KEEP ANTIBIOTICS WORKING
The Campaign to End Antibiotic Overuse

October 15, 2018

Rakesh Raghuwanshi, M.P.H.
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
White Oak Bldg 1, Room 3309
10903 New Hampshire Ave
Silver Spring, Maryland 20993
E-mail: rakesh.raghuwanshi@fda.hhs.gov

Dear Mr. Raghuwanshi:

The undersigned Keep Antibiotics Working (KAW) member groups and allies appreciate this opportunity to comment to the Food and Drug Administration (FDA) Science Board on the National Antimicrobial Monitoring System (NARMS). Formed in 2001, KAW is a coalition of advocacy organizations that joined together to ensure that difficult-to-treat superbugs resulting from the overuse of antibiotics on farms do not reverse the medical advances of the past century.

We applaud the FDA and its NARMS partners – the Centers for Disease Control and Prevention (CDC), and the Department of Agriculture (USDA) – for building and maintaining a strong NARMS program and for recent improvements in sampling, reporting, and the adoption of new technology. We remain deeply concerned, however, with the NARMS program's ongoing failure to include a system to collect data on the use of antibiotics on-farm. Federal agencies and policy makers need these data to better interpret the trends in antimicrobial resistance reported by NARMS. On-farm antibiotic use data are needed to make connections between use and resistance, as was recognized in the most recent and earlier Science Board reports. In that sense, on-farm antibiotic use data will greatly enhance the value of the retail, clinical, and food animal data already being collected by NARMS.

Additional changes should be made to NARMS to better identify and elucidate emerging antibiotic resistance problems such as with carbapenem- and colistin-resistant *Enterobacteriaceae*. KAW also requests that the FDA continue to strive to speed up release of data from all three NARMS partners (FDA, CDC, and USDA) and to work with partners to harmonize reporting.

We ask that the FDA Science Board continue to work with the FDA to make sure that the Science Board's recommendations are followed, and to challenge the FDA and other federal agencies to do more with respect to addressing the urgent threat posed by worsening antibiotic resistance. In addition, we encourage the FDA Science Board to engage with the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to help drive needed change.

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

More specifically, we ask that the Science Board support the following recommendations to strengthen NARMS:

- FDA should work with the USDA to create a system to collect data on how antibiotics are used on-farm including information on quantities of antibiotics used and the specific indications for use.
- FDA should improve upon its ability to monitor for and detect emerging antimicrobial resistance threats such as carbapenem- and colistin-resistant *Enterobacteriaceae.*
- NARMS infrastructure should be used to periodically sample a broader range of bacteria (e.g. *Clostridium spp*., *Staphylococcus spp*., and *Enterobacteriaceae* other than *E. coli*) in order to identify other potential resistance threats transmitted through food and food animals.
- The FDA should incorporate sampling of imported foods, including imported animal feed, feed ingredients and seafood, into NARMS.
- Federal agencies should more fully use whole genome sequencing (WGS). WGS applied to all NARMS *E. coli* isolates could be used to monitor emerging resistance.
- Federal agencies should increase use of metagenomics approaches to identify the diversity and frequency of resistance genes in the food chain outside the limited number of bacteria that NARMS currently monitors.
- Federal agencies should collect more metadata on sample sources such as whether or not antibiotics were used in the production of animals or meat and include that information in the analysis.
- The FDA and partner agencies should commit to releasing annual NARMS reports in the year following the data collection. It is late 2018 now, and the most recent NARMS data are from 2015.
- The FDA and partner agencies should move toward integrated analysis and reporting of resistance and food producing animal antibiotic sales data adjusted by animal biomass.

The NARMS program is a vital public health surveillance program that has undergone continuous improvement despite serious resource challenges. We hope that these comments will help guide future improvements for this important program.

Sincerely,

Antibiotic Resistance Action Center, the George Washington University
Center for Biological Diversity
Clinician Champions in Comprehensive Antibiotic Stewardship
Consumer Federation of America
Consumers Union
Food Animal Concerns Trust
Health Care Without Harm
Humane Society Legislative Fund
Humane Society Veterinary Medical Association
Johns Hopkins Center for a Livable Future
Natural Resources Defense Council
San Francisco Bay Area Chapter, Physicians for Social Responsibility
Waterkeeper Alliance