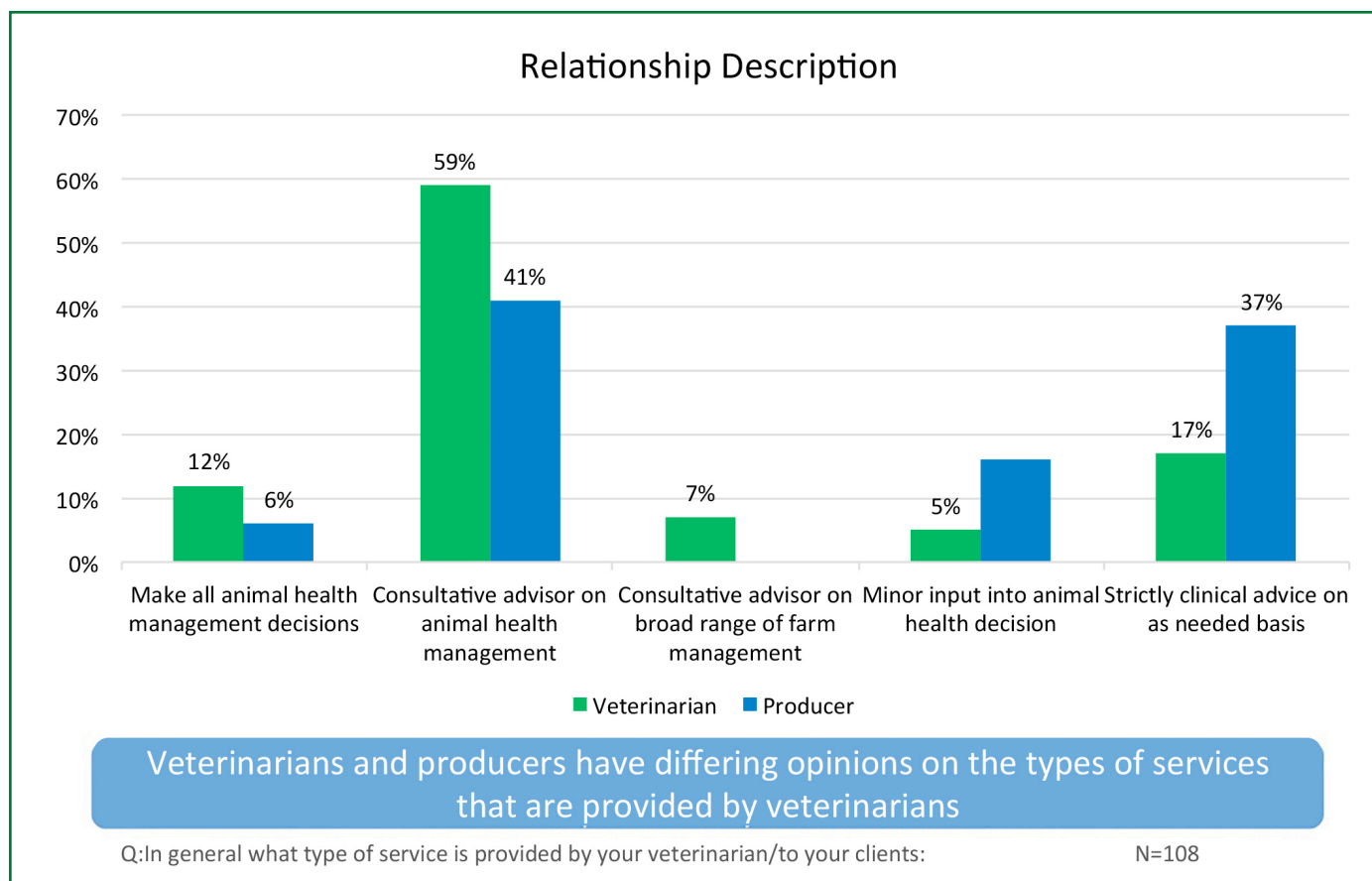
Changes in federal policy on the use of medically-important antibiotics in food animals are not occurring in a vacuum. The market has been driving changes as more restaurant chains and retailers, including McDonalds, Subway, Papa Johns, Chick-fil-A and Walmart, have announced new policies on the use of antibiotics in their supply chains. Large integrated meat producers, including Tysons, Perdue and Smithfield, have also committed to the judicious use of antibiotics in their operations. These market-driven changes have already led to many producers, especially those that are part of integrated production systems and supply chains, to eliminate the use of antibiotics for production enhancement purposes. These integrated swine and poultry operations will see less impact since they already have procedures and processes in place, sophisticated record keeping systems, and on-staff veterinarians—and thus VCPRs. Integrators concerns generally revolve around making necessary adjustments to internal record keeping systems, and the transfer of VFDs from one feed mill to another.

However, many farmers and ranchers, especially those raising beef cattle and small ruminants such as sheep and goats, operate independently from large integrated supply chains. These producers will face greater impacts than those who are part of an integrated system. Some small ruminant and other “minor species,” such as deer, elk, bison or honey bees, along with turkey producers, see reduced access to antibiotics as a potentially large impact to their operations. A limited number of products are currently approved for specific use for these minor species.

