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

August 22, 2022

RE: Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals Preliminary Summary Report; Docket Number: FDA-2022-N-0824

We, the undersigned member and colleague organizations of Keep Antibiotics Working[i], appreciate the opportunity to comment on the Food and Drug Administration's (FDA's) decades-old discussion on how to collect better antibiotic use data for food-producing animals.

Any data collection program supported by public funds should provide public benefits and support reductions in antibiotic use. We do not think that a public-private partnership is the best approach for collecting these data and seems more likely to lead to further delays or the collection of data of such poor quality that it will provide no public benefit. We recommend as an alternative, the collection of feed distribution data from firms distributing medicated feed to farms and feedlots. The Reagan Udall report suffers from serious flaws that result from it prioritizing the interests of drug makers and antibiotic users over the public.

Any antibiotic use data collection system created with public resources should be used for public benefit, including the public health goal of reducing use.

Data collection is useful from a public health perspective to the extent that it guides reduction in the use of antibiotics. The public interest in contrast to private interest in antibiotic use data is primarily linked to the relationship between antibiotic use and antibiotic resistance. Since use is a primary driver of resistance, preserving the efficacy of antibiotics means reducing the use of these lifesaving drugs to when it is absolutely necessary, not when it is convenient or cheaper to do so.

In a program funded by the Department of Health and Human Services (HHS) through the Agency for Healthcare Research and Quality (AHRQ) long-term care facilities use reduction targets to reduce overuse and curb antibiotic resistance.[ii] The first U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB) has a goal to reduce use in outpatient settings.[iii] CDC reports that "total inappropriate antibiotic use, inclusive of unnecessary use and inappropriate selection, dosing and duration, may approach 50% of all outpatient antibiotic use." Healthy People 2020 has goals to reduce the number of courses of antibiotics for certain infections.[iv] The World Health Organization has set targets for reducing use in animals in order to preserve their effectiveness for human medicine.[v] Likewise, the World Organization for Animal Health has called for reductions in antimicrobial drugs in the food system.[vi]

3525 W. Peterson Avenue, Suite #213 • Chicago, IL 60659-3314 • PHONE: 773-525-4952

The Reagan Udall report fails to make clear that reducing use is a critical component of antibiotic stewardship strategies aimed at combating antibiotic resistance. The report only addresses reduction of antibiotic use in a negative fashion when it states (pages 3 and 9) "recognizing that the goal is not to reduce AMU [antimicrobial use] to zero use." In this way the report conflates "reductions in use" with "no use". For marketing purposes some companies choose to sell products from animals raised without antibiotics but none of the major groups calling for reductions in antibiotic use in food animals are calling for the elimination of antibiotic use in food producing animals.

The report does hint at reducing antibiotic use when it mentions "benchmark data to help veterinarians work with producers to promote antimicrobial stewardship and cost-effective use." Presumably the benchmarks would be a target amount of antibiotic use for a specific species that producers should aim to meet, however, the report does not make this clear. Similarly, it discusses "antimicrobial stewardship" throughout but never defines stewardship. In a few places, the report does recognize that the goal of stewardship is to "preserve antimicrobial efficacy for animals and people" which will happen only if stewardship leads to reductions in use.

Input from industry affiliated stakeholders and the decision to only consider a public-private partnership approach to data collection diminishes the public benefit of this report. Namely, it promotes the optimization of antibiotic use for livestock producers rather than preserving antibiotic efficacy for all. It may be optimal (i.e. cheaper) for cattle producers to use critically important antibiotics to reduce liver abscesses that result from the producer's choice of cattle feed, but that choice is not necessarily optimal for society as a whole. If antimicrobial stewardship is narrowly characterized as choosing the right drug at the right time without considering preventive measures that mitigate disease challenge in the first place then this will lead to unnecessary antibiotic use and the associated unnecessary resistance. The report fails to recognize that what is optimal for an individual livestock operation may not be optimal for society as a whole. FDA's data collection efforts should be focused on protecting public health not on optimizing the benefits to individual antibiotic users.

A voluntary public/private partnership is unlikely to provide data needed to meet the public health challenge of antibiotic resistance.

It is unlikely that a public-private approach to antibiotic use data collection will work in the context of U.S. food animal production if the goal is to provide a public benefit. If a data collection system is to guide policy such as setting antibiotic use reduction targets, guiding drug approval decisions, and identifying areas of overuse it needs to be national and representative.

The United States Department of Agriculture (USDA) has continuous and ongoing challenges related to low response rates.[vii] Staff at the National Animal Health Monitoring System during a meeting with Keep Antibiotics Working indicated low participation rates, close to 20% for their surveys on farm antibiotic use, especially in swine. In terms of antibiotic use data collection, which addresses a controversial issue for livestock producers, it is unlikely that participation will be high. In addition, there will be no way to determine whether those that choose to participate use antibiotics in the same way as those who choose not to participate. It is likely that

participation will be high among those who prioritize antimicrobial stewardship and low among those who do not since one of the benefits of the data collection is to support stewardship.

