

October 31, 2023

Food And Drug Administration
5600 Fishers Lane
Rockville, MD 20852

RE: Comment on the Summary Report: Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals (Docket FDA-2022-N-0824)

To Whom It May Concern,

The Center for Science in the Public Interest (CSPI)¹ submits these comments to the United States Food and Drug Administration (FDA) on the above-referenced Reagan-Udall Foundation summary report² that addresses data collection regarding antimicrobial use on farms through a public-private partnership (PPP).

CSPI supports the FDA objective of developing an antimicrobial use monitoring system for food-producing animals, as such a system can both better allow for policies targeted at reducing the practices that foster antimicrobial resistance and enable veterinarians and producers to better evaluate and consequently improve their own antimicrobial usage by comparing their practices to others.

FDA asked the Reagan-Udall Foundation to investigate creating a PPP for food animal antimicrobial use monitoring in 2021.^{3,4} The Foundation released a 2022 preliminary report⁵ which explored the feasibility of creating a PPP. CSPI commented⁶ on the preliminary report and detailed the components of a monitoring system that should be prioritized, like ensuring a representative sample for the primary segments of industry and publishing results that allow veterinarians and producers to compare their own practices to others’.

¹ CSPI is your food and health watchdog. Since 1971, CSPI has worked to improve the public’s health through better nutrition and food safety. The organization’s work is supported by subscribers to its Nutrition Action Healthletter, one of the nation’s leading health newsletters. CSPI is an independent organization that does not accept government donations or corporate funding.

² Summary Report: Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals. Reagan-Udall Foundation for the FDA. August 2023. Accessed October 10, 2023. https://reaganudall.org/sites/default/files/2023-09/072823_Summary%20Report_Final%209.19.23.pdf

³ FDA Asks Reagan-Udall Foundation to Gather Stakeholder Feedback About Collection of Antimicrobial-Use Data in Food Animals. Published December 2, 2021. Accessed October 19, 2019. <https://www.fda.gov/animal-veterinary/cvm-updates/fda-asks-reagan-udall-foundation-gather-stakeholder-feedback-about-collection-antimicrobial-use-data>

⁴ Exploring the Potential for A Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals: Preliminary Summary Report. Reagan-Udall Foundation for the FDA. Published May 2022. Accessed August 11, 2022. https://reaganudall.org/sites/default/files/2022-05/Report_%20Tracking%20and%20Monitoring%20Antimicrobial_Final.pdf?eType=EmailBlastContent&eId=3cedead79-9297-46b6-8442-14ca4445a76b

⁵ Ibid.

⁶ Comment on the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals Preliminary Summary Report (Docket FDA-2022-N-0824-0001). Center for Science in the Public Interest. Published August 22, 2022. Accessed October 10, 2023. https://www.cspinet.org/sites/default/files/2022-08/Comment%20on%20the%20Tracking%20and%20Monitoring%20of%20Antimicrobial%20Use%20in%20Food-Producing%20Animals_0.pdf

The summary report expands on the preliminary report and details a potential framework for a PPP use monitoring system. Our comments on the final report primarily reflect the comments we submitted for the preliminary report. Furthermore, we urge FDA to ensure that sufficient consumer input and transparency are incorporated into any PPP.

Background

Antimicrobial use in food animals is a public health concern because it can foster the development of resistance to antimicrobials in pathogenic bacterial populations.⁷ This resistance limits the available treatments for bacterial infections in humans and animals. The Centers for Disease Control and Prevention (CDC) estimates that 35,000 people in the United States die each year as a result of antimicrobial-resistant infections.⁸ The Review on Antimicrobial Resistance, a project commissioned by the United Kingdom to explore this public health problem in depth, predicted that, if resistance control measures fail, antimicrobial-resistant pathogens will cost 100 trillion US dollars globally between 2016 and 2050 and the annual death total will exceed 10 million by 2050.⁹

Ideal Components of an Antimicrobial Use Monitoring System

CSPI again urges FDA to consider and prioritize the following components of an antimicrobial use monitoring system.

