

White Paper

Antibiotic Use – Working Together for Better Solutions For Animal Agriculture and Human Health

Information synthesized from Nov. 1-3, 2016, symposium in Herndon, Va.: “Antibiotic Use – Working Together for Better Solutions For Animal Agriculture and Human Health”

DISCLAIMER: The information provided in this White Paper is strictly the perspectives and opinions of individual speakers and results of discussions at the 2016 symposium, “Antibiotic Use – Working Together for Better Solutions For Animal Agriculture and Human Health,” and does not represent the position of the National Institute of Animal Agriculture.

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BACKGROUND

The symposium “Antibiotic Use – Working Together for Better Solutions For Animal Agriculture and Human Health” was developed by the National Institute for Animal Agriculture (NIAA) and was conducted Nov. 1-3, 2016, at the Hyatt Regency Dulles in Herndon, Va. See the proceedings at www.animalagriculture.org/proceedings/2016ABXSymposium.

The unique gathering focused on a collaborative and continued dialogue about antibiotic use and antimicrobial resistance. Not about one point of view, the 2016 symposium provided a setting for a thoughtful exchange of ideas for the betterment of animal and human health.

The symposium hosted by NIAA and its partners heard presenters from organizations such as the CDC, FDA, and USDA along with industry leaders, retailers, processors, producers and experts in human, animal and public health. They sought to define what appropriate use of antibiotics really means and identify the core elements of stewardship.

This sixth annual symposium continued the discussions and sharing of information and built on previous sessions that began in 2011. Those earlier symposia were:

- Oct. 26-27, 2011, Antibiotic Use in Food Animals: A Dialogue for a Common Purpose, Chicago, Ill.
- Nov. 13-15, 2012, A One Health Approach to Antimicrobial Use & Resistance: A Dialogue for a Common Purpose symposium, Columbus, Ohio.
- Nov. 12-14, 2013, Bridging the Gap Between Animal Health and Human Health Kansas City, Mo.
- Nov. 12-14, 2014, Antibiotics Use and Resistance: Moving Forward Through Shared Stewardship, Atlanta, Ga.
- Nov. 3-5, 2015 Antibiotic Stewardship: From Metrics to Management, Atlanta, Ga.

NIAA is a non-profit, membership-driven organization that unites and advances animal agriculture in the aquatic, beef, dairy, equine, goat, poultry, sheep and swine industries. NIAA is dedicated to furthering programs working toward the eradication of diseases that pose a risk to the health of animals, wildlife and humans; promoting the efficient production of a safe and wholesome food supply for our nation and countries abroad; and promoting best practices in environmental stewardship, and animal health and well-being.

The 2016 symposium was funded in part by the Beef Checkoff®, U.S. Department of Agriculture Animal and Plant Health Inspection Service – Veterinary Services, Merial – A Sanofi Company, United Soybean Board, Merck Animal Health, Zoetis™, Auburn University Food Systems Institute, Elanco™, GlobalVetLINK, Norbrook® and Phibro Animal Health Corporation™.

SYMPOSIUM PLANNING COMMITTEE

Co-chairs

Dr. Steve Solomon, Global Public Health Consulting

Dr. Eric Moore, Director of Technical Services, Norbrook, Inc.

Symposium Planning Committee Members

Dr. Christopher Braden, Deputy Director, National Center for Emerging and Zoonotic Infections Diseases, CDC

Ms. Kelley Garner, Program Coordinator/Epidemiologist, Healthcare-Associated Infections Program, Arkansas Department of Health

Dr. Kerry Keffaber, Chief Veterinarian, Scientific Affairs and Policy, Elanco Animal Health

Mr. Jeff Morelli, Associate Director for Policy, Division of Foodborne, Waterborne & Environmental Diseases, CDC

Dr. Roger Saltman, Group Director, Cattle and Equine Technical Services, Zoetis

Dr. Nate Smith, Interim Director and State Health Officer, Arkansas Department of Health

Dr. Susan Weinstein, State Public Health Veterinarian, Arkansas Department of Health

Dr. Jean Whichard, Associate Director of Antimicrobial Resistance, CDC

SYMPOSIUM TOPICS AND SPEAKERS (in order given at the symposium)

Welcome and Opening Comments

Dr. Steve Solomon – Global Public Health Consulting

Sixth annual, each builds on the previous ones. The goal is to promote communications.

Dr. Eric Moore – Norbrook, Inc.

Overview of the Symposium

Moderator Dr. J. Scott Vernon, professor agricultural communications, California Polytechnic Institute

Drug-Resistant Foodborne Campylobacteriosis in Humans: Is There a Link to Antibiotic Use in Agricultural Animals? - Dr. M.A. McCrackin, DVM, PhD, Veterinary Medical Officer and Associate Professor, Comparative Medicine, Medical University of South Carolina

Medically Important Antimicrobials in Animal Agriculture - Dr. Michael Murphy, Veterinary Medical Officer, FDA Center for Veterinary Medicine

PANEL – Learning from the June Roundtable

Dr. Christopher Braden, Deputy Director, National Center for Emerging and Zoonotic Infectious Diseases, CDC

Dr. Christine Daugherty, Vice President Sustainable Food Production, Tyson Foods

Dr. Roger Saltman, Group Director, Cattle and Equine Technical Services, Zoetis

Dr. Angie Siemens, Vice President, Food Safety, Quality & Regulatory, Cargill

Stewardship of Antimicrobial Use in Animals: Defining Goals and Objectives - Dr. Bill Flynn, Deputy Director for Science Policy, FDA Center for Veterinary Medicine

Stewardship of Antimicrobial Drug Use in Food Animals: Farmers' Perspectives and Implementation Consideration – Dr. Constance Cullman, President, Farm Foundation, NFP

Antibiotic Stewardship Updates by Species: Swine, Beef, Poultry, and Aquaculture

Dr. Joel Nerem – DVM, Pipestone Veterinary Services, Minnesota; Mr. Kevin Hazelwood, Chief of Staff, Cactus Feeders, Texas; Dr. John Glisson, Vice President of Research

Programs, U.S. Poultry & Egg Association, Tucker, Ga.; Dr. Dave Starling – Faculty at Iowa State, Owner and Private Practitioner of Aquatic Veterinary Services and International Consultant

Antibiotic Stewardship Updates by Sector: Veterinarians, Producers, Feed Manufacturers, and Pharmaceuticals: Dr. Kerry Keffaber, Chief Veterinarian, Scientific Affairs and Policy, Elanco Animal Health; Mr. Richard Sellers, Senior Vice President of Public Policy and Education, American Feed Industry Association; Dr. Tyler Holck, Feed His People, LLC; Mr. Jay Hill, Farmer/Produce Sales, Hill Farms, New Mexico

Government Initiatives to Implement Antibiotic Stewardship

Complying with California's Senate Bill 27 on Antibiotic Use in Livestock - Dr. Annette Jones, State Veterinarian and Director, Animal Health and Food Safety Services, California Department of Food and Agriculture

Role of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria - Dr. Tom Shryock – Chief Scientific Officer, Antimicrobial Consultants, Greenfield, Indiana

Antimicrobial Stewardship and Judicious Use Initiatives of the USDA National Animal Health Monitoring System: NAHMS - Dr. Kathe E. Bjork, Veterinary Medical Officer/Biostatistician, USDA-APHIS

Updates from the CDC - Mr. Michael Craig, Senior Advisor for Antibiotic Resistance Coordination and Strategy, National Center for Emerging and Zoonotic Infectious Diseases, CDC

Antibiotic Stewardship: The Role of Consumer Demand and Retailer Initiatives - Dr. Scott Vernon, Professor, Agriculture Communications, California Polytechnic State University

Retail Panel on Stewardship Programs - Dr. Terry Coffey, Chief Science and Technology Officer, Smithfield Foods; Dr. David French, Veterinarian, Sanderson Farms; Dr. Ashley A. Johnson, Staff Veterinarian, PFFJ, LLC, a Subsidiary of Hormel Foods Corporation

Getting to Yes: What Each Sector Needs to Forge a Collaboration for Antibiotic Stewardship - Dr. Christine Daugherty, Vice President Sustainable Food Production, Tyson Foods

How do we Bridge the Communications Gap? - Kim Essex, Partner, Director North America Food and Beverage, Ketchum Public Relations; Jacque Matsen, Senior Vice President, Fleishman Hillard

Building a Coalition for One Health Approach to Preserving Antibiotic Effectiveness - Dr. Bernadette Dunham, Visiting Professor, Milken Institute School of Public Health, George Washington University; Dr. Amanda Beaudoin, Director of One Health Antibiotic Stewardship, Minnesota Department of Health

Leadership and Responsibility for Antibiotic Stewardship Panel 1 – Moderated by Dr. Leah C. Dorman, Director, Food Integrity & Consumer Engagement, Phibro Animal Health Corporation

Dr. Bob Easter, AAVMC, APLU, President Emeritus, University of Illinois; Dr. Kurt Stevenson, Medical Director, Microbial Stewardship Program, Wexner Medical Center, The Ohio State University; Dr. Tim LaPara, Professor, Department of Civil, Environmental and Geo-Engineering, University of Minnesota

Leadership and Responsibility for Antibiotic Stewardship Panel 2 - Moderated by Dr. Barry Eisenstein - Distinguished Physician, Antimicrobial, Merck & Co., Inc.

