Situation Analysis:
The antibiotic resistance report from the President’s Advisory Council on Science and Technology (PCAST) provides additional support for the Food and Drug Administration’s policy on judicious use of antibiotics in food animals. In supporting the FDA policy they join the Animal Health Institute, farmers and ranchers and veterinarians who are working every day toward compliance.

We expect media outlets to pick up messaging from the detractor voices in this issue and further their argument of a “prevention loophole”: the idea that antibiotics previously used for purposes of promoting growth will continue to be used under the guise they are being administered for prevention.

What is PCAST?
Beginning in 1933 with President Franklin D. Roosevelt’s Science Advisory Board, each President has established an advisory committee of scientists, engineers, and health professionals. Although the name of the advisory boards has varied over the years, the purpose of each remains the same—to provide scientific and technical advice to the President of the United States.

What does the report say?
The report calls for three things to be done: more surveillance, stewardship and continued antibiotic development.

1). More Surveillance
The report will recommend strengthening of state and local infrastructure and new, high end tools like DNA sequencing.

2). Stewardship
In human healthcare the report will call for the federal government to use tools at its disposal to promote acute adoption of best practices, including things like CMS reimbursement, physician reporting and Federal grants.

3). Continued antibiotic development
The Chair touched on the issue of alternatives to agricultural antibiotics. He said the group recognized and valued the benefits of antibiotics in agriculture but would like to develop alternative approaches for growth and prevention in order to decrease the need for antibiotics. On the human side, the report will call for streamlined clinical trials, FDA changes to the regulatory pathway and more financial incentives for research.

How is the idea of antibiotics use for growth discussed?
On the topic of judicious use, the report will say the FDA Guidance is an important step and he cited the full cooperation of all companies in agreeing to withdraw growth claims. He said there should be a decrease in use as a result.

Also, he addressed the objection that producers will continue to use ABX for growth using the “prevention loophole’ but he said he doesn’t think veterinarians will do that.
Lastly, during the public comment timeframe, there were brief oral comments from Pew, KAW and USPIRG, claiming that statements by AHI and companies show they will continue selling products for growth under the guise of prevention, claiming that use must come down if the FDA process is to be effective, and complaining about the weakness of veterinary oversight due to removal of VCPR.

**What are the expected media implications on this?**
We expect media outlets to pick up messaging from the detractor voices in this issue and further their argument of a “prevention loophole”: the idea that antibiotics previously used for purposes of promoting growth will continue to be used under the guise they are being administered for prevention.

**What has been reported thus far?**
A Reuter’s story dated July 23, 2014, titled “Panel’s report likely to tie farm antibiotics to human resistance,” highlights that “a White House advisory committee is expected to acknowledge the link between antimicrobial resistance in humans and livestock being fed antibiotics when it issues its report in the next few weeks, according to the transcript of a committee meeting held earlier this month. But how much of the public health problem can be attributed to such farming practices remains unclear, according to the transcript of a July 11 meeting of the President's Council of Advisors on Science and Technology (PCAST).”

Also, an OpEd was run in the New York Times on July 31 by Ruth Reichl. Titled “The F.D.A.’s Blatant Failure on Food,” the OpEd states “The F.D.A. has issued a toothless voluntary guidance document for the industry, which requires no action to reduce antibiotic use and will therefore do little to nothing to stop the spread of antibiotic-resistant superbugs.