Many of these same producers lack an established relationship with a veterinarian and may struggle to establish a VCPR. In some areas, shortages of veterinarians will be a barrier to establishing a VCPR. Difficulty in accessing veterinary services is not simply the result of an overall shortage of veterinarians, but of veterinarians who treat food-producing animals. Workshop participants identified issues with access to veterinary services not only in remote areas, but also in urban fringe areas where many veterinary practices are limited to companion animals. Additionally, as veterinary practices have become increasingly specialized in treating a single species, e.g. bovine or swine, finding a veterinarian to treat small ruminants and other “minor species” is a challenge for some producers.

One of the challenges facing farmers and veterinarians as they work to establish VCPRs is a fundamental difference in how they see their roles in managing animal health. (Chart 8) Nearly 80% of veterinarians see themselves as an advisor with a significant role in making animal health and/or management decisions. However, more than half of farmers and ranchers see the role of the veterinarian either as purely clinical, or as a limited advisor with minimal input into animal health decisions on their operation. The requirement for a VCPR is likely to change and strengthen relationships between many producers and their veterinarians. As a result veterinarians are likely to play an increasing role in a broader range of animal health decisions on farms and ranches. This may mean expanded business for veterinarians as producers who currently lack a veterinarian are motivated to establish a VCPR.

Chart 8: Veterinary/Producer Relationship



Another sector identified as facing challenges is stock show exhibitors—specifically FFA and 4-H members and clubs. The show animal breeding and supplier segments are likely to have a VCPR, or have the resources to establish one. There is concern, however, about the youth segment of stock show exhibitors. This multi-species segment—whose show animals might include cattle, swine, goats or poultry—often rely on club leaders, agriculture teachers or Cooperative Extension Agents for direction on animal care and disease prevention/treatment. Depending on ownership of the animals, the previous practice may have been for a club, school or individual owner to purchase medicated feed or water products. The FDA’s GFIs and VFD rule require the caretaker—whether it be the club, school or individual owner—to establish and maintain a VCPR. Workshop participants raised the need for outreach and education to this important segment of exhibitors. Participation of food-animal exhibitors in county and state fairs, as well as regional and national livestock shows, may be impacted.

Under the revised VFD rule, veterinarians will take on increased responsibility and liability as they will be required to maintain the original copy of each VFD. For veterinary practices, this will mean investments in new record keeping systems and increased insurance costs.

The GFIs and changes in the VFD rule will also drive important changes in the relationship between veterinarians and feed suppliers. Under the new system, veterinarians will be responsible for estimating the number of animals to receive the medicated feed. In the past the calculations of the amount of feed have generally been performed by nutritionists or the feed manufacturer. As a result, veterinarians will now need to understand ration formulations, and develop closer relationships with feed manufacturers and suppliers.

Feed suppliers will be on the front lines of this change. They may experience the most pressure from these changes when farmers and ranchers who are not aware of the GFIs and revised VFD rule go to purchase products at a local feed store after Jan. 1, 2017, and discover they now need a veterinarian's order.

As a group, feed suppliers had the highest level of awareness about impending changes in the regulation of antibiotic use. However, feed industry participants in the online survey and workshops were generally involved in the feed manufacturing and bulk feed business. Manufacturers and bulk distributors are already accustomed to dealing with VFDs under previous rules. However, changes in the rules and record keeping requirements will require adjustments. The increased number of products now falling under the 2015 VFD rule, combined with separate expiration dates for products and VFDs, will increase the complexity of managing inventories.

Many small producers now purchase medicated feeds in bags from an agricultural retailer for whom feed is only one part of the business. These retailers will now be required to ensure that the purchaser has a valid VFD for medicated feeds or a valid prescription for water soluble products. Retailers will also be required to retain a copy of each VFD.

Many of these retailers will need to develop new record keeping systems and train their retail staff. Anecdotal evidence suggests that feed sales are not a profit center for some retailers, yet they continue to sell feed as a service to customers. If some of these retailers decide that the costs of handling medicated feeds are too great, they may no longer carry these products. If this occurs, small producers who have relied on the local agricultural retailer will have more difficulty accessing medicated feeds and water-soluble products.

While market pressures have already put much of the livestock and poultry industries on a path toward ending the use of antibiotics for growth enhancement, FDA's changes in the rules governing the use of medically-important antibiotics will require substantial changes in management and relationships for many producers, veterinarians and feed suppliers. How well prepared are they for implementation of these changes by the end of 2016? Some are clearly well prepared, yet more than 30% of producers and nearly 20% of other stakeholders—primarily veterinarians and feed suppliers—responding to the online survey indicated they had not yet taken any steps. (Chart 9)