Dr. Nate Smith, Director and State Health Officer at Arkansas Department of Health; Dr. Eric Moore, Director of Technical Services North America, Norbrook, representing the veterinary profession; Dr. Kathy Talkington, Project Director, Antimicrobial Resistance, The Pew Charitable Trusts

EXECUTIVE SUMMARY

The veterinarian's oath, adopted by the American Veterinary Medical Association (AVMA), took on a new and important meaning with the arrival of new FDA guidelines that mandate all antibiotic use in animal agriculture come under the supervision of a licensed veterinarian.

The first sentence the oath, simply and eloquently, commits the practitioner to "use my scientific knowledge and skills for the benefit of society through the protection of animal health and welfare, the prevention and relief of animal suffering, the conservation of animal resources, the promotion of public health, and the advancement of medical knowledge."

Some of many experts, veterinarians and non-veterinarians, who addressed the sixth annual symposium on animal antibiotics, made reference to that oath in describing how producers and the rest of the industry practice stewardship in response to the new policy.

Antibiotic resistance is one of biggest and most complex topics facing animal and public health. But despite uncertainty, FDA believes that risk can be mitigated by limiting the use of medically important antimicrobial drugs in food-producing animals considered necessary for assuring animal health and requiring veterinary oversight or consultation for their use. Thus FDA no longer approves antimicrobials for weight gain or improved feed efficiency but allows therapeutic uses to be retained for treatment, control and prevention of disease. It will require a veterinary-client patient relationship (VCPR) and a veterinary feed directive (VFD)

Animal agriculture as a whole is complying not only with FDA guidelines on judicious use but also to meeting evolving marketplace demands for a safe, wholesome and affordable food supply. Suppliers feel pressure from consumers, expressed through retailers, to eliminate or reduce antibiotics. Companies that produce the largest shares of meat and poultry in the United States have taken steps in recent years to abide by both imperatives.

For example, Tyson Foods achieved an 80 percent reduction in use of human antibiotics in broiler chicken in 2011 and has a goal of zero "shared class" antibiotics in its broiler chicken flocks. Cargill's policy on antibiotics for its extensive cattle and turkey production business seeks to avoid using antibiotics that are important in human medicine.

Extensive collaboration within the industry and with government is under way to promote antibiotic stewardship. There is recognition of the need for a data collection mechanism to inform decision-makers about the current status of antibiotic use and to provide a way to measure progress. Data collection will cost money, some of which will come from government and some from industry. The poultry industry has begun its own voluntary data collection program to provide antibiotic use statistics to USDA's Animal and Plant Health Inspection Service, in addition to what APHIS currently collects through its ongoing surveys.

There is widespread agreement that animal agriculture needs to do a better job educating the public about the realities of food production and the progress it has made in optimizing antibiotic use to keep animals healthy and produce safe and affordable protein food.

The current marketplace is marked by confusion and hyperbole. Agriculture's response must differentiate between the small minority that opposes animal agriculture and the wider public that wants to continue buying meat, poultry and dairy products without worries over safety.

At the same time, those non-governmental organizations that are interested in finding a solution should be brought into the conversation to seek common ground.

Over the three days of the symposium, speaker after speaker emphasized that antibiotic use in both human and animal medicine has an effect on the emergence of antibiotic-resistant bacteria and, therefore, its use must be judicious in both settings. However, the keynote speaker added that the development of antimicrobial resistance (AMR) in animal enteric bacteria only rarely resulted in AMR in human enteric bacteria. The development of AMR in human enteric bacteria almost always comes from the use of antimicrobials in people.

Because practitioners who treat human patients and those who treat food-producing animals can learn from one another, experts in human medicine were invited to the symposium. They described the reasons that antibiotics sometimes are overused, or used improperly, in treating human illness and said that efforts are under way to reduce unnecessary use. The Centers for Disease Control and Prevention (CDC) has a goal of seeing all U.S. hospitals with an antibiotic stewardship program by 2020. Long-term care facilities, where antibiotic use is common, also are under pressure from regulators to adopt stewardship programs.

State agencies and the academic community also have a role in encouraging judicious use of antimicrobials through the “One Health” concept that bridges human, animal and environmental health. Universities can promote collaboration between veterinary and human medicine disciplines to tackle the emergence of antibiotic resistance.

The scarcity of food animal veterinarians in some areas may challenge producers who want to comply with guidelines effective at the beginning of 2017. Increasing the supply of food animal veterinarians is daunting, particularly in remote rural areas. Recent data found 105,000 veterinarians in government or industry but only 66,000 veterinarians in private practice. Some 1.8 percent of them serve exclusively food animals, another 5 percent practice mostly in food animals and 6.3 percent have a mixed practice -- a total of 13.1 percent of veterinarians serving food animals at least part time.

The symposium can be summed up in the words of a participant – a veterinarian who also raises cattle – who appreciated speakers’ candid comments and the absence of “finger-pointing” that seeks to blame others. “We’ve got a job to do on our own side to use antibiotics judiciously and we have a welfare obligation to these animals entrusted to our care, because healthy animals are more productive.” Physicians should be commended for not pointing a finger at agriculture. In turn, food producers did not seek to blame physician overuse.

Working together in the “One Health” concept is a step forward. It will accomplish a lot more than agriculture trying to exist on its own island. Animal agriculture needs antibiotics to prevent and control disease and to treat sick animals. Few if any veterinarians or producers will miss those feed grade antibiotics that had production claims on their labels and recognize that was probably a mistake that dates from 50 years ago. Removing them is a step forward for animal agriculture. Animal health and judicious use is an important part of sustainability.

Drug-Resistant Foodborne Campylobacteriosis in Humans: Is There a Link to Antibiotic Use in Agricultural Animals?

The authors of the most exhaustive analysis of the current state of scientific knowledge about the link between on-farm use of antibiotics and the emergence of antimicrobial-resistant (AMR) pathogens conclude, “The current literature is inadequately detailed to establish a causal relationship between antibiotic use in agricultural animals and antibiotic-resistant campylobacteriosis in humans.”

However, the review, published in the Journal of Clinical Science and Nutrition, also established that antibiotic-resistant Campylobacter can be transmitted to humans in raw animal products.

“On-farm antibiotic treatments increase colonization of animals with antibiotic-resistant Campylobacter,” said one of the paper’s lead authors. “I don’t think that’s in dispute. It’s basic biology,” said Dr. Mary A. McCrackin, who is Veterinary Medical Officer at the V.A. Medical Center and Associate Professor at the Medical University of South Carolina. “It is one of the biggest and most complex topics I’ve ever studied in my career,” she added. “It’s really easy to become paralyzed and wonder whether we are able to do anything about the problem.

McCrackin said the literature review of Campylobacter and antibiotic use in agricultural animals was intended to be “as objective and unbiased as possible.” The papers we reviewed included one or two of the three steps in food production from farm to fork, most often animals on the farm or packaged retail products. Some articles included animals on the farm and their meat products at the processing plant. We looked at the same thing with poultry. We didn’t look at the environment. We didn’t look at pets and we excluded travelers’ diarrhea which is when bacteria are brought here from another country.

The study authors recommended better standardization of testing in future research on the topic, saying existing literature is hard to compare over time because of differences in tests. They also urged transparency about the use of antibiotics – both on the farm and in humans – and saw the need to determine appropriate metrics for public policy development.