Because the program relies on voluntary participation, the design of the program will likely be influenced by the need to maintain participation levels. This can lead to avoiding controversial but policy relevant topics. For example, one of the most policy relevant questions is the extent to which antibiotics are used in U.S. food animals for disease prevention versus disease treatment. There was significant discussion around the appropriateness of disease prevention at the 2020 Codex Alimentarius Task Force on Antimicrobial Resistance. The World Health Organization has recommended medically important antibiotics not be used for disease prevention, and the European Union has recently restricted use of antibiotics for this purpose. Despite the policy relevance, recent surveys by USDA's National Animal Health Monitoring Service and the FDA's pilot projects on antimicrobial use avoid questions related to preventive use.

Several of the organizations that participated in the stakeholder outreach prior to the release of this Reagan Udall report raised these issues with Reagan Udall staff but there is no mention of them in the report.

FDA should begin collecting feed distribution and manufacturing data from firms that distribute feed to final users as a verified source of information on the 62% of medically-important antibiotics delivered in feed.

As an alternative to the private public partnership under consideration here, we recommend that FDA begin collecting and reporting data from the firms that manufacture and distribute animal feeds with medically important (MI) antibiotics mixed into them. These data would provide the best available information on how and why most MI antibiotics sold in the United States (by volume) are being used. Sixty-two percent of medically important antibiotics are sold as additives to animal feed, which are then given to entire flocks or herds of animals.[viii] The focus should be on feed distributed to final users and the associated veterinary feed directives. Since it is unlikely that large quantities of feed are wasted this provides accurate information on what antibiotics are administered in feed on farms.

This action relies on existing FDA authority and on data already available to the FDA.[ix] FDA rules prohibit shipping feeds that contain MI antibiotics without a veterinarian's order ("veterinary feed directive" or VFD) and require feed mills to keep and make available for inspection both the VFDs and records of the feed distributed for two years. The combination of feed records and VFDs will provide information on the amount of antibiotics delivered to farms along with the reason for use - both critical pieces of information not supplied by current data collection systems. Veterinarians and farms are also required to maintain records of VFDs written by them.

Collection of feed distribution data from the 10,000 distributors is much more practical than trying to collect data from the 1.3 million farms where livestock are raised. In fact, data from California where a state program collects data on antibiotics in feed suggests the number of

entities distributing medicated feed to farms is likely much smaller.[x] California is the 5th largest livestock producer in the U.S. but under 50 firms distribute feed under VFDs in the state.

Collecting these feed distribution data does not rely upon voluntary participation since the records are required under federal law. If a public-private partnership does move forward these non-voluntary data could be used to determine whether there are differences in participants and non-participants in the voluntary program at least for the feed portion.

The Reagan Udall report reflects the opinions of a limited number of stakeholders and therefore has serious flaws.

As noted above, the Reagan Udall Report ignores the input provided by consumer organizations that there are problems with voluntary approaches to data collection. Even more troubling are some of the statements in the report that seem to reflect a perspective that efforts to reduce antibiotic overuse in animal agriculture are problematic.

We are concerned that the report states as a matter of fact that "sales and distribution data are often incorrectly used as a proxy for use data, even though sales do not represent actual use of the products." A proxy is something that can be measured when the thing you want to measure cannot or in this case is not measured. A proxy by definition is not the same thing as the thing it is representing. Both FDA[xi] and industry [xii] in their plain language use the sales data as a proxy for use when discussing the reductions in use that occurred in 2017 as a result of Guidance for Industry #213. The use of sales data as a proxy for antibiotic use is recommended by the World Organization of Animal Health which the U.S. government has promoted as the appropriate source for information on collecting these antibiotic use data in animals.[xiii]

In addition, the report claims that "[w]ithout appropriate context, the public may associate "high" use of antimicrobials with "bad", and similarly associate "low" use of antimicrobials with "good." From the perspective of the public good, high use is bad and low use is good because high use leads to more resistance and low use leads to less. Context can be used to better understand what is high or low but the point of stewardship should be to move antibiotic use lower. This should be done by eliminating unnecessary use and taking steps to avoid disease so that the need for use is reduced. In each case, the goal is to get to a low level of use of antibiotics. If use goes up due to a new health threat, as it did for COVID-19 in human medicine, that is still a setback and something to work towards overcoming.[xiv] For both humans and animals, we should be trying to reduce the number of people or animals that need antibiotic treatment.

An additional troubling claim in the report is that "species specific data should not be directly compared to other species". Many factors contribute to differences in antibiotic use between species, however proper contextualization of these data allow for valid comparisons between species. From a public health perspective, meat produced with lower amounts of antibiotic use will contribute less to antibiotic resistance. A consumer may choose to consume poultry because it is produced with less antibiotic per pound than a pound of beef. In terms of poultry versus beef, along with differences in species and production systems there are differences in the effort

that the respective industries have made to reduce antibiotic use. An analogy can be made with making diet choices based on green-house gas emissions where people choose to change their diet because of lower levels of emissions from pork rather than beef.[xv] It is not the role of the FDA, Reagan Udall, or a potential public private partnership to limit discussion around consumer choice related to antibiotics.

