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November 9, 2017

Anna K. Abram,  
Deputy Commissioner for Policy, Planning, Legislation, and Analysis  
Food and Drug Administration  
5630 Fisher Lane, Rm. 1061  
Rockville, MD 20852

**RE: FDA's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals Using a Biomass Denominator,” Docket No. FDA-2017-N-1197**

Dear Ms. Abram,

The Pew Charitable Trusts (Pew) appreciates this opportunity to comment on the U.S. Food and Drug Administration’s (FDA) proposed method to adjust U.S. animal antibiotic sales data by the respective animal population that may require antibiotics. Pew has a longstanding interest in addressing the public health risks posed by the inappropriate use of antibiotics in humans and animals by encouraging implementation of judicious use principles and practices and fostering innovation in drug development.

Pew applauds FDA’s efforts to better understand trends in animal antibiotic sales data, which could help evaluate the impact of recent policy changes and guide future efforts to ensure judicious antibiotic use. We offer comments below to assist FDA in ensuring that the proposed method is transparent and understandable, consistent with other international efforts, and cognizant of data limitations, but overall we support the proposal as a mechanism to improve the usefulness of animal antibiotic sales data.

**Utilizing U.S. data will account for geographic variation**

As drafted, the proposed biomass denominator estimates the animal population that may require antibiotics based on U.S. data. As summarized in FDA’s technical paper outlining the proposed biomass calculation methodology,<sup>i</sup> other international entities have established, or are in the process of establishing, similar estimates for other geographic regions. However, U.S.-specific estimation methods are useful because average animal weights differ considerably across geographic regions. Moreover, the data sources available for these calculations vary across countries, and the compositions of animal populations tend to be country or region-specific. Therefore, a U.S. specific estimation method for the animal population that may require antibiotics will be valuable.

**Given data limitations, using average animal weights is a reasonable near-term solution**

The proposal would utilize average animal weights and livestock numbers. Given the current data limitations with regard to animal antibiotic use patterns in the U.S., Pew also agrees with the approach outlined in FDA’s technical paper<sup>ii</sup> of using average animal weights in the calculation rather than trying to predict average weights at the time animals are at greatest risk of requiring antibiotics – although that decision may be revisited once reliable data have become available. Pew also supports FDA’s decision to re-estimate average animal weights periodically to account for trends in animal agriculture production – although it may be sufficient to recalculate these numbers every couple of years rather than annually as suggested in FDA’s proposal.

## **The biomass denominator will make sales data more useful, but is not a replacement for antibiotic use data**

The ability to adjust antibiotic sales data by an estimate of the animal population that may require antibiotics will improve the usefulness of these data. By accounting for the impact of changes in animal populations on antibiotic consumption patterns, the adjusted estimates could help provide some valuable insights into broad shifts in U.S. sales data and why sales may increase or decrease over time, and contribute to a more comprehensive picture of antibiotic use practices in animal agriculture. However, the adjusted sales data estimates are still subject to most of the limitations inherent in antibiotic sales data, including the fact that sales are only proxies of antibiotic use and can be affected by factors such as drug inventories and stockpiling. In addition, sales data provide little context for when, why or exactly how antibiotics are used, and whether these uses are appropriate. Therefore, Pew strongly urges FDA to continue current efforts, undertaken in close collaboration with other U.S. government agencies including the United States Department of Agriculture (USDA) and the Centers for Disease Control and Prevention (CDC), as well as other key stakeholders to collect more detailed antibiotic use data through mechanisms such as surveys conducted as part of the National Animal Health Monitoring System (NAHMS).

### **Improvements in three key areas would further enhance FDA's proposal**

Specifically, Pew encourages the Agency to consider the following issues in its consideration of the proposed method:

- 1. FDA's biomass calculation method should be transparent, understandable to stakeholders, and provide the appropriate level of detail.**

The proposed methodology is more complex than other methods that have been, or are in the process of being, developed by other international entities.<sup>1</sup> For instance, calculating biomass based on the average weight of animals in specific production classes listed on the product label (e.g., day-old chicks) for some drug classes as proposed by FDA will lead to different biomass denominators for different drug classes. This approach will make the data considerably more complex for stakeholders to understand and which may hamper the ability to compare antibiotic consumption trends across drug classes and years. Because information on the sales volumes of individual drug products (which may be approved for varying subsets of production classes) is available to FDA but not to the general public, the proposed approach makes the biomass calculation considerably less transparent. External factors such as approvals of drug products in new production classes may alter biomass estimates and therefore adjusted sales estimates from one year to another. Finally, FDA should carefully consider whether the proposed biomass adjustment process is too complex given the limitations inherent in sales data.