An abstract of a second article by the same group that focused on drug-resistant Salmonella <http://www.tandfonline.com/doi/full/10.1080/10408398.2016.1230088> states in part, “Controversy continues concerning antimicrobial use in food animals and its relationship to drug-resistant infections in humans. We systematically reviewed published literature for evidence of a relationship between antimicrobial use in agricultural animals and drug-resistant meat or dairy-borne non-typhoidal salmonellosis in humans. Based on publications from the United States (U.S.), Canada, and Denmark from January 2010 to July 2014, 858 articles received title and abstract review, 104 met study criteria for full article review with 68 retained for which data are presented. Antibiotic exposure in both cattle and humans found an increased likelihood of Salmonella colonization, whereas in chickens, animals not exposed to antibiotics (organic) were more likely to be Salmonella-positive and those that had antibiotic exposure were more likely to harbor antimicrobial-resistant Salmonella organisms. In swine literature, only tylosin exposure was examined and no correlation was found among exposure, Salmonella colonization, or antimicrobial resistance. No studies that identified farm antimicrobial use also traced antimicrobial-resistant Salmonella from farm to fork.”

Medically Important Antimicrobials in Animal Agriculture

Animal agriculture has been focused for the past three years on complying with new directives from the Food and Drug Administration (FDA), the most recent of which takes effect January 1, 2017. The intent of the directives is to “implement measures to protect human health while insuring that agriculture’s needs were met,” in the words of Dr. Michael Murphy, Veterinary Medical Officer at FDA’s Center for Veterinary Medicine.

While antibiotic use in animal agriculture has been the subject of scientific and policy debate for decades, the science behind it continues to evolve. FDA has determined that, despite complexities and uncertainties, steps can be identified to mitigate risk.

The controlling FDA documents are Guidance 209

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf> and Guidance 213

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>.

The principles of FDA’s judicious use policy include 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting medically important antimicrobial drugs to uses in food-producing animals to those that include veterinary oversight or consultation. See <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/default.htm>.

In December 2013, FDA’s Guidance 213 document proposed to withdraw approval of certain antimicrobials previously used for “increased rate of weight gain” or “improved feed efficiency.” The cumulative intent of FDA’s guidance is that therapeutic uses of antibiotics are to be retained for treatment, control and prevention of disease.

While a veterinarian is not required to be involved in the actual administration of antibiotics, all uses of those considered medically important for therapeutic use in humans must be approved by a licensed veterinarian through a written Veterinary Feed Directive (VFD).

The framework for veterinary oversight was enacted by Congress in 1966, implemented by FDA regulation in 2000, and updated in October 2015 with changes designed to make the process more efficient. Beginning in January 2017, certain medications previously available over-the-counter (OTC) will be allowed only with VFD supervision.

A complete list of affected applications is posted at

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm>.

The NIAA Effort: Learning from the June Roundtable

NIAA convened a roundtable discussion in Atlanta in June 2016 to discuss the results of the 2015 Antibiotics Symposium, “From Metrics to Measurement,” and to help prepare for this year’s Symposium. Four of the more than two dozen participants were invited to give their impressions about what they learned from the discussions.

The Center for Disease Control and Prevention (CDC), with its focus on human medicine, and animal agriculture can learn from one another, said Dr. Christopher Braden, Deputy Director of CDC's National Center for Emerging and Zoonotic Infectious Diseases.

Antibiotic use needs to be judicious whether for human medicine or animal medicine. The challenge is improving our ability to use them judiciously.

Data collected by CDC shows significant variation in how antibiotics are prescribed. In 2014, the antibiotic prescribing rates per 1,000 population varied from 501 in Alaska to 1,285 in West Virginia.

More than half of all hospital patients in the United States receive an antibiotic. Nationally, 48.1 percent of hospitals (2,199 of 4,549) had adopted an antibiotic stewardship program in 2015. They also varied geographically, from 7 percent in Vermont to 77 percent in Utah. CDC's goal is to see all U.S. hospitals with an antibiotic stewardship program by 2020.

The data collected on antibiotic use in human medicine could have a corollary in animal medicine, Braden said. Information to become available from veterinary feed directives beginning in January could be very helpful in developing metrics for antibiotic use in animals, in addition to that collected in the National Antimicrobial Resistance Monitoring System (NARMS) conducted by CDC, FDA and the U.S. Department of Agriculture (USDA).

Tyson Foods, one of the largest integrated meat and poultry producers in the United States, was invited to the discussion in June to describe its antibiotic policies. Tyson is responsive because consumers want food that is authentic and they want a level of transparency that never has been known in the society that we live in, said Dr. Christine Daugherty, Tyson Foods Vice President for Sustainable Food Production.

Last year, Tyson produced 68 million pounds of meat and poultry per week from the slaughter of 35 million chickens, 128,000 head of cattle and 401,000 hogs. Daugherty cited several milestones in antibiotics reduction.

- In 2011, an 80 percent reduction in use of human antibiotics in broiler chicken.
- In 2014, elimination of all antibiotics at 35 broiler hatcheries.
- In 2015, stopped using human antibiotics in feed mills.

Tyson Foods' goal is to achieve zero human antibiotics in its broiler chicken flocks.

Dr. Roger Saltman, Group Director, Cattle and Equine Technical Services, Zoetis, described challenges to the creation of metrics that would be useful in decreasing antimicrobial resistance. Several questions need to be answered. What is the goal we are trying to achieve? Are we willing to accept a decline in animal health? How will metrics be collected? Who will collect it –veterinarians, government, the animal protein industries? What about the cost to create the systems to garner these kind of metrics?

Other challenges include differentiation between the amount manufactured and sold to distribution, the amount that went to veterinarians or animal production units, the amount prescribed or the amount actually used. Decisions must be made about what to measure – the amount per production unit per year, amount per animal per year, or doses per animal per year. Finally, the data on antibiotic use must be paired with health outcomes.

Cargill's policy on antibiotics for its extensive cattle and turkey production business seeks to avoid using antibiotics that are important in human medicine, use a narrow spectrum of antimicrobials whenever possible, and have the fewest number of animals possible to treat, prevent or control disease, said Dr. Angie Siemens, the company's Vice President, Food Safety, Quality & Regulatory.

In 2016, Cargill eliminated 20 percent of shared class antibiotics from eight cattle feedyards with 1.2 million cattle per year, and by 2018 Cargill will have 90 percent of its cattle harvested with Beef Quality Assurance certification, a program that stresses antibiotic stewardship.

After 80 studies, Cargill now offers the Promote^R BiacidTM Nucleus feed additive with essential oils as an alternative to antibiotics in poultry feed. However, Siemens said that replacements are not always as effective as antibiotics.

Its turkey business probably made the most dramatic change, she said. In early 2015, it eliminated growth-promoting antibiotics. In summer 2016, it eliminated gentamicin from turkey hatcheries and in 2017 will offer Honest Turkey brand featuring products from turkeys that never received antibiotics. She said that Cargill's integrated turkey chain can make progress faster than is possible in the segmented cattle chain.

Processors feel pressure from consumers, expressed through retailers, to eliminate or reduce antibiotics. Dougherty said that marketing claims on packaging often lead to confusion, including a belief that added hormones or steroids are in poultry when they are not. Siemens detected an "anti-technology" wave among consumers. Many are confused by technology and are persuaded to choose "free" or "free of" products. The concept that one product is labeled "free" would infer that other products have it when they may or may not.

There remains concern that such marketplace pressure will negatively impact the food production system. Dougherty said Tyson seeks to produce food that is safe, wholesome and affordable. "If you remove one leg of the stool it gets pretty wobbly," she said. You have to have all three of those. Remove one of those legs it's not a pretty situation for agriculture."

What entities will collect and disseminate antibiotics data?

CDC's Braden said the mechanism will have to be created and it's going to require funding. Some will have to come from government but some will need to come from industry. For a system to be credible, stakeholders must be at the table when it is created, and that means non-governmental organizations too, Dougherty said. "Everyone has to have buy-in and that makes it difficult." Siemens said some data collection methods do not involve government; third party food safety audits of Cargill's plants are accepted by all of its customers.

Stewardship of Antimicrobial Use in Animals: Defining Goals and Objectives

Dr. William T. Flynn, Deputy Director for Science Policy in FDA's Center for Veterinary Medicine, described some of the considerations that went into development of its judicious use policy and told how the agency intends to see the directives implemented.

Factors to keep in mind in designing stewardship policies include the wide variety of animal species, the wide variance in animal husbandry and the wide differences among

stakeholders. FDA looked at the major food producing animals, cattle, swine, chickens and turkeys and the minor species, such as sheep, goats, fish, quail and even honeybees. It also considered companion animals, including horses, dogs, cats and exotic or zoo animals.