Finally, with respect to limited perspectives being included in the report we would like to point out that the list of stakeholder organizations in Appendix II obscures who actually participated. For example, Zoetis, the world's largest animal health company is listed not as an animal health manufacturer but with veterinarians.[xvi] Similarly, the Animal Health Institute which is the trade group for drug manufacturers is listed under trade organizations for producers not drug makers.

We strongly support better collection and reporting of data on antibiotic use in all sectors including human medicine, animal agriculture, and in crop production. We do not think that a public private partnership is the best approach to collecting these data both because of challenges to getting representative data and because of the ability of the antibiotic users to control what types of data are collected and reported. Both of these problems diminish the public benefit from the data collection. The Reagan Udall report itself reflects a prioritization of these interests by dismissing sales data as a proxy for use, questioning whether low use is actually good, and warning against comparisons between species. As an alternative, we pose that FDA use its existing authority to begin collecting data on antibiotics distributed in feed to farms and feedlots.

Antibiotic Resistance Action Center, George Washington University
Food Animal Concerns Trust
Food & Water Watch
Natural Resources Defense Council
San Francisco Bay Physicians for Social Responsibility

---

[i] Keep Antibiotics Working, a coalition of 19 health, consumer, agricultural, environmental, humane, and other advocacy groups, is dedicated to eliminating the inappropriate use of antibiotics in farm animals, a significant contributor to the rise in antibiotic resistant disease. https://www.keepantibioticsworking.org/

[ii] Agency for Healthcare Research and Quality. "New Study Shows Reduced Antibiotic Use at Long-Term Care Facilities Participating in HHS-Funded Program," February 28, 2022. https://www.ahrq.gov/news/newsroom/press-releases/reduced-ltc-antibiotic-use.html.

[iii] Federal Task Force on and Combating Antibiotic-Resistant Bacteria. "National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025." ASPE, October 8, 2020. https://aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025.

[iv] Office of Disease Prevention and Health promotion. "Search the Data | Healthy People 2020." Accessed August 17, 2022. https://www.healthypeople.gov/2020/data-search/Search-the-Data?topicid=23&topic=Immunization%20and%20Infectious%20Diseases&objective=IID-5&anchor=372.

[v] WHO guidelines on use of medically important antimicrobials in food-producing animals. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

[vi] World Organisation for Animal Health. "World Leaders and Experts Call for Significant Reduction in the Use of Antimicrobial Drugs in Global Food Systems," August 24, 2021. https://www.woah.org/en/world-leaders-and-experts-call-for-significant-reduction-in-the-use-of-antimicrobial-drugs-in-global-food-systems/.

[vii] Reist, Benjamin M, Joseph B Rodhouse, Shane T Ball, and Linda J Young. "Subsampling of Nonrespondents in the 2017 Census of Agriculture," April, 2019.

[viii] Food and Drug Administration. "2015 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals," December 2016, 58.
[ix] "21 CFR Part 558 -- New Animal Drugs for Use in Animal Feeds." Accessed August 17, 2022. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-E/part-558.
[x] California Department of Food and Agriculture. "2020-2021 Veterinary Feed Directive Summary Report," June 23, 2022, 16.
[xi] Medicine, Center for Veterinary. "FDA Releases Annual Summary Report on Antimicrobials Sold or Distributed in 2020 for Use in Food-Producing Animals." FDA, December 14, 2021. https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-annual-summary-report-antimicrobials-sold-or-distributed-2020-use-food-producing.
[xii] Grant, Daniel. "NPPC: Sales of Antibiotics for Livestock Declined 41%." FarmWeek Now, January 8, 2020. https://www.farmweeknow.com/livestock/nppc-sales-of-antibiotics-for-livestock-declined-41/article_50583d8a-322b-11ea-b8df-0fd795b3ee60.html.
[xiii] World Organisation for Animal Health. "Terrestrial Code Online Access | Monitoring of the Quantities and Usage Patterns of Antimicrobial Agents Used in Food-Producing Animals." Article 6.9. Accessed August 17, 2022. https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/.
[xiv] CDC. "COVID-19 & Antibiotic Resistance." Centers for Disease Control and Prevention, July 12, 2022. https://www.cdc.gov/drugresistance/covid19.html.
[xv] Haspel, Tamar. "Perspective | How Subbing Pork for Half Your Beef Can Cut Your Climate Impact." Washington Post, July 22, 2022. https://www.washingtonpost.com/food/2022/07/22/pork-swap-beef-climate/.
[xvi] Zoetis. "Zoetis Animal Health - Global Animal Health Company." Accessed August 17, 2022. https://www.zoetis.com/.