

Johns Hopkins Center for a Livable Future
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

To Whom It May Concern:

The Johns Hopkins Center for a Livable Future (CLF) is an interdisciplinary academic center based within the Johns Hopkins Bloomberg School of Public Health. The Center engages in research, policy analysis, education, and other activities guided by an ecological perspective that diet, food production, the environment, and public health are interwoven elements of a complex system.

We appreciate the efforts underway by the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC) to obtain public input on possible methods of collecting on-farm antimicrobial drug use and resistance data. In the comment below, we recommend methods of data collection and reporting and address the need to establish a reliable source of funding for ongoing data collection and monitoring.

1. Medically-important antimicrobial drug use data should not be considered confidential business information and should thus be publicly-accessible.

Following Guidance for Industry numbers 209 and 213, judicious antimicrobial drug use in animal agriculture is intended to be restricted to therapeutic uses. Under the assumption that medically-important antimicrobial drugs are no longer permitted for nontherapeutic uses, reporting data on the uses of these drugs will not impact the competitive position of animal producers. Thus, information on antimicrobial drug use should not be protected as confidential business information.

2. Drug use in animal agriculture should be tracked through reporting of VFDs and veterinary prescriptions to a centralized database.

Veterinary Feed Directives (VFD) and veterinary prescriptions of medically important antimicrobial drugs—required in every state in the context of a veterinarian-client-patient-relationship (VCPR)—contain information on the species, number of animals to be treated, location of the animals, date of treatment, name of the drug, indication for use, level of the drug, feeding instruction (including withdrawal time), and an expiration date.¹ According to the FDA’s VFD final rule, when a VFD or prescription is issued, the veterinarian, client (animal producer), and distributor (e.g., feed mill operator) must keep records of the VFD or prescription for a minimum of two years.

A joint program should be developed and funded under the FDA, USDA, and CDC to collect, manage, and report data from VFDs and prescriptions on antimicrobial drug use in food animals. This joint program should create an electronic database to aggregate information on the location, species, and number of food animals receiving medically important antimicrobial drugs and the type and indication for use of those drugs in food animal production. Veterinarians should submit all VFDs and prescriptions of medically-important antimicrobial drugs to this electronic database within 30 days, similar to a prescription drug-monitoring program (PDMP)—a system that is well established in human medicine.

Information contained in this database should be de-identified (but retain location information at the state level) so that a version may be made available to the public. The joint program responsible for maintaining this database should release annual reports with national and state summaries of the prescription of medically important antimicrobial drugs, comparisons among animal species, and summaries of disease and infection occurrence. Veterinarians’ rapid reporting of VFD and prescription data, the simultaneous de-identification of this information for an electronic database, and the public accessibility of such a database would provide quantitative, timely, and transparent data on the prescription of medically important antimicrobial drugs for use in food animals.

A VFD/prescription database would provide a key component of a tracking system that could be used to identify patterns in disease and antimicrobial drug use. Analysis of these patterns could raise questions (e.g., why a certain antimicrobial drug therapy is repeatedly necessary in certain geographic areas or species) that could lead to research or targeted interventions to curb the nontherapeutic use or misuse of antimicrobial drugs. Denmark’s VetStat tool provides a powerful example of a similar data collection and tracking system and was established with the following objectives: “1) monitor veterinary usage of drugs in animal production; 2) help practitioners in their work as farm advisors; 3) provide transparency as a basis for ensuring compliance with rules and legislation; and 4) provide data for pharmaco-epidemiological research.”² Early analyses of the surveillance system confirmed that data

¹ Guidance for Industry #120: Veterinary Feed Directive Regulation. U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Veterinary Medicine. September 2015. Retrieved November 20, 2015 from <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>

² Stege H, Bager F, Jacobsen E, Thouggaard A. VETSTAT-the Danish system for surveillance of the veterinary use of drugs for production animals. *Prev Vet Med.* 2003; **57**:105-115.

were of sufficient quality for valid statistical description and analysis. An analogous database tool must be created in the U.S. to similarly track prescription and usage of medically important antimicrobial drugs, allow for the analysis of patterns, and catalyze research and action in the event of misuse. Additionally, tracking administration of these drugs would allow for the identification of potential “bad actor” veterinarians with patterns of frequent prescription of medically-important antimicrobial drugs that may suggest use for nontherapeutic purposes, facilitating remedial actions.