A policy also needs to take account of the wide variance in the size of operations. Small animal-raising operations may have lower density but disease control and biosecurity may be less rigorous, while larger operations may have higher density but have more rigorous disease control and biosecurity. "Small is not necessarily always better," he noted.

Stewardship requires collaboration across a broad spectrum of stakeholders, including veterinarians, producers, animal feed industries, animal pharmaceutical industry, distributors, retailers, academia and government (local, state and federal) agencies. In order to effectively implement these at the farm level, all of these have to be involved in the process.

It is important to put enough time and energy into defining goals and objectives. More must be done to clarify the message, assess the progress to date and find a way to measure progress as we move forward. There is a need for greater clarity and agreement regarding goals and objectives. The objective probably must be to slow the emergence of antibiotic resistance. It likely can not be stopped, but common action may be able to slow it down and manage it.

From FDA's perspective, Flynn said early indications are that "some meaningful progress" is being made. There have been active support and outreach efforts to prepare for the changes sought by FDA Guidance to Industry #213. Academic organizations are incorporating judicious use principles into curricula at land grant universities and veterinary schools. Veterinarians' organizations are examining and updating policies with respect to stewardship. Producer association quality assurance programs include judicious use of antimicrobials.

Success should not focus only on reduction in overall sales or use of antibiotics but other indicators need to be identified to help assess stewardship. Ultimately, it may reduce overall use but the ultimate goal is that improved use practices will curb development of resistance. "We must keep tethered to the idea that we are trying to slow resistance emergence."

Flynn is hopeful that funding will be made available to help measure progress, but lack of new funding to date has delayed progress on enhanced data collection. USDA is preparing antimicrobial use surveys, but the work depends on getting funded. Using existing funds, FDA recently awarded two grants to researchers on strategies for collecting information.

When covered antimicrobials can be administered only under a veterinary feed directive, FDA's primary focus will be initially on education rather than penalties for noncompliance. Inspectors are focused on helping people understand the new requirements. There will be some period of time, going into the next year, Flynn said. "We are not going to be penalizing folks right out of the gate." Significant changes require a learning curve, he said. State agencies will be a key part of compliance education, through existing cooperative activities with FDA, incorporating VFD compliance within feed safety inspections.

FDA's objective as of January 1, 2017, is that all the affected products that will become available only through a veterinary prescription or under a VFD. The goal is that they used under veterinary oversight, he said, even as older products must work through the process.

Stewardship of Antimicrobial Drug Use in Food Animals: Farmers' Perspectives and Implementation Consideration

Farm Foundation, in partnership with FDA, conducted 12 regional workshops in the fall of 2015 to provide livestock producers, veterinarians and feed suppliers with detailed information on the new FDA antibiotic policies and VFD rule. The workshops were attended by 530 people with more than 300 people viewing them on webcasts.

Officials of FDA's Center for Veterinary Medicine and the USDA Animal and Plant Health Inspection Service (APHIS) with questions raised by workshop attendees and attendees left with comprehensive overview of how policies will impact management of their respective operations. Detailed information from the workshops is on the Web at <http://www.farmfoundation.org/vfdrules/>.

Farm Foundation President Constance Cullman said the workshops identified several likely impacts of the policies. The major concerns are increased paperwork, a shortage of veterinarians and changes in the relationship between producers and veterinarians.

Comments in the workshops made clear that there is a need for more education and outreach. Farm Foundation is producing radio programs for the National Association of Farm Broadcasting to explain the new procedures. Many state extension bodies and state departments of agriculture have similar efforts.

Cullman sees a need for focus on producers who may not be members of producer groups that encourage quality assurance programs with antibiotic education and those who do not have a regular veterinarian.

We are looking to develop nationwide industry-agreed upon metrics for measuring antibiotic use. We want to do that with key stakeholders to see if we can actually pull everyone together so it is not overly burdensome.

The challenge to increase access to veterinary services and improve the supply of food animal veterinarians is "one of the more daunting ones," she said. Particularly in remote areas, access to veterinarians is difficult. State and federal regulators need to work with colleges and veterinary professional societies to encourage more food animal practices.

Farmers understand the issue. They are parents and users of antibiotics who also care about resistance, Cullman said. But it's going to take a lot of conversation and listening to get producers to buy in. "If you don't have them involved, you are going to have an inconsistent return of information," she added. One avenue is to encourage simultaneous exploration of alternatives to antimicrobial medicines to fill the void if antibiotics are not available. More work must be done to find alternatives to compensate for antibiotics and still protect animals.

The challenge posed by "anti-science" public opinion is one that "all of us have been wrestling with for the last several years," she said. Some non-governmental organizations are interested in finding a solution – and it is important to talk with them and find common ground. But for those groups that are not interested in solutions, "we just have to move past them."

"It's kind of scary that there is so much scientific illiteracy in a country that is so dependent on science," Cullman concluded. "When we have a position, we have to be careful that it is scientifically grounded. This is not going to end any time soon. We're in this for the long haul."

Panel Discussion: Antibiotic Stewardship Updates by Species

Swine – Dr. Joel Nerem, a partner in Pipestone (Minnesota) Veterinary Services, a 29-veterinarian practice that operates in five states:

Commercial-scale pork producers would say they have a long history of responsible medication use, food safety and animal well being. Moreover, they would say that all the pork produced from their animals is free of antibiotics. Farms today keep accurate treatment records, a requirement of the Pork Quality Assurance Plus program since 1989. Antibiotics are used in pig farming for treatment, control and prevention of disease but no longer for improved feed efficiency. Pipestone clients have a history of non-antibiotic treatment to improve animal well being, noting that medicine is expensive. Farms maintain high biosecurity and have installed air filtration to protect pigs' health. The Pipestone practice is making available a web-based tool (PART^R, for Pipestone Antibiotic Resistance Tracker) that will help clients record total antibiotic use, allowing them to track resistance over time. It's intended to help producers who sell into a market in which retailers want high level food safety and quality measurement.

Beef – Kevin Hazelwood, Chief of Staff at Cactus Feeders, Amarillo, Texas, one of the nation's largest feeders:

While it may be tempting to respond to the fears of consumers about antibiotic residue, there is a risk that availability of antimicrobials could become limited to a level below that considered necessary and judicious to care adequately for animals. Reducing antibiotic use too severely could increase the cost of producing beef in the United States so much that beef would be imported more cheaply from countries without similar restrictions, frustrating the goal of reducing the emergence of resistance. The consumer anti-technology attitude that the industry faces in the market could affect the ability to produce beef in a sustainable fashion. Over the last 20 years, cattle producers have produced the same volume using 2000 pounds less feed and 1,250 fewer gallons of water per head. Further threats to production technology, including, antibiotics would put the industry back several decades. Restrictions that are too severe could deny feeders a method to control bovine respiratory disease (BRD) that affects 1-2 percent of cattle entering feed yards.

Poultry – Dr. John Glisson, Vice President of Research Programs at the U.S. Poultry & Egg Association, Tucker, Georgia:

Most large integrated poultry companies have already completed the transition spelled out in FDA's Guidance to Industry #209 and #213. The poultry industry has uniformly supported these changes. Compliance is facilitated by the industry's corporate structure, with large companies doing complex tasks. They have been challenged by developing and implementing processes for issuing, communicating and archiving VFDs. Many buyers tell suppliers they want poultry products never exposed to antibiotics – a tall order. The industry faces a challenge – not from FDA but from

customers – in treating coccidiosis, an intestinal disease that is prevented by ionophores, which are not important in human medicine. Respiratory diseases such as infectious bronchitis pose an even greater challenge because they can be treated effectively only with medically-important antibiotics. The dilemma facing companies: which is better, to use non-medically important ionophores for prevention or to avoid antibiotics but then to have to use medically-important antibiotics to treat disease? Companies that raise chickens with “no antibiotics ever” inevitably will have flocks that must be treated, and the treated chickens need a separate market channel.

