

United States Senate

WASHINGTON, DC 20510

November 12, 2014

The Honorable Margaret Hamburg
Commissioner
U. S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We write to urge you to quickly issue a proposed rule to increase data collection on the distribution of medically important antibiotics used in agriculture and to request that you develop a plan to estimate on-farm antibiotic use practices. We applaud your agency's recent step to issue improved, more transparent reports on annual food animal antibiotic drug sales and distribution data. However, we are disappointed to learn that your agency has decided to delay proposing a rule that would further enhance data collected on this topic until next year, when the Office of Management and Budget estimated the rule would be released in 2014.

Antibiotic resistance in foodborne pathogens remains a threat to the American public. According to the Centers for Disease Control and Prevention, foodborne pathogens that are resistant to at least one antibiotic are estimated to cause over 400,000 infections each year. In September, the president released a national strategy to combat antibiotic resistance and signed an executive order requiring all federal agencies to implement this plan. The strategy states that improving the stewardship of how antibiotics are used and increasing the surveillance of antibiotic resistance must be national priorities. These actions are clearly needed as our current antibiotic use and resistance monitoring system has shortcomings.

Given the president's national strategy, it is our view that you should expeditiously propose a rule to improve antibiotic distribution data collection. Data on antibiotic use and resistance enables federal agencies to take action to protect the public health and supports research into better understanding complex questions related to the development of antibiotic resistance and potential links to human health. Furthermore, data regarding the distribution of medically important antibiotics is needed to monitor the impact of your new policies aimed at eliminating the injudicious use of these drugs in agriculture. We particularly hope this proposed rule will allow your agency to collect more specific data on how different antibiotics are used in different species and for different indications.

We also encourage you to develop a plan to estimate how antibiotic sales and distribution data relates to on-farm antibiotic use practices. Under your agency's new policies, all medically important antibiotics added to livestock feed or water are to be distributed through a veterinary prescription or feed directive. Greater use of veterinary feed directives and prescriptions provides the agency with new opportunities to work with veterinarians and industry to gain insight into how antibiotics are used in specific species and regions of the nation. As you know, any type of antibiotic use can contribute to the development of antibiotic resistance, and data on antibiotic use practices is important for identifying and addressing risks to human and animal health.

Thank you for your leadership in protecting the public health. We look forward to continuing to work with you on improving antibiotic stewardship in both the human health and animal health fields.

Sincerely,



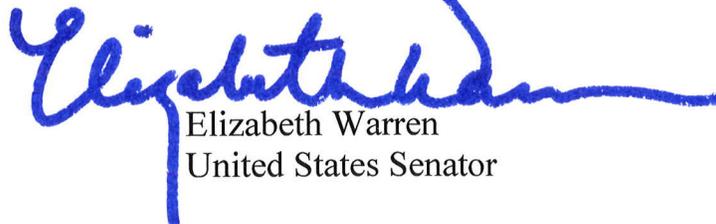
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Tom Harkin
United States Senator



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