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 organizations, 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. The FDA created the draft framework in collaboration with the Reagan-Udall Foundation (RUF). 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.

The failure to transparently address 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.

The risk that AMU data generated under the proposed framework will be sub-optimal is increased by the FDA's and the RUF's failure to consider alternative, non-voluntary means for collecting these data. The FDA could readily collect use data from feed mills under its existing statutory authority. The FDA's collection of 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.

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 this 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 (i.e. businesses raising food-producing animals), they should not be the sole 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. the 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.

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 that data was published, it was 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.

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.

- Public interest perspectives are lacking in the report, and 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 be updated to discuss and weigh 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 is accurate and representative should also be discussed.

- The RUF should explicitly discuss and address the challenge of getting representative data when participation is voluntary and look at available information on this challenge as illustrated in data being collected on antibiotic use in healthcare and challenges USDA has with non-response bias.

- The report assumes 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[1]. The FDA and the RUF should make sure that these producers' perspectives are taken into consideration when developing a data collection program.

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

Sincerely,

Farm Forward

FarmSTAND

Food Animal Concerns Trust

Lymphoma Foundation of America

Michigan Antibiotic Resistance Reduction Coalition

Northeast Organic Dairy Producers Alliance

Science and Environmental Health Network

Socially Responsible Agriculture Project

Waterkeeper Alliance

[1] https://www.legalreader.com/independent-farmers-and-ranchers-storm-capitol-hill-in-opposition-to-eats-assault on-states-rights-advocate-to-reform-usdas-scandal-ridden-checkoff-programs/