Aquatic Livestock – Dr. Dave Starling, Iowa State University College of Veterinary Medicine Faculty Member, Owner and Private Practitioner of Aqueterinary Services and International Consultant:

There are no formal products for antibiotic stewardship in aquatic livestock production but a number of veterinarians are working to reduce or make antibiotic use more effective. Globally, 40 countries have significant activity in raising 17 industrialized species of aquaculture livestock. In the United States, FDA has approved the use of Aquaflor for finfish, notably fresh water-raised salmon and catfish. Since 2006, a VFD has been required for Aquaflor. To reduce or eliminate the need for antibiotics in aquatic livestock, the industry needs biosecurity to control primary pathogens and strict environmental control. Norway is pioneering in the effort to reduce the use of antibiotics; its salmon industry uses 1,000 metric tons of antibiotics a year, compared with 50,000 tons for the human population.

Panel moderator Eric Moore of Norbrook said the industry is challenged to explain to consumers that the animal agriculture industry has stewardship programs designed to reduce antibiotic use and asked panelists for suggestions about doing so.

Nerem said pork producers can point out that arbitrary reductions could imperil animal health. Hazelwood noted that not all consumers are conversant with science and that industry needs to be transparent; Cactus Feeders opens its facilities for tours and dialogue with consumers.

Glisson said that the industry doesn't know how much is used. The poultry industry would like to know what is used and how or whether use is changing. Poultry companies have begun a data collection program. It is voluntary but the participation rate is very, very high. Companies will provide information to APHIS every year. Although it has taken some time to put together the mechanism, the broiler segment is almost finished, to be followed by egg-laying hens and turkeys. Whether FDA's Guidance #213 will make a difference is unknown, but Glisson expects to see the usage data change dramatically from 2015 to subsequent years.

Panel Discussion: Antibiotic Stewardship Updates by Sector

Pharmaceuticals – Dr. Kerry Keffaber, Chief Veterinarian, Scientific Affairs and Policy, Elanco Animal Health:

We do not have all the answers yet, but science is going to help answer the questions. In the interim, how do we find solutions now, even though the science is not finished? We can agree that the impact of antibiotics in animals in emergence of resistance is not zero. But we also can agree that some proposed solutions may have unintended

consequences, with impacts on animal health and welfare, food safety and sustainability. Moving to totally antibiotic-free animal food production may lead to the use of more medically important antibiotics, which is not the goal; the goal is to reduce resistance. To meet the January 1, 2017, deadline for new label requirements requires collaboration to help insure that people are doing things right. One cannot overestimate the importance of collaboration in meeting this monumental change. Part of collaboration is being out there and explaining. A lot of companies are out there trying to help people comply. Proper animal health is important because the reality is that 20 percent of animals are lost by death and disease. That is an untold food waste story and a serious barrier to feed a global population that is expected to double by 2050. Most Elanco research money is devoted to products designed to reduce problems that now require shared-class antibiotic use. We should make sure that our policy and our process does not get ahead of the science. Sometimes, certain tools of antibiotics are necessary for health.

Feed Manufacturers - Mr. Richard Sellers - American Feed Industry Association, Senior Vice President of Public Policy and Education:

It's going to be a rough first year but the feed industry is committed to helping make it work despite the high cost of compliance. However, with the magnitude of changes required, there are going to be mistakes. Member companies are "all over the ballpark" about whether they are going to be ready January 1. Nevertheless, we'll do the best job of compliance we can. Leftover inventory will be a big mess on January 1. We've got hundreds of millions of dollars in products in inventory and we will ask FDA to allow us to use existing products under VFDs even if they have outdated labels for growth promotion. In publishing the rule, FDA did a very poor cost assessment. It's going to be an expensive proposition but we're going to work it out. Last year, the industry manufactured 193 million tons of feed. In previous years, it was estimated that half of that feed was medicated. However, we can't say that anymore because 52 percent is for the poultry industry and many of those companies have taken it out. The association has asked FDA to allow our members to keep records electronically rather than imposing a "monstrous paperwork record requirement." After election, we expect an onslaught of letters from members of Congress asking the agency to do this.

Veterinarians – Dr. Tyler Holck – MS, MBA – Feed His People, LLC, Independent Consultant, Gilbert, Iowa:

The first paragraph of the veterinary oath taken by all veterinarians, among other things, confers an obligation to prevent animal suffering. In today's market environment, there is a risk of decreasing animal welfare and increasing animal suffering by arbitrarily reducing antibiotics in some situations, just because the consumer thinks it's a good idea. It is clearly not an easy issue. Clearly, antibiotics are one of the key tools for animal health and welfare. The new guideline will require producers, some of whom have not used veterinarians in the past, to have a veterinary relationship. Doing so will be a challenge in some instances because there likely is a lack of food animal veterinarians in parts of the country. The United States has more than 110,000 veterinarians but only 1.8 percent of those serve exclusively food animals, another 5 percent who practice predominantly in food animals and 6.3 percent who have a mixed practice, for a total of 13.1 percent of veterinarians serving food

animals at least part time. We need to encourage more students in veterinary schools to pursue food animal practices and to encourage more schools to provide training for specific species.

Producers – Mr. Jay Hill, Farmer / Produce Sales, Hill Farms, New Mexico:

Looking at different labels in a grocery store, agricultural producers are worried. I want to provide you with the healthiest food I can, a safe, nutritious food, and whenever we sit across the table there needs to be a trust there. And we are seeing people start to label our food in different ways. Faced with this challenge as producers, we need help to tell our story. What we get to do is the most wholesome thing in the world. But farmers and ranchers have spent time with their head down, making sure that you've had that right to eat good food, but we lost our voice. Now when we talk about what's facing agriculture it's up to you guys to help us.

Moderator Dr. Roger Saltman of Zoetis asked panelists how to deal with what he called "the very small segment of bad actors who want to skirt the regulations on prescriptions or VFDs" and use antibiotics indiscriminately.

Sellers noted that it is a criminal felony to violate the Food, Drug and Cosmetic Act, which is the governing authority for FDA's regulations. However, he said the feed industry does not expect such violations and that any mistakes will be due to a lack of knowledge. With 280 new drugs classified under VFD practices, there will be mistakes, he said. Member companies have done a lot of education to prepare for the new rules.

Keffaber said Elanco seeks to motivate people who want to do it right with educational materials. Producers who participate in the Pork Quality Assurance and Beef Quality Assurance programs take their responsibility seriously.

Saltman said that Zoetis has logged over 400 presentations on the new procedures. Everyone's intentions are quite good, he said. In the first months, he expects no one to be willfully skirting the regulations but that there will be mistakes. He is encouraged that FDA has expressed a willingness to educate instead of regulate.

Asked who is liable for products on the shelf that is not compliant under the new guidance. Sellers is concerned about premixed, bagged medicated feeds in retail stores, in some cases with expiration dates two or three years from now.

FDA's William Flynn told the audience that it was never FDA's intent to recall products but that it would continue to be used under the VFD procedure. There will be a spectrum in terms of products – some with new labels, some old labels and transition labels in some cases – a mix of those products in the market January 1. FDA's primary goal is that the products, regardless of how they are labeled, be used under new use conditions from January 1 going forward. Any growth promotion indications that are on the label will no longer be effective.

Complying with California's Senate Bill 27 on Antibiotic Use in Livestock

Legislation (SB27) adopted by the California legislature and signed into law by Governor Jerry Brown in 2015 will require, as of January 1, 2018, that injectable and other medically important antibiotics not delivered through feed or water to be sold only with a prescription by a veterinarian or a VFD.

Dr. Annette Jones, State Veterinarian and Director, Animal Health and Food Safety Services, California Department of Food and Agriculture (CDFA), explained that the new state law is specific to medically important antimicrobials as defined by FDA. It limits the use of antibiotics to treat, control and in some cases prevent disease or infection. They can not be used solely for weight gain or feed efficiency.

California may have gone beyond the federal guidance by banning the use of some antibiotics without a prescription from a veterinarian. It also requires producers to follow best practices, such as vaccination and proper sanitation, in an effort to limit the need for antibiotics, and requires veterinarians to obtain continuing education credits for antibiotic stewardship.

It also requires the CDFA to gather data on antimicrobial use sales and use data, conduct surveillance for antibiotic resistance, and collect management practices data. Individual producer and company data will be kept confidential, protected from freedom of information inquiries, and released only in aggregated form. The law also directs extensive use of ad hoc advisory committees of stakeholders and technical specialists. Guidelines will be developed in coordination with the Department of Public Health, the Veterinary Medical Board and the University of California Veterinary Medical School.

CDFA was allowed to create eight positions to carry out the program, with an allocation from the state general fund because the governor believes antibiotic resistance is a serious issue for future generations of animals and people, Jones said, citing broad support for the program as a One Health issue.