Chart 9: Preparation for Implementation of VFD – Producers

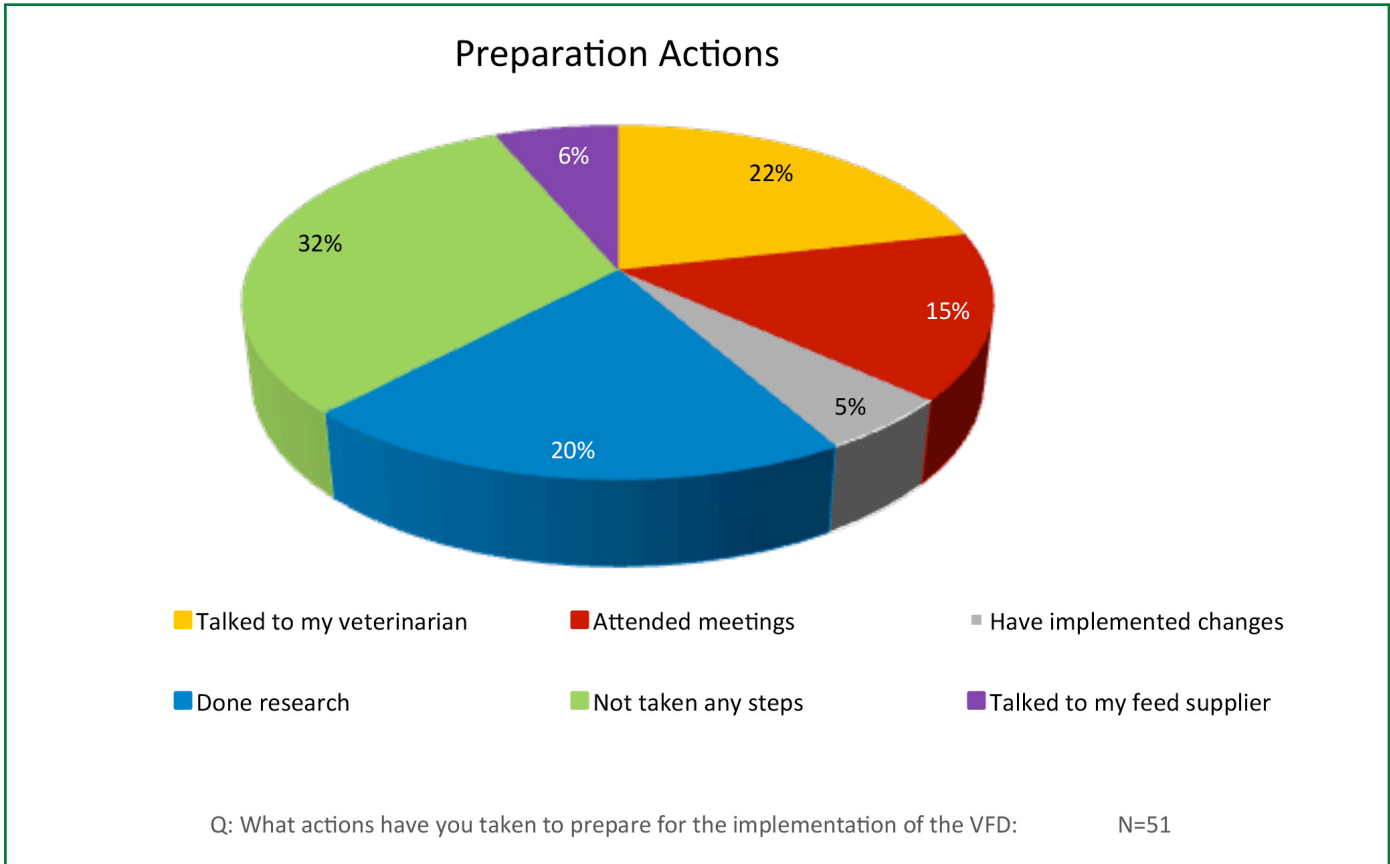
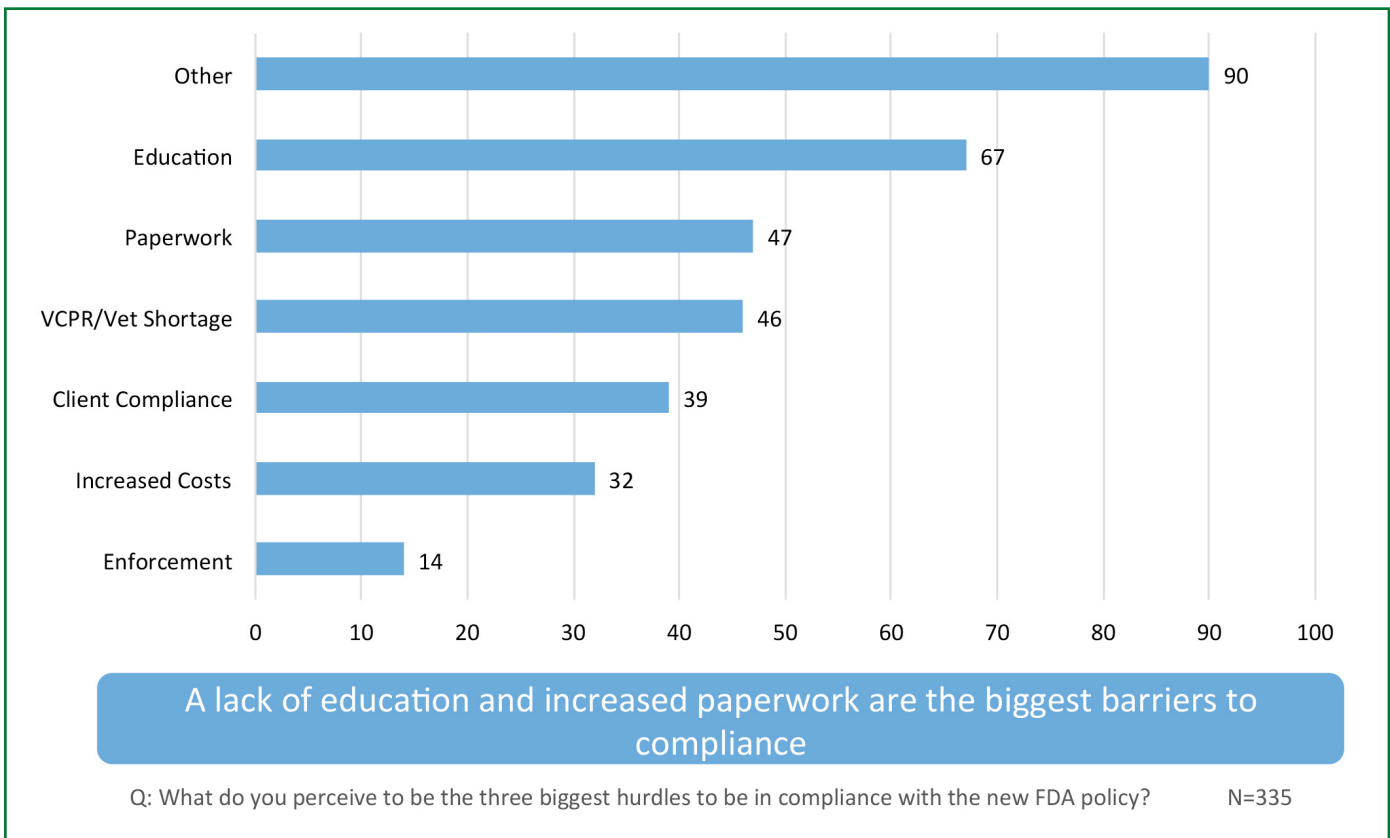


