

United States Senate

WASHINGTON, DC 20510

November 9, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell,

We write to express our support for the Food and Drug Administration's proposed rule to enhance data collection on the sale and distribution of medically-important antibiotics in agriculture, including species-specific estimates of antibiotic use. Antibiotic resistance in foodborne pathogens is a growing threat, and we therefore urge the department to submit a final rule to the Office of Management and Budget quickly.

The Centers for Disease Control and Prevention estimate that antibiotic-resistant foodborne pathogens cause more than 400,000 illnesses each year. The Centers also report that 24 individuals have been hospitalized with multidrug-resistant antibiotic infections in Washington linked to pork, which is another reminder that the federal government needs to follow through with a comprehensive strategy to monitor antibiotic resistance in the food supply.

President Obama's National Strategy to Combat Antibiotic-Resistant Bacteria identifies strengthening surveillance of resistance in communicable diseases as a key goal, and the Food and Drug Administration's proposed rule is a step forward toward meeting that goal. Species-specific estimates will provide valuable new information, which will help link existing data collected by the agency. In 2013, the agency finalized *Guidance for Industry 213*, which will phase out the use of medically-important antibiotics for production reasons over three years and require veterinary oversight for these drugs. We believe that a comprehensive strategy to monitor the sale, distribution, and use of antibiotics is needed to evaluate to what extent this policy improves antibiotic stewardship and public health.

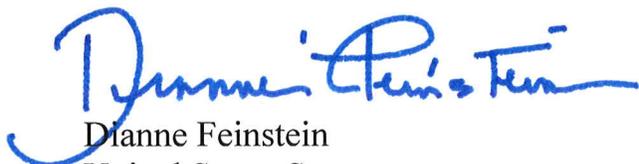
We understand that some feed and pharmaceutical industry groups have expressed a view that the agency lacks the authority to collect species-specific estimates on antibiotic sales from drug sponsors. This is wrong; the agency has clear authority to propose this rule. Section 512 (l) (1) of the *Federal Food, Drug, and*

Cosmetic Act provides the department authority to require reporting of information the secretary determines necessary to ensure animal drug safety. Species-specific estimates of antibiotic sales are well within this authority and clearly support the agency's public health mission to combat antibiotic-resistant communicable diseases. Additionally, Congress provided the agency broad direction in the 2008 reauthorization of the *Animal Drug User Fee Act* to collect and report data on the distribution of veterinary antibiotics.

The proposed rule on sales and distribution data will not provide all of the data needed to ensure the safety of medically-important antibiotics, but it is a critical step to improve our understanding of antibiotic resistance. Additional efforts can and should be taken by your department and the U.S. Department of Agriculture to collect actual on-farm antibiotic use data, as well as more data on the trends in antimicrobial resistance in bacteria. We appreciate that these efforts are underway. However, public health is at stake, and we believe your department should act quickly to implement new data collection tools to fill in the remaining gaps in our knowledge of antibiotic use and resistance in the food supply.

Thank you for your leadership in protecting the public health. We look forward to your response, and eagerly await the issuance of a final rule to improve the monitoring of medically-important antibiotics used in agriculture.

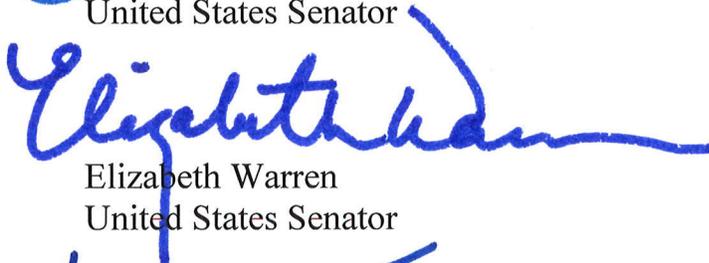
Sincerely,



Dianne Feinstein
United States Senator



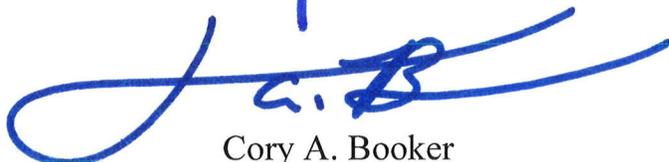
Kirsten E. Gillibrand
United States Senator



Elizabeth Warren
United States Senator



Richard Blumenthal
United States Senator



Cory A. Booker
United States Senator

cc: The Honorable Thomas J. Vilsack
Secretary of Agriculture

Dr. Stephen Ostroff
Acting Commissioner of Foods and Drugs