

November 30, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20855

RE: Docket No. FDA-2015-N-2768
Collecting On-Farm Antimicrobial Use and Resistance Data

To Whom It May Concern:

The American Farm Bureau Federation (Farm Bureau) appreciates the opportunity to comment on the proposed efforts to collect on-farm antimicrobial use and resistance data, an objective of the President's Action Plan to Curb Antibiotic-Resistant Bacteria.

Farm Bureau's ranch and farm family members across the country raise all species of food-producing animals—from beef and dairy cattle, chickens and pigs to an array of smaller species such as sheep, ducks, goats and honeybees. We are proud to provide America's consumers and those around the globe with safe, affordable and high quality food. We are committed to responsible stewardship of land and livestock and take very seriously the well-being of livestock raised for food production.

Our Philosophy

Good production practices and humane care for farm animals are paramount in our efforts to provide wholesome meat, milk, eggs and other animal-based food products. We agree that antibiotics must be used in a responsible way—the right drug, the right dose, at the right time—in order to protect animal health and welfare as well as drug efficacy.

Farm Bureau supports a reliance on sound science as the basis for decision-making and policy development on the use of antimicrobials. We support compliance with antibiotic withdrawal guidelines and residue restrictions. Farm Bureau encourages livestock producers to participate in industry-led quality assurance programs (such as Pork Quality Assurance Plus or Beef Quality Assurance) to improve animal care, to reduce risk of violative drug residues and to help ensure food safety. We recommend the veterinarian-client-patient-relationship (VCPR) for on-farm guidance to manage animal health and use of animal health products; the VCPR should remain confidential, along with animal health records of the farm.

The multi-agency approach of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service and Food Safety and Inspection Service is crucial to the effective surveillance of resistance trends. Farm Bureau advocates for the continued critical role of the National Antimicrobial Resistance Monitoring System and the National Animal Health Monitoring System as mechanisms to gather antibiotic use and bacteria-resistance data. We encourage the additional research and survey work of the Agricultural Research Service, National Agricultural

Statistics Service and Economic Research Service to contribute to antibiotic use and resistance data.

Priorities for Data Collection

Farm Bureau opposes required on-farm reporting of antibiotic use for animals. However, we do recognize that more information could be useful in helping to better understand resistance trends and to also refine animal agriculture's efforts to use antibiotics responsibly. Toward that end, we have identified several priorities that we think must characterize any on-farm data collection effort.

- **Voluntary Participation**—Farmers and ranchers should be allowed optional involvement in surveys, studies and on-farm research projects. We do not support mandatory participation.
- **Confidentiality**—Participants in data collection efforts (surveys, sampling or studies) must be assured of the confidentiality of their farm information, including assurance that any farm-level data will be exempt from Freedom of Information Act requests.
- **Cooperation with Industry Efforts**—Industry-led work to develop antibiotic use models, engage farmers and ranchers in research projects, etc., should be viewed as valuable additions to the data collection goal. Private data sources may also provide useful and substantive data on farm use of antibiotics.

Concerns and Challenges

This ambitious proposal to collect antibiotic data regarding on-farm use amounts, purposes, duration, etc., does prompt concerns which cannot be overlooked.

- **Trust and Cooperation**—The accusatory tone of some antibiotic resistance discussions suggests that antibiotics use in livestock is the sole culprit of resistance in humans. Such unfair and unsubstantiated accusations have left farmers and ranchers understandably wary of regulatory agencies and skeptical of unbiased research claims.

How will the agencies provide assurances for data privacy and confidentiality? Who will access farm information and results of survey and research work? Will good faith participation by farmers and ranchers be used for future enforcement actions? These are the types of questions that must be addressed. Agencies must conduct this work ever mindful of the cooperative and trusting relationship that must be maintained with the industry.

- **Funding and Infrastructure**—The array of expanded surveys, increased frequency and types of studies, and other expanded monitoring come at a substantial impact to the agencies involved. Adequate budget and resources will be an obstacle for plan implementation. Will additional appropriations be sought? Will existing programs or services be reduced or terminated to pay for the data collection? How might public-private partnerships support this plan with funding or infrastructure resources?
- **Outcomes and Application**—Collected data will require thoughtful interpretation and application. For example, gross volume of antimicrobial use will not reveal potency or

efficacy of products used in animals. Reducing the volume of antimicrobials in food animals will not necessarily indicate improvement to judicious use.

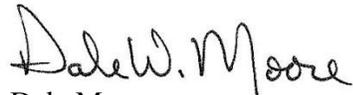
Will public health stakeholders demand hasty regulatory changes, rather than allowing for long-term transitions and the development of workable alternatives? How might best practices change without removing tools from livestock producers and jeopardizing animal health?

Conclusion

Farm Bureau thanks the Department of Agriculture, the Food and Drug Administration and the Centers for Disease Control and Prevention for their collaborative work in this data collection effort. We recommend sustained efforts to build and maintain working relationships with farmers and ranchers, academic experts, food processors and other stakeholders.

Antibiotics have transformed the fields of human medicine and animal health. All users must be responsible stewards so that these critical tools will remain effective. Better data on the use patterns of antimicrobials on farms will be a valuable contribution in efforts to combat resistance.

Sincerely,

A handwritten signature in black ink that reads "Dale W. Moore". The signature is written in a cursive style with a large initial "D" and "M".

Dale Moore
Executive Director
Public Policy