Chart 10: Hurdles to Compliance



Section V – NEXT STEPS

While farmers, ranchers, veterinarians and feed companies have made progress toward the successful implementation of FDA’s GFIs and revised VFD rule, much remains to be done. Even after Dec. 31, 2016, stewardship of antimicrobial drugs will require an ongoing effort. Based on the findings from Farm Foundation’s 12 regional workshops, here are some immediate next steps that will help with implementation of the policies in the GFIs and VFD, and build a framework to support the ongoing stewardship of antimicrobial drugs.

Education and Outreach

The online survey and workshops identified a lack of awareness of the changes required by the GFIs and the VFD rule, and the need for education as critical barriers to successful implementation. (Chart 10) Despite significant efforts by farm, industry and professional organizations, federal and state agencies, cooperative extension and agricultural media to inform and educate farmers, ranchers, veterinarians and feed suppliers about the impending changes, a significant awareness gap remains, especially among small and independent producers. Reaching these producers will be a challenge, but it is of critical importance. All of the above stakeholders have a role to play in reaching small producers, but Cooperative Extension, with its responsibility for public education, and feed suppliers, who interact directly with farmers and ranchers on a daily basis, are especially important in closing the awareness gap and providing educational materials.

Continuing Dialogue Between the Industry and State and Federal Regulators

Workshop participants emphasized the importance of direct interaction with FDA and USDA officials in their comments about the value of the workshops. One of the results of this interaction was the development of a list of unanswered questions for FDA (see Appendix E). The agency is working to answer these questions, which will help lead to the resolution of many implementation issues (GFI #120). A continuation of this kind of dialogue is critical not only to successful implementation of the GFIs and VFD, but to help support a continuing process of stewardship. The commitment of state and federal regulators to dialogue is clear, but their resources are limited. Ensuring that this dialogue continues will also require the commitment of private and non-profit sectors.

Focus on Access to Veterinary Services and the Supply of Food-Animal Veterinarians

In the near term, state and federal officials, working with colleges of veterinary medicine and professional organizations of veterinarians, need to move quickly to develop options to provide access to veterinary services to small producers in underserved areas.

Long-term, part of the solution will be efforts by colleges of veterinary medicine to increase the number of veterinarians with food-animal practices. However, increasing the number of trained veterinarians alone will not solve this problem; these veterinarians also need to be able to establish an economically-sustainable practice. Veterinarians participating in the workshops emphasized the difficulties in building a successful practice, especially in areas where producers have generally viewed the veterinarian as a clinician who is called only when there is a need for critical care. The requirement that producers establish a VCPR to access antibiotics under the VFD may lead to the development of more viable practices in some areas. There may also be opportunities for other stakeholders in the system—including feed suppliers, Cooperative Extension and state regulatory authorities—to explore new models of delivering veterinary services in underserved areas.