3. The scope of NARMS should be expanded to consider other health-relevant foodborne pathogens linked to antibiotic use in food animals.

Examinations of an expanded set of pathogens, including those arising from animal agricultural antibiotic use, by the National Antimicrobial Resistance Monitoring System (NARMS) are needed to investigate relationships between antimicrobial drug use—provided by the proposed VFD/prescription database—and resistance data in humans, animals and retail animal products.

To accommodate these needs, NARMS should be expanded to include isolation of *Staphylococcus aureus* and *Klebsiella pneumoniae* in addition to the bacteria it currently monitors. There are an estimated 80,000 cases/year of Methicillin-resistant *Staphylococcus aureus* (resulting in 11,000 deaths/year) and 7,900 cases/year of *Klebsiella pneumoniae* (resulting in 520 deaths/year).³ Studies have isolated methicillin-drug resistant *Staphylococcus aureus* (MRSA) and resistant *Klebsiella pneumoniae* on retail meats and suggest that contaminated meat is a potential vehicle for transmission of these resistant bacteria from food animals to humans.^{4,5} Considering their potential links to food animal production and their significant public health burdens, it is critical that these pathogens be included in future iterations of NARMS.

Additionally, limitations of NARMS identified in a 2011 GAO report must be addressed in order to collect data that better estimates antimicrobial resistance in food animals and retail meat; namely, farm and processing plant sampling should be randomized, and the number of state participants in the retail meat sampling program should be increased.⁶

³ Centers for Disease Control and Prevention (CDC). Antibiotic resistance threats in the United States, 2013. Atlanta: CDC; 2013. Available from: <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>

⁴ Davis GS, Waits K, Nordstrom L, et al. Intermingled *Klebsiella pneumoniae* Populations Between Retail Meats and Human Urinary Tract Infections. *Clin Infect Dis*. 2015:1-8. doi:10.1093/cid/civ428.

⁵ O'Brien AM, Hanson BM, Farina SA, Wu JY, Simmering JE, Wardyn SE, et al. (2012) MRSA in Conventional and Alternative Retail Pork Products. *PLoS ONE* 7(1): e30092. doi:10.1371/journal.pone.0030092

⁶ United States Government Accountability Office. Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals. GAO-11-801: Published: Sep 7, 2011. Publicly Released: Sep 14, 2011. Available from: <http://www.gao.gov/products/GAO-11-801>

4. A sustainable funding stream is needed to support this critical public health data collection effort.

The September 30, 2015, public meeting on this issue clarified that funding for on-farm antimicrobial drug use data collection has not been identified. A joint program under the FDA, USDA, and CDC must be developed and funded to create, monitor, and publish reports on an electronic VFD/prescription database. This system would have lower costs than other suggested methods of data collection because it would aggregate data from VFDs, which veterinarians will be required to generate.

5. A substantive evaluation plan should be established and launched in tandem with the data collection effort.

Evaluation is an integral part of public health practice and must accompany federal guidance for industry on the use of antimicrobial drugs in order to establish and maintain judicious, therapeutic use of such drugs. It is required in order to assess progress in the elimination of non-therapeutic uses of antimicrobial drugs and identify areas where more research or alternative production systems are necessary.

We urge you to consider these data collection, aggregation, and reporting strategies and fund a program to oversee these efforts. We firmly believe that the proposed measures described in this comment would allow for the generation of usage information that would be critical for informing sound public health policy regarding antibiotic use in food animal production. Please do not hesitate to contact us if you have any questions.

Sincerely,

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