

Friday, September 9, 2016

Mr. Kevin Shea  
Administrator of the Animal and Plant Health Inspection Services  
U.S. Department of Agriculture  
1400 Independence Avenue, S.W.  
Washington, D.C. 20250

ATTN: Comment Docket No. **APHIS–2016–0023; Notice of Request for Approval of an Information Collection; National Animal Health Monitoring System; Antimicrobial Use Studies**

Dear Mr. Shea:

The Pew Charitable Trusts (Pew) strongly supports the U.S. Department of Agriculture (USDA)'s efforts to work collaboratively with the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and other stakeholders to improve the collection of on-farm antimicrobial use and resistance data. Pew urges the agency to commence the planned collection of new antimicrobial use data associated with the National Animal Health Monitoring System (NAHMS) as quickly as possible, to continue the data collection for more than the currently-requested three years, and to consider expanding the data collection beyond the current scope of antimicrobial use in swine and feedlot cattle.

Pew is an independent non-partisan research organization which applies a rigorous, analytical approach to improve public policy, inform the public, and stimulate civic life. In our work on antibiotic resistance, we seek to reduce the inappropriate use of antibiotics in human healthcare and animal agriculture and to foster innovation in drug development.

Data on the use of antimicrobial drugs in animal agriculture should be nationally representative, timely and reflective of current use practices, as well as detailed and specific. Such data are foundational for the development and evaluation of public policies to reduce the inappropriate use of antibiotics, with the ultimate goal of containing the emergence of antimicrobial resistance. For this reason, improving on-farm antimicrobial usage data collection is a central component of the World Health Organization (WHO)'s Global Action Plan on Antimicrobial Resistance<sup>i</sup> and a priority for governments around the world.<sup>ii</sup> Pew supports the efforts of USDA, FDA and CDC to improve and harmonize national data collection efforts in the United States and appreciates the various outreach efforts the agencies have engaged in over the past months to solicit stakeholder comments on this important topic.

Pew generally agrees with the approach outlined in July's Federal Register Notice<sup>iii</sup> and further described in USDA's publication 'Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan',<sup>iv</sup> including the proposals to conduct surveys annually, to afford the same confidentiality protection to the collected data as to current NAHMS data, and to use the data to, among other objectives, evaluate the impacts of FDA policy changes. However, Pew makes the following recommendations to further strengthen the antimicrobial use data collection:

- **Collect information on antimicrobial use through all relevant drug administration routes.**

According to USDA’s publication ‘Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan’,<sup>v</sup> the planned studies will “provide annual national estimates of antibiotic use in feed or water.” The vast majority of antimicrobials are currently administered to food-producing animals through feed or water<sup>vi</sup> and the FDA’s policy changes specified in Guidance 213<sup>vii</sup> only impact their use in feed or water. However, other administration routes can be common in certain operations. For instance, according to the NAIIMS ‘2011 Feedlot’ study, about 50% of queried feedlots routinely gave injectable antibiotics as part of new cattle processing, and nearly 20% of feedlots used a second processing procedure that involved injectable antibiotics.<sup>viii</sup> Therefore, injectable antibiotics are an important part of antibiotic use practices on these feedlots. Moreover, because FDA’s policy changes only affect feed and, to a lesser extent, water drugs, some antibiotic use practices may shift to a greater use of other administration routes such as injections. Therefore, antimicrobial use through all relevant administration routes should be tracked.

- **Collect detailed antimicrobial use data that contains information on dosage, duration and indication.**

According to USDA’s publication ‘Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan’,<sup>ix</sup> the planned study “would likely be limited in terms of providing percent of animals treated and percent of operations using products, not total kg used or animal daily doses.” Quantitative data on the amount of antibiotics used and the duration of use are important to understand antibiotic use practices and evaluate the impact of policy changes. For instance, one commonly voiced concern by some stakeholders is that FDA’s policy changes may inadvertently lead to treatment delays and a shift to higher average doses. Without tracking treatment dosages, it will not be possible to evaluate whether this concern is warranted. Similarly, average durations of use for different indications are important to track, for instance to evaluate where best to focus research efforts on alternatives (e.g., vaccines) that can prevent or treat these diseases without the need to use antibiotics. Antibiotic surveys should include at least the following data elements: antimicrobial class; indication (i.e., the reason why a drug is used; e.g., treatment of respiratory disease); operation type / size; age group / animal production class (e.g., pigs immediately after weaning); administration route, dosage and duration.