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<sup>1</sup> FDA's recent publication cited below provides a summary of other biomass calculation methods that have been developed or are in the process of being developed.

A simplified approach would be more in line with calculation approaches chosen by other entities such as the World Organisation for Animal Health (OIE),<sup>iii</sup> more transparent and easy to communicate to stakeholders, and potentially generate more robust adjusted sales data estimates.

**2. FDA should consider ensuring that its biomass calculation methodology demonstrates consistency with efforts established or under development by other international entities to the extent possible.**

As outlined above, the specifics of the U.S. animal agriculture industry (e.g., average animal weights and slaughter ages that differ from those in other countries, data availability regarding animal populations) merit the development of a U.S. specific biomass calculation method that considers the unique situation in the U.S. However, the general approach to calculating the biomass denominator (e.g., how animals that are usually kept for more than one year are considered in the calculation, or whether average animal weights are estimated at slaughter or at another time during the animal's life cycle) can and should be aligned with existing biomass calculation methods to the extent possible. Such agreement of approaches across entities and geographic regions reduces confusion and the potential for erroneous interpretations, can help support international coordination efforts, and may allow for comparisons across different settings where appropriate. Where the U.S. chooses to differ from approaches taken by other entities such as OIE, it would be helpful to have a description of the differences to other established methodologies such as the European Union's population correction unit (PCU) method, why the chosen method is most appropriate for the U.S situation, and a discussion of how these differences may have affected the biomass and adjusted antibiotic sales estimates.

**3. FDA should consider the data limitations including the robustness of the estimates in developing reporting options for adjusted sales data, provide clear guidance in the report on appropriate and inappropriate analyses of the data, and limit reporting to robust estimates.**

As discussed above, sales data have inherent limitations associated with them, and not all comparisons and analyses that may be technically possible are meaningful and robust – for instance because of data scarcity and small sample sizes. In addition, as also discussed above, the specific biomass calculation methodology adopted by FDA can limit the comparability of the data, for instance with data collected in other jurisdictions that estimate biomass using a considerably different approach. FDA should be clear in the reporting of adjusted sales data – similar to the qualifications on interpretation provided in FDA's annual sales data reports regarding data interpretation – what inference is and isn't appropriate. Also, when breaking down the adjusted sales data by species and antibiotic class, care must be given to assure the robustness of the estimates (in particular given the data scarcity that may result from the data partitioning) and to avoid inappropriate conclusions to be drawn. For instance, comparing trends in biomass-adjusted sales data across species over time may be influenced by external factors, such as the emergence of a new disease that may have temporarily driven antibiotic use in one species. At the same time, animal species are affected by different diseases and conditions, and the age and weight at which animals of different species are most likely to require antibiotics may vary considerably. Comparisons of

antibiotic consumption patterns across species may therefore be challenging. In the report, FDA should discuss potential confounders and other potential influences on the data and provide guidance on appropriate interpretation.

In conclusion, Pew commends the agency for developing this proposed method to adjust animal antibiotic sales data based on animal populations calculated based on animal species and weight. A transparent, easily reproducible method that enables FDA to gain additional insights from sales data while continuing to work with other agencies to collect other, more granular antibiotic use data will improve the collective understanding of antibiotic consumption trends, which is paramount to improving antibiotic stewardship and targeting innovation around antibiotic alternatives to areas of greatest need. We encourage the FDA to finalize the proposed method swiftly and to release adjusted sales data calculated based on the methodology periodically.

Sincerely,



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Kathy Talkington, Director  
Antibiotic Resistance Project  
The Pew Charitable Trusts



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Karin Hoelzer, Senior Officer  
Antibiotic Resistance Project  
The Pew Charitable Trusts

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<sup>i</sup> U.S. Food and Drug Administration, “FDA’s Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, Using a Biomass Denominator,” August 14, 2017, <https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM571099.pdf>.

<sup>ii</sup> Ibid.

<sup>iii</sup> Ibid.