

## **STRENGTHENING ANTIBIOTIC OVERSIGHT ACT**

**Senators Warren (D-MA), Gillibrand (D-NY), Feinstein (D-CA), and Blumenthal (D-CT)**

Antibiotic drugs are critical tools for treating serious bacterial infections, but they are becoming less and less effective. Today, resistance has been seen in almost all antibiotics ever developed.<sup>i</sup> The CDC estimates that 2 million people in the U.S. develop antibiotic-resistant infections every year, resulting in over 23,000 deaths and adding \$20 billion in health care costs to an already-overburdened system.<sup>ii</sup>

The overuse of medically important antibiotics in food animals can encourage the growth of drug resistant bacteria that can cause hard-to-treat human diseases. One in five antibiotic-resistant infections in humans come from bacteria in animals and food.<sup>iii</sup> Bacteria can spread from animals to animal products, contaminated water or soil, or the environment. In order to prevent the development of antibiotic-resistant bacteria, it is important that antibiotics be used judiciously in animals.

The Food and Drug Administration (FDA) approves drugs used in animals and helps oversee veterinary use of animal drugs, including antibiotics used in animals. A 2017 Government Accountability Office (GAO) report found that while the Department of Health and Human Services (HHS) has increased oversight and data collection of medically important antibiotics in food animals in recent years, gaps still exist.<sup>iv</sup> Current FDA rules do not contain duration limits regulating how much of an antibiotic can be used in an animal for a specified amount of time for all medically important antibiotics. The FDA has long acknowledged that using medically important antibiotics in food animals for long or unlimited durations increases the risk of antibiotic resistance, yet roughly one-third of the products containing medically important antibiotics for use in in feed or water still have label indications without duration limits.<sup>v</sup> In addition, the FDA lacks important data on antibiotic use in animals. The GAO recommendations included that the FDA establish duration limits for all medically important antibiotics used in food animals and that better data on antibiotic use in animals be collected.

### **Strengthening Antibiotic Oversight Act**

The *Strengthening Antibiotic Oversight Act* strengthens the oversight of medically important antibiotics administered to food animals in order to prevent antibiotic resistance. The bill:

- Requires the FDA to review the durations of use of approved indications of medically-important antibiotics labeled for use in animals;
- Gives the FDA authority to withdraw approvals for unjustified duration limits;
- Directs the FDA to use funds collected through animal drug user fees to collect and report data on antibiotics delivered to farms, through sampling of veterinary feed directives and feed distribution reports.

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<sup>i</sup> P&T, “The Antibiotic Resistance Crisis,” C. Lee Ventola, April 2015,  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/>.

<sup>ii</sup> Centers for Disease Control and Prevention, “Antibiotic/Antimicrobial Resistance,”  
<https://www.cdc.gov/drugresistance/index.html>.

<sup>iii</sup> Centers for Disease Control and Prevention, “Antibiotic Resistance from the Farm to the Table,”  
<https://www.cdc.gov/foodsafety/challenges/from-farm-to-table.html>.

<sup>iv</sup> U.S. Government Accountability Office, “Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals,” [https://www.gao.gov/products/GAO-17-192?mobile\\_opt\\_out=1#summary\\_recommend](https://www.gao.gov/products/GAO-17-192?mobile_opt_out=1#summary_recommend).

<sup>v</sup> Food and Drug Administration Center for Veterinary Medicine, “Guidance for Industry #213,”  
<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>; Food and Drug Administration, “FDA Seeks Public Input on Next Steps to Help Ensure Judicious Use of Antimicrobials in Animal Agriculture,”  
<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm520110.htm>.