Role of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

President Obama signed an executive order in September 2014 to create the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PCARB) within the U.S. Department of Health and Human Services. It directs the Secretary of HHS to appoint the council and to develop a strategy and a National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan) to fight antibiotic-resistant bacteria.

Dr. Tom Shryock, Chief Scientific Officer, Antimicrobial Consultants, Greenfield, Indiana, one of 15 members, described the advisory council and provided an overview of its recommendations. Dr. Lonnie King, a former administrator of USDA's Animal and Plant Health Inspection Service now acting agriculture dean of the Ohio State University and head of its veterinary school, is vice chair of the agriculture council.

The council said the first goal under is to slow the emergence of resistant bacteria and prevent the spread of resistant infections in both the human and animal health sectors. It aims to eliminate the use of medically important antibiotics for growth promotion in food-producing animals and strengthen national One Health surveillance efforts to combat resistance.

Inclusive of animal and human health sectors, additional objectives are to advance rapid diagnostic tests for identification and characterization of resistant bacteria, accelerate basic and applied research and development for new antibiotics other therapeutics and vaccines (primary for human health without specific mention of animal health needs).

By 2020, the council seeks major reductions in urgent serious threats, in part through improved stewardship in healthcare settings. It also calls for enhanced surveillance of resistance in animal and zoonotic pathogens by strengthening the National Antimicrobial Resistance Monitoring System (NARMS) and other enhanced data collection.

Antimicrobial Stewardship and Judicious Use Initiatives of the USDA National Animal Health Monitoring System (NAHMS)

Depending on allocation of funds, USDA will collect data in 2017 on antibiotic use for 2016 and previous years. USDA is in the process of updating the cow-calf survey and will pursue the feedlot survey and antibiotic usage surveys as resources and interest demand. The survey proposes to ask a number of stewardship questions such as who makes decisions on farms, whether the producer has a veterinarian-client patient relationship (VCPR) and whether the producer is aware of VFD changes.

Dr. Kathe E. Bjork, Veterinary Medical Officer/Biostatistician, USDA-APHIS, explained the process. USDA's National Agricultural Statistics Service (NASS) begins by selecting a random sample of names from its data base to identify producers willing to participate in a NAHMS study. NASS gives APHIS Veterinary Services the names of those who agree to take part and APHIS field veterinarians visit farms to work with producers on the comprehensive survey.

The surveyors will collect data on the previous year's antimicrobial use, focusing on feed and water uses, and on several other aspects of farm management and animal husbandry relating to health. Producers are assured that individual farm data will remain confidential under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), a 2002 law that exempts such information from disclosure under the Freedom of Information Act.

APHIS has extensive experience over many years in collecting and publishing aggregate data on the health of several species of livestock and poultry. It is described on the agency's web page at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nahms> Depending on the species or commodities, surveys are repeated every 5 to 10 years. This year, APHIS is completing an equine study.

Update from the Centers for Disease Control and Prevention (CDC)

CDC launched a national campaign for appropriate antibiotic use in 1995, refined it in 2003 with a focus on antibiotic use for respiratory infections in children and adults in doctors' offices, later expanding the effort to cover hospitals and long-term care facilities.

But CDC's Michael Craig, Senior Advisor for Antibiotic Resistance Coordination and Strategy, said the agency recognized that more was needed, "In some cases, the message has not resonated," he said. "We are revamping, testing new messages."

Although data is incomplete, CDC estimates that at least 30 percent of outpatient antibiotic

prescriptions are unnecessary. It has established a target of 50 percent reduction in prescriptions for acute respiratory conditions and a 15 percent reduction in use of other conditions by 2020. Up to 70 percent of nursing home residents are estimated to receive antibiotic treatment every year, with about 40-75 percent of it inappropriate or unnecessary.

Accreditation authorities for hospitals, nursing homes and other health care facilities, working with CDC and other agencies in the Department of Health and Human Services, have begun requiring facilities to adopt antibiotic stewardship programs that meet CDC standards. The Centers for Medicare and Medicaid Services (CMS) in HHS will require all hospitals that accept funding from Medicare and Medicaid to have a antibiotic stewardship program.

CDC is optimistic about the potential for whole genome sequencing (WGS), initially of salmonella, to provide a great deal more information about resistance and how that resistance may have developed. Craig said it could allow understanding of the relationship between use in human health and use on the farm and “give us better information to take appropriate action when we need to take it.”

WGS, by providing a very precise DNA fingerprint of the pathogen, will enable rapid detection of genes that make bacteria resistant to antibiotics and allow public health officials to pinpoint investigations of outbreaks. It also will provide more detailed data to track resistance patterns.

Antibiotic Stewardship: The Role of Consumer Demand and Retailer Initiatives

Producers of meat and poultry products are making progress in their effort to reduce the incidence of antibiotic-resistant pathogens but they need the help of manufacturers, scientists and others to tell the much broader audience of consumers how they are meeting their needs.

That was the message of Dr. J. Scott Vernon, Professor of Agricultural Communications at California Polytechnic Institute, San Luis Obispo, California, as he described the often confusing message that consumers are sending, through food retailers, in the marketplace.

Consumers are part of the equation when we talk about antibiotic stewardship, but it is not clear what they want, even though many say they want no antibiotics in their food. From an agricultural perspective, it is necessary to ask why and to understand how they get their information. Much of the dialogue is taking place in the media, and younger people especially are getting information on their smart phones. However, their depth of understanding perhaps is waning and most of them do not comprehend what animal agriculture is doing.

The mixed message comes from a segmented public, some that want organic or natural food, others confident in conventional, modern food production, and others concerned about the size of farms, about whether food is local or imported.

Producers are caught in the middle because they must respond to what consumers want. When the consumer puts pressure on the marketplace then the retailer responds, demanding “natural” and “wholesome” products. That puts pressure on producers to satisfy marketplace demands at the same time that they keep animals healthy and productive.

More producers need to talk about how they respond to marketplace signals. When consumers say they want antibiotic-free meat, producers can say they have done that,

providing a product free of antibiotics that meet federal withdrawal and residue standards.

California's 2008 ballot initiative – which prohibits confinement of farm animals in a way that does not allow them to turn around freely, lie down, stand up and extend their limbs – illustrates the challenge to animal agriculture. Animal rights advocates used very emotional video images. Agriculture tried to respond with scientific data and logic but discovered that emotional response often wins the day. Agriculture lost that initiative by a 63-37 margin.

Agriculture must tell its story in many different ways. One is to invite people to come to the farm, learn that safety protocols and employee training are in place. Another is to let consumers know about quality assurance programs that give them metrics that measure progress. Most producers want to make science-based decisions, to show the data that supports the way they raise animals. They want to see data that supports the way consumers want it done.

The level of collaboration among producers, industry, government and science will be critical to the outcome. Expect to see more innovation in science and techniques in raising animals and antibiotic resistance. The academic community needs funds to support the research at land grant universities to push the levels of science and technology to help animal agriculture.

There will be more confusion, marketing hype and hysteria. Agriculture needs to be careful how it responds to the majority of consumers and how it responds to the voice of the radical fringe. The loudest voices in the market are the activists who have time on their hands and have the money. Agriculture needs to respond in order to influence the debate.

In an environment in which people are skeptical about "big pharma," "big government" or "big ag," it is important that real people carry the message. When producers can look people in the eye and tell them what they are doing to solve the problem, they can succeed. What's necessary is to tell consumers that agriculture is a people business caring for people. Tell them that you want them to be well, you want them to be healthy, and you want them to be able to afford to buy the food you produce.

Panel Discussion: Retailers and Stewardship Programs

Dr. Terry Coffey, Chief Science and Technology Officer, Hog Production Division, Smithfield Foods, Smithfield, Virginia:

Stewardship entails communication not only externally to retailers and their customers but internally with people responsible for proper care of animals, emphasizing the importance of using antibiotics as little as possible but as much as necessary to insure animal health and well being and safety of food. Smithfield Foods, the largest hog producer in the United States, eliminated the use of medically important antibiotics in 2014, essentially adopting the tenets of FDA guidance. Consumer preferences are changing and the company is challenged to align its practices with customer values. Smithfield has some facilities that produce meat from hogs raised without antibiotics, an emerging theme in the market, and has been “in and out” of the practice depending on what customers want. Our customer, the retail meat buyer, is struggling as much, trying to respond to consumer demands. “Even if you don’t think the customer is always right, the customer is always right,” he said. It is important to consider a broad strategy to manage animal disease pathogens both viral and bacterial. Development of new tools for prevention and treatment must be encouraged in order to maintain animal health, well being and food safety. Having effective therapeutic antibiotics is essential.