Meeting the Challenge of Minor Species

Successful stewardship of antimicrobial drugs in food animals requires the commitment of the entire food-animal sector and all stakeholders—not just major commercial producers of poultry swine and cattle. The regional workshops made it clear that some of the most difficult challenges will be meeting the needs of producers raising other species, including small ruminants, deer, elk, bison, fish, honey bees and other so-called “minor species.” Few products are approved for use in these species, which risk becoming “orphan indications” due to the limited market size. FDA and the veterinary pharmaceutical industry along with industry groups will need to seek solutions to these challenges.

Section VI – Appendix

A. Sample Workshop Agenda

Stewardship of Medically-Important Antimicrobial Drug Use in Food Animals: Understanding the FDA Guidances and Veterinary Feed Directive

*Bailey Center Auditorium, Wallace State Community College - Hanceville, AL
Aug. 25, 2015*

- 8:30 a.m. Welcome**
*Sheldon Jones, Farm Foundation, NFP
Kevin Ochsner, Adayana Agribusiness Group, Meeting Facilitator*
- 8:45 a.m. Opening Address**
*U.S. FDA: Craig Lewis, DVM, MPH
USDA APHIS: Larry Granger, DVM
Survey results: Kevin Ochsner
Regional livestock producer: Eric Smith
Regional veterinarian: M. Gatz Riddell, DVM
Regional feed industry representative: Stephen Donaldson, Alabama Farmers Cooperative
Group Discussion*
- 11:45 a.m. Breakout Group Instructions and Assignments**
- 12:00 p.m. Lunch**
- 12:30 p.m. Breakout Group Discussions**
Identify barriers to and proposed solutions for implementation of the Guidances.
- 2:45 p.m. Breakout Groups Report Back**
Full group discussion
- 3:45 p.m. Overview of outcomes & next steps of Farm Foundation initiative**
- 4:00 p.m. Adjourn**

B. List of Workshop Speakers

Workshop Speakers

Raleigh, NC – August 14, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: David Dargatz, DVM

Producer: Terry Coffey, DVM Smithfield Foods

Veterinarian: Randy Jones, DVM, Livestock Veterinary Services

Feed Industry: David Funderburke, Ph.D., Cape Fear Consulting

Dover, DE – August 18, 2015:

FDA: Bill Flynn, DVM, MS

USDA APHIS: Chuck Fossler, DVM, Ph.D.

Producer: Sara Steinlage, DVM, MAM, Dipl. ACPV, Elanco

Veterinarian: Craig Shultz, DVM, Pennsylvania State Veterinarian

Cobleskill, NY – August 20, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: Chuck Fossler, DVM, Ph.D.

Producer: Phil Trowbridge, Trowbridge Farms

Veterinarian: Carie Telgen, DVM, Battenkill Veterinary Bovine

Feed Industry: Andy Dugan, Gold Star Feed & Grain

Hanceville, AL – August 25, 2015:

FDA: Craig Lewis, DVM, MPH, DAVPM

USDA APHIS: Larry Granger, DVM

Producer: Eric Smith

Veterinarian: M. Gatz Riddell, DVM, American Association of Bovine Practitioners

Feed Industry: Stephen Donaldson, Alabama Farmers Cooperative

Mesa, AZ – September 9, 2015:

FDA: Bill Flynn, DVM, MS

USDA APHIS: Larry Granger, DVM

Producer: Paul Rovey, Rovey Dairy

Producer: Job Luque, Five Rivers Feeding

Veterinarian: Jim Lytle, DVM

Feed Industry: Billy Thompson, Maid Rite Feeds

Amarillo, TX – September 11, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: Kathe Bjork, DVM, MSPH, Ph.D.

Producer: Shelby Horn, Great Plains Cattle Feeders

Veterinarian: Thomas Portillo, DVM, Friona Industries

Feed Industry: Brice Tabor, MS, Hi-Pro Feeds

Ames, IA – September 16, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: Larry Granger, DVM

Producer: Gene Gourley, SGE Enterprises

Veterinarian: Josh Ellingson, DVM, AMVC Management Services

Feed Industry: David Kier, DFS Animal Nutrition

Denver, CO – September 28, 2015:

FDA: Craig Lewis, DVM, MPH

USDA APHIS: Larry Granger, DVM

Producer: Steve Irsik, Irsik Farms

Veterinarian: Del Miles, DVM, MS, Veterinary Research & Consulting Services

Feed Industry: Nathan Hubbard, Agfinity

Davis, CA – October 6, 2015:

FDA: Craig Lewis, DVM, MPH

USDA APHIS: Kathe Bjork, DVM, MSPH, Ph.D.

Producer: Chuck Ahlem, Hilmar Farms

Producer: Bill Mattos, California Poultry Federation

Veterinarian: Stuart Hall, DVM, Feedlot Health Management Services

Feed Industry: Marit Arana, Ph.D., A.L. Gilbert Co., and Farmers Warehouse

Dr. Annette Jones, DVM, California State Veterinarian

Rapid City, SD – October 13, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: Larry Granger, DVM

Producer: Adam Schuchhardt, Intertribal Agriculture Council

Veterinarian: Christopher Chase, DVM

Feed Industry: Nathan Hubbard, Agfinity

Twin Falls, ID – October 15, 2015:

FDA: Mike Murphy, DVM, JD, Ph.D.

