KEEP ANTIBIOTICS WORKING
The Campaign to End Antibiotic Overuse
www.KeepAntibioticsWorking.org

October 30, 2023

RE: Possible Framework for Collecting and Analyzing Data on Antimicrobial Use in Food-Producing Animals; Docket Number: FDA-2022-N-0824

We, the undersigned member and colleague organizations of Keep Antibiotics Working (KAW), appreciate the opportunity to comment upon the "Summary Report: Establishing a Draft Framework for a Public-Private Partnership to Support the Tracking of Antimicrobial Use in Food-Producing Animals." Any data collection program supported by public funds must provide public benefits and therefore deserves public input into its design and operation.

The FDA created the draft framework in collaboration with the Reagan-Udall Foundation (RUF). Both entities have ignored critical public input to the proposed framework, as we discuss below. Given that our previous comments are not reflected in the current report we have attached them again here. The public – whose health is endangered when antibiotics are overused, whatever the setting – is being left out of the process; the taxpaying public instead is treated as a mere passive recipient of collected data, rather than as a true stakeholder.

In addition, Keep Antibiotics Working and its member advocacy groups have repeatedly flagged evidence-based concerns about the FDA's determination to only pursue voluntary approaches to collecting antibiotic[1] use data, specifically in the context of food-animal production. These concerns have been shared repeatedly with the FDA and RUF, in presentations and written comments. They, too, have been entirely ignored. Our concerns have never been responded to, nor are they mentioned in the RUF's summary report.

The failure to transparently address these public health concerns is an abrogation of the FDA's mandate to protect the public. Antibiotic use and overuse are the primary drivers for the selection of resistance in food-animal production, just as they are in human medicine. The RUF summary report implies that stewardship is merely a question of the FDA "fostering" conditions under which individual veterinarians and producers optimize their use of antibiotics. However, stewardship has unavoidable implications at the population (e.g. public health) level as well. If the FDA determines antibiotic use is being optimized, and yet no diminution of total antibiotic use occurs, then there may be no discernible benefit to public health. And if the collection of voluntary data results in data of low quality, any public health benefit from that collection is eroded as well.

[1] Throughout this document we use antibiotic instead of antimicrobial since it is better understood by the public and most data collection programs in food-producing animals focus on antibiotics, not all antimicrobials.

The risk that AMU data generated under the proposed framework will be sub-optimal is increased by the FDA's and RUF's failure to heed our recommendation that alternative, non-voluntary means for collecting these data be explored. We provide one example of available use data that the FDA could readily collect from feed mills under its existing statutory authority. Over the past year, one KAW member group (NRDC) has shared a summary of this legal authority with FDA officials both orally and in writing. At the least, we urge the FDA's collection of these feed mill data, which existing FDA regulations already require feed mills to maintain on site, could and should be used as a way to check the quality of the voluntary data.

KAW History of Work on Antibiotic Use Data Collection

Antibiotic use is the primary selective force behind the emergence of resistant bacteria.[2] Better stewardship is essential to combat the spread of resistance. However, veterinary antibiotic use and stewardship cannot be optimized without measurement.

We strongly support better data being collected on antibiotic use in food-animal production. KAW, since its creation in 2001, has consistently called for the collection of these data. We played a critical role in getting Congress to add the antibiotic use provisions in the 2008 reauthorization of the Animal Drug User Fee Act. Even earlier, KAW founding organization Union of Concerned Scientists published the first estimate of antibiotic use in food-animal production in the U.S. in the 2004 Hogging It Report.

Justification for Public Funding of Antibiotic Use Data Collection

The primary public interest for collecting data on antibiotic use in agriculture is to protect the public from resistant bacterial infections. There are potential private benefits from the collection of these data such as optimizing treatment to reduce production costs and improve productivity or the ability to meet buyer transparency requirements. While these private benefits create an incentive for participation by drug users, they should not be the primary focus of a publicly funded program.

Given the link between use and resistance, the program should be designed in a way that the public and policy makers can identify areas of antibiotic overuse and determine whether or not progress is being made to reduce and eliminate this overuse. This may inform efforts to eliminate uses that currently benefit livestock producers but simultaneously create an unacceptable public health risk (e.g. FDA's prohibition on the use of fluoroquinolone antibiotics in poultry). If this public interest cannot be fulfilled by a public private partnership because the partners are not interested in identifying areas of antibiotic overuse or even acknowledging the probability that antibiotics are overused, then another approach should be taken. If the assumption is that antibiotics are used in optimal fashion in animal agriculture unlike in other sectors, then there is no justification for this publicly funded program. If antibiotic overuse exists in animal agriculture, as it does in all other sectors, then data collected through a public private partnership may potentially obscure overuse. This is especially true if voluntary participation in the partnership is limited to a subset of producers that use antibiotics on a more limited basis or if partners refuse to make data public when it may be indicative of problems with antibiotic stewardship.