Dr. David French, Veterinarian, Sanderson Farms, Laurel, Mississippi:

Whether poultry is produced traditionally or raised without antibiotics to fulfill a market niche, the goal is really the same – producers don’t want to use antibiotics unless absolutely necessary. Chain restaurant buyers tell us that their purchasing decisions are made with absolutely no science whatsoever, but on consumer survey findings that antibiotics to be the No. 1 concern and animal welfare No. 2. When the marketing manager of a retail chain says no science is involved, that bothers me as a veterinarian. So consumer education is critical. Sanderson explains its process to retailer customers and to consumers. It has increased advertising, launched a web site <http://www.sandersonfarms.com/truth-about-chicken/> and held opened its facilities to influential food bloggers. A group of about a dozen food bloggers toured from the hatchery to the broiler house to the packing plant, with only positive stories resulting. That kind of educational campaign pays off. Technology is crucial for sustainability of animal agriculture in the United States. A return to the 1950s way of raising chickens or cattle or swine would mean a lot of hungry people in the world. If technology is rejected, inefficiencies raising poultry without antibiotics would result in a bigger carbon foot print, more land, more houses, more water, more fecal waste and less food.

Dr. Ashley A. Johnson, Staff Veterinarian, PFFJ, LLC, a Subsidiary of Hormel Foods Corporation

Hormel Foods is committed to reducing the use of antibiotics at its hog production subsidiary, operating in four western states. The most important thing is keeping pigs healthy so there less need for antibiotics. It takes commitment; it takes time and demands proper biosecurity to prevent disease. Treatment costs money. The most important thing in reducing the use of antibiotics is having high health herds. Hormel Foods last year recognized the importance of the issue and created an antibiotic

working group that includes not only its internal personnel but also industry experts, subject matter experts, government officials and non-governmental organizations attacking the issue head on. The PFFJ subsidiary also has a health summit every year to keep up date, bringing in other veterinarians and experts to help us make sure that we are reducing the use of medically important antibiotics. Each of its four locations operates with a VCPR and monitors all its herds for antibiotic use and outcome. It allows the company to make decisions based on data, not on just guessing. It is important to tell consumers that our company has a quality management system to permit consistency and employee training in how to treat the animal. The typical consumer does not realize there is veterinary oversight of every animal in our care. It's something we need to tell consumers.

In responding to questions, the three veterinarians on the panel expressed unanimity about the need to do more to get the industry's message out in a variety of channels. PFFJ's Johnson said that consumers can come in and have one-on-one conversations at the meat case, presentations to schools and community groups, outreach to bloggers and social media messaging, using a uniform message.

They also agreed that the message should not disparage other segments of the protein industry. Smithfield's Coffey said that honest, truthful advertising is crucial. Sanderson's French said there was no problem with a competitor trying to serve a market niche but it was important to not "throw other segments under the bus." Public comment on Sanderson's advertising campaign has been mixed, he said, with some of it completely supportive but others confused in thinking that growth-promoting antibiotics must be a hormone.

Consumer opinion is shifting very fast, French said, and appears to be evolving into a market that will support three segments. One will be products raised without antibiotics, another will be poultry raised with only shared-class antibiotics but verified as raised with responsible use, and a third will be products raised with traditional antibiotics. "I hope all three persist," he said.

Getting to Yes: What Each Sector Needs to Forge a Collaboration for Antibiotic Stewardship

Animal agriculture needs to pursue continual collaboration within its own subdivisions – meat, poultry, dairy, aquaculture – and with many others to drive home the message that we will not allow antimicrobial resistance to wipe out all of us or to wipe out the food industry. That's the advice of Dr. Christine Daugherty, Vice President Sustainable Food Production, Tyson Foods.

She said that those stakeholders, among others, include the medical community, universities, consumers, retailers and food service companies, veterinarians, non-governmental organizations and nonprofits. All these interests need to be involved in finding solutions.

The decisions on antimicrobial use must allow for sustainable food production level if it is to benefit people, animals and the planet, she said. Knee jerk reactions will not solve anything.

The dilemma facing agriculture is that only 2 percent of the American population today are on the farm and that only 15 percent of Americans produce, process and market the nation's food. Tomorrow's consumer will be three generations removed from the farm, Dougherty said. It's no wonder they don't understand agriculture, let alone antimicrobial resistance.

The consumer today wants safe, affordable and nutritious food. Some willing to pay more for attributes such as organic or “natural” products and the marketplace gives those consumers choices. We all like choices. But such choices often are based on misinformation.

Agriculture and its allies have a responsibility to tell the story. It is important to educate consumers about what happens on the farm. Producers are being asked to provide answers. Retailers and others want to know what's happening and they often ask tough questions.

How Do We Bridge the Communications Gap?

Agriculture generally, and animal production specifically, face a never-ending challenge in helping the non-farm public understand how food is produced and the challenges of delivering the safe and wholesome food supply that consumers depend on at an affordable price.

Two communications executives with strong backgrounds in food and agriculture suggested several methods to bridge the gap in understanding between the perception of many in the non-farm community and the reality that confronts producers in their daily work.

Kim Essex, Partner and Director of the North America Food and Beverage Practice at Ketchum Public Relations, Denver, Colorado, likens the gap in understanding food to the rural-urban divide in American politics. It is almost like the two groups are on different planets, coming at the discussion from very different perspectives.

There is no magic message, she said, but public opinion research can help agriculture develop a message that will help others understand. Research has shown that farmers and veterinarians are credible, trusted messengers. It has found that most people accept that animals need to be treated for disease; they don't want animals to suffer. They also agree that it's good that medically-important antibiotics will no longer be used for growth promotion and accept the responsible use of antibiotics on sick animals.

Essex was surprised by what consumers said in focus groups. They believe that over-prescribing and patient misuse of antibiotics are the major contributors to the emergence of antimicrobial resistance but that agricultural use also contributed. That should suggest that agriculture's message is that everyone should do their part and we're doing ours.

Jacque Matsen, Senior Vice President of the Food and Agribusiness Practice at FleishmanHillard, Kansas City, Missouri, sees an opportunity to communicate with “Generation Z” – those born between 1995 and 2010 – a generation equally or more important than the millennial generation.

It is the first all-digital generation, very technology savvy, connected, diverse, realistic and future-focused and which wants to be part of the solution. This group is more likely to understand how agriculture uses technology. Agriculture can engage them in helping solve its challenges – or they will fix it themselves.

Because this generation is visual and demands brevity, they can be reached best with stories, Matsen said. People, rather than organizations, are natural story tellers. Many farmers and ranchers have begun to use social media to tell their stories. Those who succeed will have authentic, compelling stories that capture attention. They have to be better story tellers or

others will tell their story for them. There is power if we let those people loose to tell their stories. However, too many corporate legal policies creates a culture in which people think they have to be silent. It's holding back one of our most powerful armies of story-tellers.

Both expressed concern that animal rights activists may be doing a better job communicating their message because they use emotional arguments. "They do a very good job mobilizing," Essex said, "but we have the ability to tell better stories. We are better story tellers and we know animals better. From an organizational perspective, they have the advantage right now. The better we can connect with our communities and learn from that model is an opportunity."

Matsen said that agriculture should take a page from animal rights campaigners' playbook, recognizing that they sometimes lack factual information. Although they are saying things that are inaccurate, they are doing so from a place of passion and conviction. Agriculture needs to summon its own passion and conviction to tell its story without using inaccurate information.

Building a Coalition for a One Health Approach to Preserving Antibiotic Effectiveness

Dr. Bernadette Dunham, Visiting Professor, Milken Institute School of Public Health, George Washington University, Washington, D.C., and former director of the FDA Center for Veterinary Medicine, said efforts to combat antimicrobial resistance have gone global.

International travel increases opportunities for microbes to share genetic material and to spread globally. The 2015 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) has been shared by international bodies in a global action plan to slow the emergence of resistant bacteria and strengthen national One Health surveillance efforts.

The United Nations General Assembly, at a high level meeting on AMR in September 2016, embraced the World Health Organization (WHO) Global Action Plan on Antimicrobial Resistance and supported a multi-sector One Health approach to address the problem. She said the One Health Act of 2016 (S.2634) introduced in March 2016 by Senator Al Franken of Minnesota is an example of political action that is a positive step forward. The bill would encourage federal agencies to create a comprehensive strategy to outline ways they can work together to address infectious diseases in animals and the environment in order to prevent spread into human populations.