- **Outline a plan for annual data collection for all major food producing species.** Collecting antibiotic use data that adequately capture the breadth of food-producing species, operation types and sizes, age groups and production systems in the United States clearly poses a formidable challenge. However, in order to be able to evaluate the impact of FDA’s policy changes, including potential unintended consequences, this information is crucial, and it is important to have information on the impact of these policy changes on all aspects of food animal production. Therefore, USDA should publically outline a plan for the annual collection and reporting of antimicrobial use data for all major food producing species. If USDA plans to rely on data from sources outside of the NAHMS surveys, the agency should set forth a plan for obtaining, evaluating, analyzing and reporting such data, and discuss how comparable those data may be to data collected within the NAHMS surveys.
- **Outline a plan for data collection for minor food producing species.** It is important to have information on the impact of FDA’s policy changes on all aspects of food animal production, including minor species. In fact, FDA’s policy changes may create particular challenges for minor species, for instance because of more limited access to veterinarians with relevant expertise and fewer available drug choices, in particular for feed drugs that are not permitted to be used off-label. It is important to collect data on antibiotic use in minor species to evaluate what impact the currently policy changes have on this particular subset of operations, and whether further policy action specific to them may be warranted. Such data would also provide other valuable information, such as whether certain key health challenges in minor animal species may warrant particular research investments to find alternatives. Recognizing that resource constraints may limit the amount of information that can be realistically collected for minor species, USDA should nonetheless seek such information. The agency should outline a plan for the collection of antimicrobial use data for minor food-producing species, for instance by collecting the antibiotic survey data as part of the regular NAHMS studies for these species and potentially increasing the frequency of these surveys beyond every 5-7 years.
- **Include key data on animal health into the annual survey.** As outlined above, according to USDA’s publication ‘Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan’,<sup>x</sup> survey questions will provide annual estimates of antimicrobial use. However, to accurately interpret these data and evaluate trends in antimicrobial use over time, it is important to consider these estimates within the context of animal health and disease pressures. Moreover, concerns have been voiced by some stakeholders that FDA’s policy changes may inadvertently result in deteriorating animal health, for instance due to treatment delays and disincentives to treat. To provide proper context for the interpretation of antimicrobial use data, and to evaluate the potential impact of FDA’s policy changes on animal disease patterns, the annual survey should include key data on animal health, such as mortality rates due to infectious causes or incidence rates for key animal diseases such as respiratory disease.

- **Include questions to evaluate the prerequisites for improvements in antimicrobial stewardship, including the role of the veterinarian in animal health decision-making.** A key objective of FDA's policy changes is to assure antimicrobial drugs are used judiciously in animal agriculture, for instance by placing the use of medically important antibiotics under veterinary oversight. Some previous NAHMS surveys have evaluated the (historical) role of the veterinarian on the queried operations. For instance, according to the NAHMS 'Beef 2007-08' study, which focused on cow-calf operations, veterinarians played an important role in making antibiotic use choices.<sup>xi</sup> However, the likelihood of veterinarians being the primary influence for antibiotic treatments differed by condition, animal age group and operation type. For many conditions, less than half of the operations cited veterinarians as the primary influence in their decision making regarding antibiotic use. Even for potentially highly contagious and very serious conditions such as respiratory or digestive diseases in unweaned calves, only 70% or less of operations identified veterinarians as the primary influence for treatment choices.<sup>xii</sup> In contrast, according to the NAHMS 'Feedlot 2011' study, veterinarians are highly influential in making antibiotic treatment decisions on feedlots. In fact, for 87 % and 12 % of feedlots, veterinarians 'strongly' or 'somewhat' influenced treatment choices.<sup>xiii</sup> Because veterinarians play a crucial role in assuring antimicrobial drugs are used judiciously, questions demonstrating the changing role of veterinarians on operations should be included in the annual antimicrobial survey.

To effectively evaluate federal policies and better understand how antibiotic resistance relates to antibiotic use in animal agriculture, federal agencies and the public require a more informed understanding of how, when, and why antibiotics are used in livestock and poultry species. The proposed data collection will be a major step towards obtaining a more comprehensive picture of antimicrobial use in food-producing species. While no one source of information will be sufficient alone to measure antibiotic use in agriculture and monitor the development and spread of antibiotic resistant bacteria, a combination of approaches can fill in the puzzle over time.

Collecting and releasing data in the public domain and discussing the limitations, rather than waiting to find the perfect quantitative approach, is the best path forward. We therefore urge USDA to start the annual antimicrobial survey data collection as soon as possible, and to continue the data collection beyond the three years specified in the current Federal Register notice because changing antimicrobial use practices will take time and it will be important to monitor and evaluate changes in antimicrobial use patterns for longer periods of time. This data collection will be an iterative process that will need to be periodically refined to get closer to the goal of optimizing antimicrobial use and reducing the emergence of resistance. To guide this process and provide the needed context, it will be important to take a comprehensive approach as outlined above. The antimicrobial surveys should include information beyond antimicrobial use in feed or water for swine or feedlot cattle, and capture key aspects of animal health and stewardship, such as the role of the veterinarian on operations.