1. FDA should develop a food animal antimicrobial use monitoring system that fully captures the nuances of antimicrobial use detailed by both the previous pilot studies¹⁰ funded by FDA and the Reagan-Udall summary report,¹¹ such as animal characteristics, and indications.
2. FDA should develop a method of data collection and publication that allows producers to easily compare their own detailed usage information to anonymized aggregate data from similar segments of the industry. Producers and other industry members could then more easily compare their usage to industry baselines and be more motivated to improve stewardship.
3. An antimicrobial monitoring system like a PPP should ensure adequate transparency by clearly disclosing its participation rates, assessing whether the resulting sample is biased, and develop outreach efforts to encourage participation.
4. FDA should require that every farm record its usage data and that these data be made available to the agency for sampling, and request authority from Congress if it believes that is needed to create this requirement. These records would then be sampled on a random basis, to assure representativeness, while minimizing intrusiveness for producers. In contrast, a voluntary system like the PPP envisaged by the Reagan-Udall Foundation

⁷ Hoelzer K, Wong N, Thomas J, Talkington K, Jungman E, Coukell A. Antimicrobial drug use in food-producing animals and associated human health risks: what, and how strong, is the evidence?. *BMC Vet Res.* 2017;13(1):211. Published 2017 Jul 4. doi:10.1186/s12917-017-1131-3

⁸ CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019. <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf>

⁹ Background. Review on Antimicrobial Resistance. Published 2016. Accessed July 22, 2022. <https://amr-review.org/background.html>

¹⁰ Special issue: Antimicrobial Use Data Collection and Reporting. *Zoonoses and Public Health.* Volume 67, Issue S1. November 2020. <https://onlinelibrary.wiley.com/toc/18632378/2020/67/S1>

¹¹ Summary Report: Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals. Reagan-Udall Foundation for the FDA. Published August, 2023. Accessed October 10, 2023. https://reaganudall.org/sites/default/files/2023-09/072823_Summary%20Report_Final%209.19.23.pdf

could result in an inadequate number of producers participating and the resultant sample is likely to be non-representative.

5. Such a system would be useful to multiple parties.
 - a. For FDA and other agencies, representative data would allow for better-targeted public health interventions. For example, FDA plans to take various actions to ensure appropriate antimicrobial use as part of its strategy on antimicrobial resistance.¹² A better understanding of on-farm uses within different sectors of the food industry could help the agency formulate the details of these actions and measure their public health impact.
 - b. For producers, a requirement that usage data be recorded could provide substantial monetary benefits. Producers could better evaluate their usage practices over time to see how various changes to their production practices and animal health interventions influence antimicrobial usage and associated costs, allowing them to tailor their antimicrobial usage more narrowly. Further, if a representative sample were collected and used to estimate aggregate prevalences and trends, farms could compare their own usage more accurately to other producers. This should result in decreased antimicrobial purchasing costs as farmers gather better information.
 - c. For veterinarians, uniform antimicrobial use recording will allow them to better evaluate how antimicrobials are used on individual farms over time and compare a farm's usage to different farms within their client base, as well as to nationally representative data. Veterinarians can then more closely monitor and critically evaluate their prescribing practices and improve usage practices.

PPP Structure

While we have concerns about a PPP that utilizes voluntary data being able to sufficiently capture the antimicrobial use data needed, if FDA decides to develop the PPP, the agency should prioritize ensuring continuous consumer input and transparency.

In the framework described by Reagan-Udall, a steering committee would be formed to provide direction and guidance to the PPP.¹³ Membership in the steering committee would “be limited to representatives of organizations which contribute data and resources to the PPP,” ostensibly excluding consumer representatives or independent organizations focused on supporting public health by addressing antimicrobial resistance. The lack of consumer and independent public health representation on the steering committee raises concerns that the PPP would not adequately collect and analyze data to address public health concerns, but rather focus on concerns that are relevant primarily to the agriculture industry. This exclusion should be remedied. Any confidentiality concerns can be accommodated through nondisclosure agreements and aggregated and de-identified data.

¹² Supporting Antimicrobial Stewardship in Veterinary Settings Goals for Fiscal Years 2024-2028: Key Phase 3 and Phase 4 Actions. September 2023. Accessed October 12, 2023. <https://www.fda.gov/media/172347/download?attachment>

¹³ Summary Report: Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals. Reagan-Udall Foundation for the FDA. August 2023. Accessed October 10, 2023. https://reaganudall.org/sites/default/files/2023-09/072823_Summary%20Report_Final%209.19.23.pdf

Conclusion

Thank you for providing an opportunity to comment again on the elements of an antimicrobial use monitoring system. We emphasize the need for the agency to explicitly address the limitations of a PPP (primarily its voluntary nature and resultant non-representativeness) and actions the agency could take to mitigate these shortfalls. We look forward to working with the FDA as the agency further develops an antimicrobial use monitoring system.

Sincerely,

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