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November 30, 2015

The Honorable Stephen Ostroff, MD
Acting Commissioner
US Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

The Honorable Thomas Frieden, MD, MPH
Director
US Centers for Disease Control & Prevention
1600 Clifton Rd
Atlanta, GA 30329

The Honorable Tom Vilsak
Secretary
US Department of Agriculture
1400 Independence Ave, SW
Washington, DC 20250

RE: Collecting On-Farm Antimicrobial Use and Resistance Data Public Meeting, FDA-2015-N-2768.

[Submitted via www.regulations.gov]

Dear Acting Commissioner Ostroff, Secretary Vilsak, and Director Frieden:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to comment on the September 29th public meeting, jointly-sponsored by the Food and Drug Administration (FDA), the US Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC), to obtain public input on approaches for collecting additional on-farm antimicrobial drug use and resistance data. IDSAs represents over 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the field of infectious diseases. Our members care for patients of all ages with serious and often life-threatening infections, including those caused by drug-resistant microorganisms.

There is substantial and compelling scientific evidence supporting the claim that non-judicious use of antimicrobials in both humans and food animals advances antimicrobial resistance in human pathogens. Better information on the use of antimicrobial drugs in food animals will enable public health officials and scientists to better understand and interpret trends and local variations in antimicrobial resistance. This will improve the understanding of the relationship between animal uses of these drugs and antimicrobial resistance in animals and humans, to identify agricultural sectors that use antimicrobials non-judiciously, and to evaluate interventions to prevent and control resistance.

The current lack of adequate US antimicrobial consumption data impedes our understanding of geographic and temporal trends in antimicrobial resistance. To

effectively combat the antimicrobial resistance crisis, government- and non-government public health, animal health and infectious diseases experts need ongoing access to reliable data on the scope and nature of antimicrobial consumption in animals. In addition, measurements should be standardized so that they can be assessed for products across time, species, and geography. IDSA strongly supports the FDA's recent proposal to collect species level data for swine, cattle, chickens, and turkeys and we also appreciate the agency's proposal to set a deadline for annual reporting of antimicrobial sales data summaries so that the public can have more reliable access to information. However, sales data alone will not significantly increase our knowledge about how and why antimicrobials are used in animals. Such data must be coordinated with other sources of on-farm and antimicrobial usage and resistance data in order to yield meaningful information.

During the September 29 meeting, several promising ideas were presented by USDA, FDA, and CDC staff. We support your efforts to communicate these proposals to a broader stakeholder audience. We also understand that any new efforts will require financial support from Congress. In 2014, IDSA convened the [U.S. Stakeholder Forum on Antimicrobial Resistance \(S-FAR\)](#) to help mobilize stakeholder support for the President's National Action Plan for Combating Antibiotic-Resistant Bacteria ("CARB plan"). S-FAR now includes over 110 organizations, including medical, veterinary, public health, and industry partners committed to moving the CARB plan forward and ensuring that it is sustainably funded by Congress.

We look forward to working with all three agencies to build stakeholder support for improved antibiotic sales, use, and resistance data collection on farms. We will be in touch with respective offices to set up meetings with S-FAR partners in the near future. In the meantime, IDSA offers the following recommendations:

- ***Publish monthly sales data.*** Since 2008, the FDA has collected data from animal pharmaceutical manufacturers about the amounts of antibiotics sold every month. Accordingly, FDA should include a table that reports aggregate unit (e.g. container, strength, dose) sales by month for each drug class. This information may help scientists identify connections between antimicrobial use and the occurrence of specific diseases and resistance patterns, which could help advance novel treatment or prevention approaches.
- ***Publish state- or regional-level data.*** FDA should report state-by-state data as reported by the manufacturers (and where possible, smaller geographic areas) on antimicrobial sales rather than a national aggregate. Such data would be useful to benchmark antimicrobial use based on the density of food-animals in a particular state or region. The Centers for Disease Control and Prevention (CDC) has successfully used outpatient antimicrobial prescribing for humans by region.
- ***Work with the US Department of Agriculture (USDA) to improve the National Animal Health Monitoring System (NAHMS) reporting of on-farm antimicrobial use.*** NAHMS collects qualitative information on antimicrobial use in livestock production but reporting is voluntary, not comprehensive, and sporadic. Better information about on-

farm antimicrobial usage (e.g., prophylactic vs. therapeutic use), including what factors influence livestock producers' decisions about using antimicrobials, a method to quantify use, and annual surveys in all major production classes will help to target outreach and education activities related to antimicrobial use and resistance.

- ***Work with USDA and CDC to develop a public communication plan to share and explain the implications of collected data for human and animal health.*** It is important that farmers, ranchers, and the public understand exactly what data on antimicrobial sales and use mean in terms of threats to human and animal health. FDA should work with the USDA in advance of data publication to create a public dissemination and education plan so that confusion is minimized.

We commend the FDA, USDA, and CDC for collaborating to improve what we view as an inadequate data collection system. We appreciate the opportunity to attend the public meeting and provide comments on these joint efforts to promote judicious use of antimicrobials in food animals. Should you have any questions, please contact John Billington, IDSA Director of Health Policy, at jbillington@idsociety.org / (703) 299-0015.

Sincerely,

A handwritten signature in black ink that reads "Johan S. Bakken MD, PhD". The signature is written in a cursive, slightly slanted style.

Johan S. Bakken, MD, PhD, FIDSA
IDSA President