[2] Randall S. Singer, "Antibiotic Use Data Collection in U.S. Poultry and Swine Production," abstract of FDA grant received for 2016-2021, accessed at https://grantome.com/grant/NIH/U01-FD005878-05.

Since 2016, the FDA has given out two grants of $300,000 each to researchers and/or external consultants to work with regulated industry on a voluntary basis to collect farm-level data on antibiotic use. These two efforts are the crux of FDA reporting under the CARB National Action Plan with respect to improved data collection around antibiotic use as an essential component to combat the spread of antibiotic resistant bacteria. By the time those data were published, they were long out of date. Moreover, the research leaders have noted in print their trepidation that a lack of voluntary participation raises questions about the utility of their very limited results. To base a future public private partnership on these FDA-funded pilot studies without acknowledging concerns raised about them is not acceptable.

Reagan-Udall Process for Work on Antibiotic Use Data Collection

We have serious and longstanding concerns about the process by which the FDA and the Reagan-Udall Foundation are moving forward with developing a national data collection program. KAW member organizations have raised concerns about the feasibility of the approach chosen by the FDA and pursued by the Reagan-Udall Foundation from the beginning. Despite our consistent participation in the process, our concerns have been ignored.

Staff from KAW member organizations were included in oral interviews during phase one of the Reagan-Udall project, as was appropriate given our two-decades of experience advocating around antibiotic resistance and the need for robust, quality work on data collection.

The concerns we raised during the interview phase (challenges to collecting representative data from a voluntary program, failure to consider alternatives, challenges to balancing divergent public and private interests) were not reflected in the May 2022 "Preliminary Summary Report."

Subsequently, we participated in the June 14 virtual public forum and also submitted written comments to the FDA docket last August on the preliminary report. To date, no final summary report updating the May 2022 preliminary summary has been issued. As such, there is no written evidence that all of the feedback we have provided has had any impact whatsoever on the current report to which these latest comments are directed. In any case, the bulk of the comments received raised concerns about the challenge of getting nationally representative data from a voluntary program. As such, it seems very clear that this topic should be addressed somewhere in the work of the Foundation. But to date that has not been the case.

In addition, here are more specific points that the RUF and the FDA should address:

- With respect to antibiotic use tracking, public and private interests at times diverge. The report must recognize this fact, and its description of the proposed framework should be updated to include mechanisms to address this divergence. This must include more involvement from public advocacy and public health interests in decision making, including in the proposed steering committee.
- Not only are public interest perspectives lacking in the report, but public interest voices and participation were also excluded from phase two of its development. This pattern will continue if, as is being proposed, participation on the steering committee is limited only to the FDA and industry. The exclusion of public interest voices and perspectives has had predictable ripple effects. For example:
    - The report is highly unbalanced towards private not public interests.
    - There is an extreme focus on protecting data privacy and almost zero focus on the importance of ensuring data quality or the identification of relevant

stakeholders.

- In addressing the proposed framework, the report should have discussed and weighed the pros and cons of alternative approaches to a public private partnership. Non-voluntary measures, such as requiring the submission of antibiotic use and distribution data from feed mills, should have been discussed as a means for complementing other on-farm data being collected via the public private partnership. The use of non-voluntary mechanisms as a means of determining whether data collected via a public private partnership are accurate and representative should also be discussed.
- Reagan-Udall should explicitly discuss and address the challenge of getting representative data when participation is voluntary and look at available data on this challenge as illustrated in data being collected on antibiotic use in healthcare and challenges USDA has with non-response bias.
- The report assumed that industry trade organizations are trusted partners representing the interests of individual producers. Many producers, particularly smaller, independent producers, do not feel represented by trade organizations, however. Food Animal Concerns Trust, a KAW member group, maintains a network of tens of thousands of producers that in general are not well represented by industry trade organizations.

We hope that moving forward, Reagan-Udall and the FDA will adopt an approach that is as concerned with data quality, public health and consumer interests as with obtaining industry buy-in.

Signed,

Antibiotic Resistance Action Center, George Washington University
Consumer Reports
Center for Biological Diversity
Center for Food Safety
Environmental Working Group
Food Animal Concerns Trust
Humane Society Legislative Fund
Humane Society Veterinary Medical Association
Natural Resources Defense Council (NRDC)
The Humane Society of the United States
US PIRG