USDA APHIS: Larry Granger, DVM

Producer: Jared Brackett

Veterinarian: Randall Raymond, DVM, Simplot

Feed Industry: Marty Short, PAS, Intermountain Farmers Association

Lexington, KY – October 22, 2015:

FDA: Bill Flynn, DVM, MS

USDA APHIS: Chuck Fossler, DVM, Ph.D.

Producer: Dan Wilson, DVM, Rose Acre Farms

Producer: Todd Worley, Worley Ranch

Veterinarian: Fred Gingrich, DVM, Country Roads Veterinary Services

Feed Industry: Scott Ringger, JBS United

C. Handouts and links

U.S. Food and Drug Administration: Guidance for Industry #120 *Veterinary Feed Directive Regulation Questions and Answers*, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>

U.S. Food and Drug Administration: Guidance for Industry #152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern*, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>

U.S. Food and Drug Administration: Guidance for Industry #209 *“The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals”*
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>

U.S. Food and Drug Administration: Guidance for Industry #213 *“New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food”*
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>

U.S. Food and Drug Administration: Veterinary Feed Directive
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

U.S. Food and Drug Administration, Veterinary Feed Directive (VFD) Brochures:
VFD Producer Requirements
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455413.htm>

VFD Requirements for Veterinarians
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455416.htm>

VFD Requirements for Distributors who manufacture VFD Feed
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455414.htm>

VFD Requirements for Distributors who do not manufacture VFD Feed
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455415.htm>

VFD Requirements for Veterinarians--For Veterinary Students
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455417.htm>

USDA: USDA Antimicrobial Resistance Action Plan
<http://www.usda.gov/documents/usda-antimicrobial-resistance-action-plan.pdf>

Animal Health Institute: FDA Guidance 209, 213 and VFD Educational Material
<http://www.ahi.org/issues-advocacy/animal-antibiotics/fda-guidance-209-educational-material/>

Feedstuffs: VFD Central
<http://feedstuffs.com/vfd.aspx>

Bovine Veterinarian: VFD Newsletter
<http://www.bovinevetonline.com/vfd-newsletter>

North Dakota State University Extension: Understanding the Veterinary Feed Directive
<https://www.ag.ndsu.edu/pubs/ansci/livestoc/v1719.pdf>

D. Online Survey Questions

Online Survey Questions

In advance of each workshop, a press release was sent to an exhaustive list of associations, organizations, universities, producers, and news outlets. Both the press release and the online workshop registration routed registrants to a pre-meeting online survey with questions designed to gauge their awareness, perceptions and the actions they have already taken to prepare for these changes. Then, a brief overview of the changes was presented, and participants were asked to outline any concerns, unmet needs, or challenges they had in being compliant. This online survey was open to all potential interested stakeholders, whether or not they attended the workshops. Between July 30, 2015, and Oct. 22, 2015, a total of 340 surveys were initiated and 264 were 100% completed. Following are the questions in the online survey:

Q1 Thank you for your interest in the changes being implemented to the judicious use of medically-important antimicrobial drugs in food-producing animals. We hope you plan to attend one of the 12 regional workshops. However, we encourage livestock producers, feed suppliers and veterinarians to provide their input to the survey--whether or not you attend a workshop.

The purpose of this survey is to gauge your awareness of the changes being put in place by FDA Guidance for Industry (GFI) #209 and #213, as well as the revised Veterinary Feed Directive (VFD) rule published in June 2015. We are also interested in learning more about the potential implications of these changes. Survey results will only be gathered and reported in the aggregate. Survey results will be shared with workshop participants. We appreciate your time and input on this important industry matter.

Q2 Please select your state of residence: *A listing of the 50 states was provided for response.*

Q3 Please select your principal role:

- Producer
- Veterinarian
- Nutritionist
- Feed Supplier
- Government Health Official
- University/Extension
- Animal Health Supplier
- Other _____

Q4 Please select your primary area of interest:

- Beef - feedlot
- Beef - cow/calf
- Beef - stocker/backgrounder
- Pork
- Poultry
- Dairy
- Aquaculture
- Other _____

Q5 Please rate your awareness of the changes being implemented by FDA through GFI #209 and #213 on a scale of 1 to 10, where 1 = not at all aware or never heard of them and 10 = fully aware of all details: *A 1 to 10 scale was provided.*

Q6 Please rate your awareness of the changes being implemented by FDA to the revised Veterinary Feed Directive rule (published June 2015) on a scale of 1 to 10, where 1 = not at all aware or never heard of it and 10 = fully aware of all details: *A 1 to 10 scale was provided.*

Q7 What has been your primary information and education source on GFI's 209 & 213 and the VFD:

- Veterinarian
- Feed Supplier
- Nutritionist
- University/Extension
- Magazine
- Online/Web Articles
- Friends/Family/Peers
- Animal Health Supplier
- Other _____

Q8 From your perspective, please rate the impact these policies will have on the livestock industry:

- 1 - Extreme Negative
- 2 - Negative
- 3 - Slight Negative
- 4 - No Impact
- 5 - Slight Positive
- 6 - Positive
- 7 - Extreme Positive

