Division of Dockets Management (HFA-305)
Food and Drug Administration
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The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on the Food & Drug Administration (FDA) Center for Veterinary Medicine’s (CVM) update to the Strategic Plan of the National Antimicrobial Resistance Monitoring System (NARMS). As FDA recognizes, antibiotic resistance (ABR) is no longer an emerging threat, but one that has already emerged and must be effectively managed. CSPI has begun an ongoing project on ABR, and expects to contribute both data and policy suggestions to this important subject moving forward.

The updated Strategic Plan represents a strong foundation for work on ABR—but we suggest several general improvements to enhance the program’s focus on food safety. First, we urge the participating agencies (FDA, Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA)) to adequately fund the NARMS program to perform its critical surveillance functions.

The participating agencies and sub-agencies—in particular CVM—should also work closely to develop risk management approaches to better control the over-use of antibiotics in food production. The attached White Paper includes specific data on outbreaks linked to ABR-resistant pathogens in foods ranging from meat and poultry to dairy. It is clear that the widespread and often indiscriminate use of antibiotics in food animals is having a serious impact on public health. CDC, USDA, and FDA should develop enhanced protocols for antibiotic use, testing, and evaluation. Where appropriate, we urge the agencies to take appropriate regulatory action—including by the use of formal rulemaking as well as interpretive rules—to address these issues.

\(^1\) CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.
We have specific comments on the following goals delineated in the strategic plan:

- **Goal 1.** NARMS ABR data should be integrated with other relevant foodborne disease data, such as CDC’s Foodborne Outbreak Online Database, FoodNet, and PulseNet. The integration of these data sources would make research more efficient and could provide enhanced access and understanding of the data produced.

- **Goal 1, Objective 1.2.** We applaud efforts to enhance stakeholder access to data. CSPI routinely uses data from NARMS and other sources to inform policy positions and develop testimony and statements, and increased access to this data serves the public interest.

- **Goal 1, Objective 1.3.** We urge NARMS to decrease the time between data compilation and data release. Currently, data is released approximately 2 years after it is collected. NARMS has stated its intention to decrease that time period, but has not been definitive about what improvements it expects to make.

- **Goal 2.** NARMS should expand its testing protocol to include on-farm testing. Results from these tests could greatly inform policy decisions on the over-use of antibiotics in animal production, and could have a profound impact on public health and antibiotic-resistant disease. Further, NARMS should expand its testing protocol to include testing of dairy cows and milk. Twelve of 35 antibiotic-resistant outbreaks documented by CSPI were in dairy products, with 10 of those 12 from unpasteurized milk or cheese. We also urge NARMS to expand its retail testing program to include ground chicken and ground pork products. Finally, NARMS should seek to improve tracking of human ABR foodborne outbreaks.

- **Goal 2, Objective 2.4.** CSPI applauds the effort to build a surveillance system to track antibiotic-resistant bacteria isolated from animal feeds. At least one recent study has suggested that chickens fed organic feed with no antibiotics had fewer antibiotic-resistant bacteria. More data is needed to confirm these findings.

- **Goal 3.** NARMS should work with its agency partners to better quantify the contribution of antibiotics used in agriculture—especially in food-producing animals—to antibiotic resistance in humans. Similarly, NARMS should work to quantify and monitor the use of antibiotics in agriculture, with a specific focus on those antibiotics that are important in human medicine.

- **Goal 3, Objective 3.3.** NARMS should, in collaboration with its agency partners, prepare a cost-benefit analysis of using antibiotics for growth promotion in food-producing animals, including the cost of treating antibiotic-resistant infections.
• Goal 4, Objective 4.1. NARMS should support the U.S. adoption of the World Health Organization Advisory Group on Integrated Surveillance of Antimicrobial Resistance ranking of antibiotics according to their importance in human medicine. The U.S. is currently out-of-step with the WHO on this issue, and it is crucial that the ranking of these antibiotics is reflective of their relevance to public health.

We appreciate the opportunity to comment on the updated Strategic Plan, and look forward to reviewing the data produced by the National Antimicrobial Resistance Monitoring System in the future. Attached is a White Paper developed by CSPI that may prove of use to NARMS in its work.

Sincerely,

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