**How does the CARB report play into this?**
CARB – standing for “Combating Antibiotic Resistance Bacteria”— is resource guidance for the Fiscal Year (FY) 2016 budget process to enable government departments and agencies to allocate appropriate resources to implement the CARB priorities.
- The report details a list of all areas affected by the PCAST report and offers directive of how to implement the program into 2016 budgets, including these specific actions for the agriculture community:
  - Minimize the Development of Resistant Bacteria and Preserve the Efficacy of New and Existing Antibiotics
    - Eliminate use of medically important antibiotics for growth promotion (production use) and bring remaining therapeutic use (treatment, control, prevention) under veterinary oversight.
    - Identify and implement measures to foster stewardship of existing antibiotics in animals.
  - Strengthen National One-health Surveillance Efforts to Combat Resistance
    - Develop, expand, and maintain domestic veterinary diagnostic and food safety laboratory infrastructure to conduct testing and disseminate results from standardized antibiotic susceptibility testing and bacterial characterization for select zoonotic and animal health pathogens.
    - Enhance monitoring of: (1) antibiotic drug resistance trends at multiple points in the production chain in food-producing animals and in retail meat; (2) antibiotic sales, antibiotic usage, and management practices in food-producing animals; and (3) antibiotic resistance trends in food-borne pathogens from humans through the National Antimicrobial Resistance Monitoring System.
  - Develop and Promote Use of New, Rapid, One-health Diagnostic Technologies to Identify and Characterize Bacterial Resistance
Accelerate Scientific Research and Facilitate the Development of New Antibiotics, Other Therapeutics, Vaccines, and Diagnostics

Improve International Collaboration and Capacities for Prevention, Surveillance, and antimicrobial Research and Development.

- Collaborate with WHO, Food and Agriculture Organization of the United Nations, World Organization for Animal Health, and other international efforts focused on the development of harmonized, laboratory-based surveillance capacity to monitor antibiotic resistance in relevant animal and foodborne pathogens.

**Addendum: Current USFRA Messaging**

Are antibiotics used for farm animals creating superbugs?
Farmers, ranchers and their partners recognize that the emergence of antibiotic-resistant bacteria is a concern in both human and animal medicine. They are committed to deploying and developing production practices that keep the risk of the development of resistance in human health extremely low.

Although there has been no proven link to antibiotic treatment failure in humans due to antibiotic use in animals for consumption, they are working to minimize future risk. Everyone – farmers, ranchers, veterinarians, doctors, researchers and companies working in animal or human medicine needs to work collaboratively to protect animal and human health.

The majority of MRSA clinical infections in humans are due to human (versus livestock) strains of MRSA, yet many people are unfairly blaming the prevalence of MRSA in humans on agriculture. To date, no clinical case of MRSA in a human related to livestock has been identified in the United States.

To clarify, antibiotic resistant bacteria can be foodborne or non-foodborne. Non-food strains began emerging decades ago in hospital settings and are not linked to animals in our food system. These are the vast majority of the cases that are so hard to treat and are making people sick.

There are occasional cases of antibiotic resistant foodborne bacteria such as antibiotic resistant salmonella. But salmonella is killed when food is cooked and handled properly. So, people becoming ill from antibiotic resistant foodborne bacteria and not being able to be treated in some manner, is rare if not almost non-existent.

What steps are farmers, ranchers and the agriculture industry at-large taking to minimize development of antibiotic resistant bacteria?
The industry is taking proactive steps to ensure that antibiotics are being judiciously used to minimize the development of antibiotic resistant bacteria. Specifically:

No more use for growth purposes: Antibiotics important to human medicine used for growth purposes in food animals will be eliminated within three to four years in accordance with the FDA Guidance 209 and 213 (FDA). (Note: the exact timing depends on the final issuance of the FDA guidelines expected in 2013)

Use under the care of a veterinarian: Veterinarian oversight is critical to farmers’ and ranchers’ use of antibiotics. In particular, medically critical antibiotics to human health are administered under the guidance of a veterinarian. Here are the facts: Farmers can administer antibiotics to animals through injection, feed, water or, occasionally, in pill form.
The oversight of a veterinarian for all uses of medically important antibiotics is part of FDA Guidance 209 as well part of farmers’ routine practice through quality assurance programs. Antibiotics not medically important to humans will still be available over the counter for animals use.