Q9 Please describe these impacts:

Q10 Please describe the how these changes will impact your day to day business activities:

Impact 1 _____

Impact 2 _____

Impact 3 _____

Q11 Please select your level of agreement with the following statements in relation to Guidances 209 and 213 and the Veterinary Feed Directive rule:

I will have decreased access to the antibiotics I need

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

I will have increased paperwork

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

It will increase costs of veterinary care

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

It will increase my cost of production

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

It will cause me to make significant changes in my management practices

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

| | | | | | |
|--|-------------------|----------|----------------------------|-------|----------------|
| Public perception of my operations will be improved | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
| There will be an increase in sub-clinical disease | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
| It will increase the amount of antibiotics used to treat disease | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
| Overall use of antibiotics will decrease on my operation | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
| Antibiotics will be used more judiciously on my operation | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |
| I feel positive about taking these steps in my operation | Strongly Disagree | Disagree | Neither Agree nor Disagree | Agree | Strongly Agree |

Q12 Please rank the following implications from implementing these changes in terms of impact to your business, with 1 being the most impactful and 7 the least impactful (drag and drop):

- _____ Increased paperwork
- _____ Reduced sales of total antibiotics
- _____ Improved public perception
- _____ Increased demand for veterinary services
- _____ Reduced access to antibiotics
- _____ Increased compliance costs
- _____ Need for more communication/ education

Q13 What actions have you taken to prepare for the implementation of the VFD (select all that apply):

- I have talked to my clients
- I have attended meetings
- I have created a process for managing the VFD
- I have provided customers with guidelines and a process for implementation
- I have not yet taken any steps
- Does not apply

Q14 What actions have you taken to prepare for the implementation of the VFD (select all that apply):

- I have talked to my veterinarian
- I have attended meetings
- I have implemented these changes
- I have not yet taken any steps
- I have done research
- I have talked to my feed supplier

Q15 In general, please describe the type of service provided to your clients:

- Make all animal health management decisions
- Consultative adviser on animal health management
- Consultative adviser on broad range of farm management
- Minor input into animal health decisions
- Strictly clinical advice on as needed basis

Q16 In general, what type of service is provided by your veterinarian?

- Makes all animal health management decisions
- Consultative adviser on animal health management
- Consultative adviser on broad range of farm management
- Minor input into animal health decisions
- Strictly clinical advice on as needed basis

Q17 Have you talked with your veterinarian/clients about these guidances?

- Yes
- No

Q18 When and how do you plan to have these conversations?

Q19 Below is an overview of the VFD and Guidances 209 & 213. There are additional questions after this information.

The use of medications in animal feed has been an effective and convenient method to prevent and treat certain disease conditions in groups of poultry, farmed fish and livestock.

In 1996, the Animal Drug Availability Act established a new mechanism for distributing certain new animal drugs for use in or on animal feed, the Veterinary Feed Directive (VFD). And in 2000, new regulations were issued requiring these named VFD drugs to only be administered in animal feed under a veterinarian's order and professional supervision. Since that time, US fish and livestock producers have been required to obtain a VFD order from their veterinarian to acquire and administer certain medications in feed: Aquaflor® (florfenicol), for use in catfish and freshwater-raised salmonid fish, and Pulmotil® 90 (tilmicosin), for use in pigs and cattle.

As part of an overall approach to address concerns about the development of antibiotic resistance, in 2012 and 2013, the FDA issued Guidance for Industry #209 and #213, providing a framework for improving the judicious use of medically important antimicrobial drugs approved for use in food producing animals. These policy statements lay out FDA's goal to phase out the use of medically important antibiotics for productivity improvement (rate of gain and feed efficiency) and increase the veterinary oversight of these compounds when used in animal feed or water. Compounds which are not important for use in human medicine such as ionophores, are not covered by this new policy.

The FDA guidance calls on animal drug manufacturers to voluntarily remove production claims (i.e. "increased rate of weight gain" or "improved feed efficiency") from their products containing these medically important antimicrobials and modify product labels to require veterinary oversight of the therapeutic uses (prevention, control, or treatment) of these drugs, both in feed and water administration for food-producing animals. Manufacturers have agreed to update affected product labels.

To support implementation, the FDA has updated the VFD regulation to include these medically important antibiotics. The Veterinary Feed Directive is, in essence, a mechanism requiring a producer to get a written approval from a veterinarian for the in-feed administration of certain antibiotics. This written statement authorizes the producer to obtain and use the VFD drug in or on animal feed for administration to their animals and only in accordance with the directions for use approved on the label by the Food and Drug Administration (FDA). The producer provides the VFD order to his/her feed supplier who then manufactures and/or supplies the medicated feed in accordance with the VFD order and the FDA approved product label.

As a result, as of December 2016, producers will be required to have a VFD order or prescription from their licensed veterinarian to acquire medicated feed or water soluble medication respectively. For the poultry, aquaculture and

livestock industries and their stakeholders, this means these named medically important drugs will only be available under written veterinary direction and in the context of having a valid Veterinary-Client-Patient relationship.