Antimicrobial stewardship is something in which everyone has a role to play. Each of us can be an agent of change. Willingness to reach across the aisle to bring the needed expertise to the table in a collaborative, multidisciplinary approach is rewarding and efficient as it allows us to think outside the box. We absolutely have to engage policymakers and lawmakers; antimicrobial resistance is a bipartisan issue.

Among CARB goals are to reduce incidence of infection through effective sanitation, hygiene and infection prevention; to advance development and use of rapid diagnostic tests; to optimize the use of antimicrobial medicines in human and animal health care; to develop the economic case for sustainable investment, taking account of the needs of all countries, and to increase investment in new medicines, diagnostic tools, vaccines and other interventions.

Noting that November 3 was the first global One Health Day, Dunham said that the American Veterinary Medical Association (AVMA) was one of the first to pull together task force to define

the One Health concept. Its work in 2008 set the stage for how we can reach out and work together.

The Minnesota Department of Health adopted a statewide One Health approach, appointing Dr. Amanda Beaudoin as Director of One Health Antibiotic Stewardship earlier in 2016. Beaudoin said her office grew out of collaboration among the state epidemiologist, the state Department of Agriculture, state hospital association and public health organizations.

The state's One Health planning process included a steering committee meeting in fall 2015 and a summit meeting in January 2016 with more than 100 people from multiple agencies and disciplines and the governor's office. The summer and fall of 2016 saw the launch of a strategic plan and actively seeking out resources to begin implementation.

The program's message is that human, animal and environmental health is inseparable and that all antibiotic use leads to resistance. There is a contribution from every sector using antibiotics. The lack of proof of harm is not an argument for irresponsible use, she said, and greater abuse in other discipline is not an excuse.

Beaudoin expects the effort will improve the understanding of One Health antibiotics stewardship across disciplines. In human antibiotics stewardship, it hopes to make tracking tools available, identify health care facility needs for tracking data, benchmarking and antibiotics use policies; develop state human health goals specific to syndromes and settings, and utilize an honor roll recognition system for health care facilities.

To improve animal antibiotics stewardship, her agency encourages people to come to it for information, promotes producer quality certification and facilitates public engagement on stewardship. It hopes to increase the capacity of its veterinary diagnostic laboratory.

It also plans to improve understanding of environmental impact on resistance. It will try to put together a tool that takes account of all inputs into the system, human, animal health and the impact of antibiotics disposal on the environment.

Panel 1 – Leadership and Responsibility for Antibiotic Stewardship:

Dr. Bob Easter, President Emeritus, University of Illinois

Leaders of the Association of Public and Land Grant Universities (APLU) and the Association of American Veterinary Medical Colleges (AAVMC) appointed a task force to look at their responsibilities in antimicrobial resistance. The group noted the role of the academic community in research and education. In creating a sense of responsibility, realize that livestock production is in two different systems. One is in large, integrated units (cattle feedlots, swine and poultry companies with professional staff veterinarians and sophisticated record-keeping to document diagnosis and use). Another and significant sector is the small-holder growers with a single animal to several thousand who are reliant on extension or product provider advice, who may or may not have professional vet expertise. The task force discovered that 20 percent of the counties in the United States do not have a food animal veterinarian available. Many stakeholders have responsibility for stewardship. Producer groups, especially species-specific organizations, have quality assurance programs. Veterinary

associations are responsible for continuing education and accreditation of academic programs. At some level there is an individual responsibility. The veterinarian makes a determination of proper use. The feed manufacturer makes sure that the product is appropriate. The producer is responsible for proper use on the farm operation.

Dr. Kurt Stevenson, Medical Director, Microbial Stewardship Program, Wexner Medical Center, The Ohio State University

CDC warned in 1999 that if antibiotic resistance is not addressed, we will reach the point where drug choices are not available. We are at that point now. We have patients with pathogens for which there are no drugs available to treat them. We see this on a regular but not daily basis. For some, the choice is very limited and requires more expensive drugs and those with higher toxicity. Antibiotic stewardship is not only about limiting inappropriate use but – what I try to teach -- it's also about optimizing use, the right selection of a drug, the duration of therapy. For too long, the course of antibiotics has been much longer than it needed to be. It is estimated that 200 million to 300 million antibiotics are prescribed annually, about 45 percent of them for outpatient use. Some 25-40 percent of hospital patients receive antibiotics, of which anywhere from 10 percent to 70 percent are unnecessary or sub-optimal. Antibiotics are unlike any other drugs, in that use of the agent in one patient can compromise its efficacy in another. Describing collaboration with One Health programs in Ethiopia and China, he saw “a lot of movement to address this problem as well. It's got to be addressed globally.”

Dr. Tim LaPara, Professor, Department of Civil, Environmental and Geo-Engineering, University of Minnesota, Minneapolis-St. Paul

The fact is that antibiotic use anywhere leads to antibiotic resistance. Even if they are used only in the most optimal way, resistance would emerge. Every living creature is a significant bacteria factory and human and animal fecal material is a substantial reservoir of antimicrobial resistance that ends up in the environment. Antibiotic stewardship in the environment means better treatment and disposal of fecal material, especially high temperature treatment before land application of animal waste. We don't know much on antibiotic resistance in the environment. We need a lot more money and a lot more research to understand this. We need less sludge and more land. When farmers applied waste only for agronomic purposes in Minnesota, we saw less resistance.

Panel 2 – Leadership and Responsibility for Antibiotic Stewardship:

Dr. Nate Smith, Director and State Health Officer, Arkansas Department of Health:

The idea that one-third to one-half of antibiotics prescriptions written for human medicine is inappropriate or unnecessary is unacceptable. But one would be hard pressed to find a physician who would admit that he should not have written such a prescription. The classic case is upper respiratory tract infections that almost are caused by viruses yet antibiotics are frequently written for those. As poultry farmers know, viral respiratory infections can go on to bacterial infections. So in the mind of the physician, that antibiotic may be appropriate. Many times, physicians are working under pressure and need to make decisions quickly and some level of uncertainty.

Many of them are working outside their area of expertise. Everyone feels like they can prescribe antibiotics even though they are not trained in infectious diseases. Many are under pressure from patients and their families. The frustration from the animal side about simplistic answers also exists on the human side. There is a concentration in the South of high prescribing states. Part of it is the reality we deal with, a high level of poverty, higher rates of obesity, higher rates of pulmonary disease, and general health tends to be lower. Prescription opiates see a similar pattern with high prescription rates in southern states.

Dr. Eric Moore, Director of Technical Services - North America, Norbrook Pharmaceuticals Ltd.:

Compared with what their parents and grandparents had, today's animal food producers are very fortunate to have a lot of tools, such as antibiotics. The industry does not want to lose those tools; they are essential for the care of our animals. How we maintain their continued availability is critical. Veterinarians play an important role in that. We have roughly 66,000 practicing veterinarians in the United States and 105,000 in government or industry – a very small group of people put in charge of veterinary oversight of animal agricultural production. It is a role that veterinarians will take as a challenge. But it will require a lot of education. Our current education system does not expose all veterinary students to food animal health. So there is a challenge in educating within our profession and outside. Part of the biggest issue for veterinarians is our great reputation, but we don't have a consistent brand. We have veterinarians that don't understand production medicine but they become the resource of the consumer and that results in misinformation.

Dr. Kathy Talkington, Project Director, Antimicrobial Resistance, Pew Charitable Trusts:

This is a compelling problem. It is predicted that the number of deaths due to antibiotic resistance will outpace deaths from cancer. Recognizing this, it is important not to stay on the current course. Society does not have all the information needed to know the exact next steps but there is enough information to make progress. Three areas need leadership. First, the goal must be defined. Can antibiotics use be reduced and also maintain both human and animal health? Second is the definition of stewardship. It is important because it is a useful tool to demonstrate progress. The third focus is difficult but critical – data and metrics. There is some data but not enough to begin to demonstrate progress. Part of the need is more resources for USDA and FDA to collect the appropriate information. Part of what the Pew Trusts does is advocate for resources for those agencies. Now that we know that one of three antibiotics prescriptions in human medicine is not necessary, it is not perfect but it gives us a benchmark for improvement. There is an opportunity for leadership to develop a set of metrics that a broader community can agree on. There is a heightened interest and awareness on a global level. We need to agree on the key components of metrics.

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