Using less medically critical antibiotics: Not all antibiotics are the same. For example, some are used in both people and animals. Some are used primarily in animals and are not medically important to people – and aren’t leading to the development of antibiotic resistant bacteria that is harmful to people. Of the antibiotics used in farm animals today, about one third are called ionophores and are neither medically important, nor used in humans. Further, use of medically important antibiotics actually decreased from 2010 to 2011 on farms while meat production increased (hurdhealth.com; FDA reporting)

Strict Approval Process and Monitoring: The FDA has a rigorous approval process for antibiotics labeled for use in animals raised for food. Farmers, ranchers and veterinarians are legally and ethically obligated to follow FDA’s requirements for the use of antibiotics on the farm. The FDA has used its authority to limit the use of critically important antibiotics. For example, these critically important antibiotics are only used in animals for the treatment and control of diseases – and not for promoting growth or preventing disease. In addition, regulatory approval of antibiotics is, in many ways, stricter for farm animal use than for human use because antibiotics used in animals must be proven to be safe for the animals, the environment and for people. Antibiotics approved for human use only need to be proven to be safe for people. And since 1998, the FDA has implemented the National Antimicrobial Resistant Monitoring System (NARMS) to create an early warning system to monitor risk of the development of antibiotic resistant bacteria in humans, animals and meat for consumption.

Has the use of antibiotics in farm animals led to antibiotic-resistant bacteria in humans?
Farmers, ranchers and their partners recognize that the emergence of antibiotic-resistant bacteria is a concern in both human and animal medicine. They are committed to deploying and developing production practices that keep the risk of the development of resistance in human health extremely low.

Although there has been no proven link to antibiotic treatment failure in humans due to antibiotic use in animals for consumption, they are working to minimize future risk. Everyone – farmers, ranchers, veterinarians, doctors, researchers and companies working in animal or human medicine needs to work collaboratively to protect animal and human health.

Is there concern that antibiotics are being overused on farm animals?
Statistics often reported in media claiming overuse of antibiotics on farms are often used in misleading ways. Consider:

- Not all antibiotics are used for all purposes. Different antibiotics are used to treat different bacteria in animals and humans.
- About 1/3 of the antibiotics used on farms aren’t used in human medicine at all – meaning if resistance to these drugs did develop, it will have little impact on public health. According to the Centers for Disease Control and Prevention (CDC), the diseases caused by antibiotic resistant bacteria with the most impact on human health are spread by human to human contact, such as through healthcare settings. For example, human MRSA strains responsible for the majority of human MRSA cases in hospital and community settings, but they are not related to livestock. (FDA and CDC).

Why do farmers and ranchers use antibiotics on farm animals raised for food?
Healthy animals are the basis of a healthy, humane and safe food system. That is why it is so important to prevent and control diseases in farm animals and to treat animals when they are sick. Farmers and ranchers use antibiotics judiciously to keep the potential risk extremely low of developing antibiotic resistant bacteria that is harmful to people.
They work closely with veterinarians and under the guidelines of the FDA in the best interests of animal welfare and public health. Farmers and ranchers use a variety of tools including vaccines, good nutrition programs and proper housing to keep animals healthy. Antibiotics are only one tool in a plan of good production practices to raise healthy farm animals.

When sick animals are being treated, farmers and ranchers carefully identify them and monitor them closely until they return to good health. If farmers did not treat sick animals, many would suffer and die. This would be inhumane – and even those who say they are against antibiotic use, such as Consumers Union, agree that sick animals should be treated.

**What kind of oversight is in place for antibiotic use in farm animals used for food?**
Veterinarian oversight is critical to farmers’ and ranchers’ use of antibiotics. In particular, medically critical antibiotics to human health are administered under the guidance of a veterinarian. Here are the facts:

- Farmers can administer antibiotics to animals through injection, feed, water or, occasionally, in pill form.
- The oversight of a veterinarian for all uses of medically important antibiotics is part of FDA Guidance 209 as well part of farmers’ routine practice through quality assurance programs. Antibiotics not medically important to humans will still be available over the counter for animals use.
- Antibiotics important to human medicine used for growth purposes in food animals are being phased out within three to four years in accordance with the FDA Guidance 209 and 213 (FDA).

Additionally, the FDA has a rigorous approval process for antibiotics labeled for use in animals raised for food. The FDA has been active in monitoring farm animal use of antibiotics and adjusting regulations accordingly. Farmers, ranchers and veterinarians are legally and ethically obligated to follow FDA’s requirements for the use of antibiotics on the farm.