Q20 As a producer, your VFD drug responsibilities include:

- Contacting your veterinarian to diagnose and treat your animals
- Following your veterinarian’s recommendations
- Administering the VFD medicated feed to your animals according to the directions on the VFD order
- Keeping copies of your VFD orders for at least two years
- Providing your VFD order copies for FDA inspectors to copy and review, when requested.
- Maintaining VFD related documents for up to two years

For veterinarians, a VFD can only be written within the context of a veterinarian-client-patient-relationship (VCPR) and for the use of a medicated feed as long as the animals and operation are under the supervision of a veterinarian and in the course of the veterinarian’s professional practice. To fulfill the obligations under the regulation, the veterinarian;

- Assumes responsibility for making medical judgments regarding the health and need for medical treatment, and the client has agreed to follow the veterinary instructions
- Must have sufficient knowledge of the animals or group to make a diagnosis.
- Must be available follow-up care
- Must be familiar with the operation and make periodic visits to the operation
- Must be licensed in the state in which the animals are located
- Maintain VFD related documents for up to two years

For the feed manufacturer, distributor or dealer, they must;

- Only provide medicated feed containing a VFD drug to a producer after receipt of a valid VFD order signed by a licensed veterinarian in the context of a valid veterinarian-client-patient-relationship
- Maintain VFD related documents for up to two years
- Notify the FDA of their intent to distribute products containing VFD drugs within 30 days of beginning distribution.

Go to these websites for more information; <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm> <http://feedstuffs.com/vfd.aspx>

Q21 Are there parts of the preceding information you find confusing?

- Yes
- No

Q22 What parts would you like additional clarification on?

Part a _____
Part b _____
Part c _____

Q23 What do you perceive to be the three biggest hurdles to be in compliance with the new FDA policy?

Hurdle 1 _____
Hurdle 2 _____
Hurdle 3 _____

Q24 What issues or unmet needs do you have around compliance with these policies?

E. Unanswered Questions

Here are some of the questions presented by participants in the 12 workshops of the Antimicrobial Education Project.

- What is the proper method of disposal for VFD feed that is no longer needed/left over?
- How will minor species be handled?
- What restrictions will be put on imports to ensure we are being held to the same standards?
- Who is responsible for enforcement?
- What are the associated penalties?
- Does a feed mill have to be in the same state as the animals/licensed vet?
- How do we get the CVM [FDA's Center for Veterinary Medicine] to answer questions?
- How will electronic VFDs work? What constitutes a valid signature (part 11)?
Does Global Vet Link satisfy requirements for the vet, producer, and feed mill?
- Can technical vets for animal health companies write a VFD?
- Do you have to write a new VFD if a feed mill goes down, and you need to switch to a new mill?
- Can a small animal vet write a VFD?
- Can a vet write a VFD if they aren't accredited?
- If a producer has medicated feed on their farm on January 1, 2017, do they need a retroactive VFD for that feed?
- Does the feed mill have to indicate how much medicated feed they produced?
- Does the veterinarian have to specify the feed mill on the VFD?
- How will internet pharmacies be regulated in terms of VFD feeds/water solubles?
- If writing a VFD that is to be distributed to multiple ranches, do you need a separate one for each physical address?
- Does the FDA have a timeline to eliminate all OTC antibiotics?
- Can a FFA advisor/4-H leader be considered the "Caretaker" of all the club's animals and therefore have the VCPR with the veterinarian?
- Are educational materials available in Spanish?
- Can video/photos count as "being familiar" with an operation to establish a VCPR?
- Will medicated milk replacer go to VFD or prescription status, i.e. medicated feed vs. medicated water?
- Is the feedmill responsible for ensuring that the VFD is valid (licensed vet, etc.)?
- If a staff vet writes a VFD for a company-owned feedmill for company animals, do they need to retain one or three copies of the VFD?
- Does a copy have to be submitted to the FDA?
- How are the veterinarians going to calculate dosages (used to milligrams, not pounds per ton)?
- What does success look like?
- If a feed manufacturer sends a truckload of medicated feed to the distributor, and they don't sell it all, who is responsible for bringing it back to the feed manufacturer, disposing of it, etc.?
- Does the FDA staff write a "warning ticket" before a "speeding ticket"?
- How will small operations that are not inspected for GMPs [Good Management Practices] be regulated and inspected?
- Will VFD feed in the future be treated as VFD feed has been in the past with respect to blending, carryover, flushing and sequencing, or will it be treated like a ~ 1900 drug?
- Will the auditing/compliance program be similar to the current VFD program or will CVM adopt a "zero tolerance" approach?
- If a producer/client conducts on farm mixing of a Type B medicated feed containing a category II VFD drug, does the producer/client need to get a feed mill license?
- Can a lawful VFD be written for 6 months by a veterinarian licensed in another state who has temporary – 30 to 60 day - permission to practice veterinary medicine in the state in which the premises exist to which the medicated feed is delivered?
- Who signs and sends an acknowledgement letter?
- For feed mixing and delivery purposes must the DVM/client/distributor calculate based on feed batches and full loads, or will short loads need to be produced (and charged for) for the duration of use calculations?



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