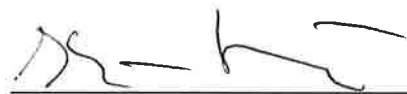
Stakeholder dialogue should continue for a deeper scientific discussion about what could serve as appropriate metrics to evaluate the effectiveness of federal policies to reduce the antibiotic resistance threat. Pew is eager to help advance such dialogue to improve public health by slowing resistance in all settings.

Sincerely,



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Kathy Talkington, Director  
Antibiotic Resistance Project  
The Pew Charitable Trusts



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Karin Hoelzer, Officer  
Antibiotic Resistance Project  
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<sup>i</sup> World Health Organization, “Global Action Plan on Antimicrobial Resistance,” 2005, [http://www.wpro.who.int/entity/drug\\_resistance/resources/global\\_action\\_plan\\_eng.pdf](http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf).

<sup>ii</sup> Government of Canada, “Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) Annual Report Chapter 1. Design and Methods,” 2013, [http://publications.gc.ca/collections/collection\\_2015/aspc-phac/HP2-4-2013-1-eng.pdf](http://publications.gc.ca/collections/collection_2015/aspc-phac/HP2-4-2013-1-eng.pdf); European Medicines Agency, “Revised ESVAC reflection paper on collecting data on consumption of antimicrobial agents per animal species, on technical units of measurement and indicators for reporting consumption of antimicrobial agents in animals,” October 10, 2013, [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/12/WC500136456.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136456.pdf); Commonwealth of Australia, “Surveillance and reporting of antimicrobial resistance and antibiotic usage in animals and agriculture in Australia”, 2014, <http://www.agriculture.gov.au/SiteCollectionDocuments/animal-plant/animal-health/amria.pdf>.

<sup>iii</sup> Docket No. APHIS-2016-0023, 81 FR 45450 (July 14, 2016), <https://www.federalregister.gov/articles/2016/07/14/2016-16612/notice-of-request-for-approval-of-an-information-collection-national-animal-health-monitoring-system>.

<sup>iv</sup> United States Department of Agriculture, “Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan,” April 2015, [https://www.aphis.usda.gov/animal\\_health/nahms/amr/downloads/ProposedInitiatives.pdf](https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf).

<sup>v</sup> Ibid.

<sup>vi</sup> United States Food and Drug Administration, “Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals in 2014,” December 2015, <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf>.

<sup>vii</sup> United States Food and Drug Administration, “Guidance for Industry 213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,” December 2013, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>.

<sup>viii</sup> United States Department of Agriculture, “Feedlot 2011 Part I: Management Practices on U.S. Feedlots with a Capacity of 1,000 or More Head,” March 2013, [https://www.aphis.usda.gov/animal\\_health/nahms/feedlot/downloads/feedlot2011/Feed11\\_dr\\_PartI.pdf](https://www.aphis.usda.gov/animal_health/nahms/feedlot/downloads/feedlot2011/Feed11_dr_PartI.pdf).

<sup>ix</sup> United States Department of Agriculture, “Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan,” April 2015, [https://www.aphis.usda.gov/animal\\_health/nahms/amr/downloads/ProposedInitiatives.pdf](https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf).

<sup>x</sup> Ibid.



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<sup>xi</sup> United States Department of Agriculture, “Beef 2007-08 Antimicrobial Drug Use and Antimicrobial Resistance on U.S. Cow-calf Operations, 2007-08,” February 2012, [https://www.aphis.usda.gov/animal\\_health/nahms/beefcowcalf/downloads/beef0708/Beef0708\\_ir\\_Antimicrobial.pdf](https://www.aphis.usda.gov/animal_health/nahms/beefcowcalf/downloads/beef0708/Beef0708_ir_Antimicrobial.pdf).

<sup>xii</sup> Ibid.

<sup>xiii</sup> United States Department of Agriculture, “Feedlot 2011 Part IV: Health and Health Management on U.S. Feedlots with a Capacity of 1,000 or More Head,” September 2013, [https://www.aphis.usda.gov/animal\\_health/nahms/feedlot/downloads/feedlot2011/Feed11\\_dr\\_PartIV.pdf](https://www.aphis.usda.gov/animal_health/nahms/feedlot/downloads/feedlot2011/Feed11_dr_PartIV.pdf).