February 16, 2023 (updated February 27, 2023)

The Honorable Bernie Sanders Chair, Senate Committee on Health, Education, Labor and Pensions 332 Dirksen Senate Office Building Washington, D.C. 20510

The Honorable Bill Cassidy, MD Ranking Member, Senate Committee on Health, Education, Labor and Pensions 455 Dirksen Senate Office Building Washington, D.C. 20510

Re: Strengthen our defense against an ever-worsening antibiotic resistance crisis

Dear Chairman Sanders and Ranking Member Cassidy,

Antibiotic resistance is a global crisis that caused over 1.2 million deaths in 2019.¹ Antibioticresistant infections kill at least 35,000 people in the U.S., each year, and possibly up to 162,000.² Ongoing spread of drug-resistant bacteria is eroding the ability of modern medicine – including interventions such as intensive care, cancer treatments, and organ transplants – to save lives.³ Antibiotic overuse drives this spread.

Overuse and misuse of these precious medicines are considered commonplace in medicine and on food-producing animals. Too often, human antibiotics are incorrectly prescribed for viral infections. Meanwhile, a 2021 study of 22 U.S. cattle feedlots, raising approximately 2.5% of all beef cattle slaughtered, found those cattle were fed erythromycin-like antibiotics for an average of 135 consecutive days, to prevent liver abscesses brought on by inappropriate diets.⁴

Federal efforts have fallen short of identifying and taking steps to curb sources of antibiotic overuse and slow the spread of resistance. We believe that governance of the nation's antibiotics, and protection of our health, demands action on three top federal policy priorities:

- Building a national program to comprehensively collect and analyze antibiotic use data;
- Establishing concrete goals to reduce the use of medically important antibiotics, especially in animals;
- Setting a target date for phasing out routine preventive use of these precious medicines.

Clear national goals would emphasize to antibiotic prescribers and consumers how critical it is for public health and national security to reduce antibiotic overuse. But overuse must be identified before it can be curbed. National data on antibiotic sales are available, but insufficient to protect public health. We need a national program to closely monitor antibiotic use in both human and non-human settings, including veterinary use. One example is a recent federal rule change so that by 2024 any hospital wanting to receive Medicare funding will need to submit antibiotic use and stewardship data to the CDC through the National Healthcare Safety Network.⁵

In contrast, no programs currently exist to regularly track the use of medically important antibiotics on animals, especially farm animals, despite expert recommendations over decades that such tracking is a public health imperative.⁶ The gap is significant because animal drug sales data show that roughly twice as many medically important antibiotics (by weight) are sold for use on food-producing animals as for human medicine.⁷ Collection of use data at the farm level would provide the kind of details needed to spot recurring patterns of antibiotic overuse. Detailed use data would enable the design of targeted, more effective interventions to curb overuse as well.

Fifteen years ago, Congress amended the Animal Drug User Fee Act (ADUFA) to require the Food and Drug Administration (FDA) to collect data on animal antibiotic sales and issue annual reports on them.⁸ Reports are now available for 2009 to 2021. With the reauthorization of ADUFA in 2023, we urge leaders in Congress to once again take action by directing and funding the FDA to collect data and report each year not only on drug sales, but also on the actual use of the 65% of all medically important antibiotics that are sold as additives to animal feed.⁹

One in three of these antibiotic additives may legally be fed to groups of healthy animals for excessive periods of time – even their entire life span.¹⁰ This is described as antibiotic use for disease prevention, which the FDA currently considers a "therapeutic" use. The World Health Organization determined in 2017 that routine disease prevention use of these antibiotics is unnecessary and recommended that countries eliminate it.¹¹ Many published studies, including the one noted above, indicate that routine disease prevention use is commonplace in U.S. food animal production. To confirm its prevalence, however, data on antibiotic use needs to be regularly collected and reported.¹² The FDA's most recent antibiotic sales figures underscore the need for more detailed, farm-level data on antibiotic use. A recent analysis of those sales, using validated European methods, concluded that current levels of antibiotic use in U.S. food animal production are higher, not lower, than they were in 2017.¹³

Under FDA regulations, feed mills are required to maintain records on the medically important antibiotics they mix into animal feeds, and on the distribution of those medicated feeds. If Congress directs the FDA to collect these records, the agency would have the ability to identify potential sources of overuse in animals. Congress also could hold the agency accountable for reporting whether its decade-long effort to foster veterinary antibiotic stewardship has had any measurable impact. If Congress takes no action, then FDA likely will continue to claim there is a lack of data to indicate whether feed antibiotics are being overused.

Investing in these policy reforms has demonstrably worked. In Europe, robust data collection and reporting around changes in antibiotic use, combined with concrete use reduction goals, has helped to significantly curb antibiotic overuse. Under the direction of Europe's parliament, the European Medicines Agency (EMA) launched a comprehensive program in 2009 to collect and report data on veterinary antibiotic sales and use in as many as 31 individual countries. Since 2011, the program has issued annual reports summarizing trends in individual countries as well as region-wide trends. According to the latest report, Europe's level of veterinary antibiotic use in aggregate fell 47% from 2011 to 2021.¹⁴ Over roughly the same decade, national use reduction goals helped the food animal sectors in the United Kingdom and the Netherlands reduce their antibiotic use by 55% and 65%, respectively.¹⁵

Notably, Europe's policymakers have placed a central focus on improving food animal health, nutrition, hygiene, and welfare so as to avoid the need for antibiotics in the first place. The rapid decline in veterinary antibiotic use suggests this too has been an effective approach. Applying EMA methods to available data from the U.S., an analysis concludes that Europe now produces around 75% more food-producing animals by total weight than the United States on a fraction of the land area, and with less than half the rate of antibiotic use.¹⁶

More recent measures promise to reduce Europe's levels of antibiotic use even further. In January, 2022 a revamped veterinary medicine regulation took effect requiring all EU member countries to collect farm-level data on antibiotic use. In addition, the new rules make it illegal for antibiotics to be given routinely to food-producing animals for disease prevention; long ago, individual European countries had already acted to ban the practice, some as early as 1995.¹⁷

As medical, nursing, infectious disease, public health, animal health and welfare, consumer, and environmental groups, we urge leaders in Congress to take action to protect the nation's health. Specifically, the Committee could close data gaps and loopholes in our nation's governance of antibiotic use by incorporating the recommended policy priorities into this year's Animal Drug User Fee Act (ADUFA) reauthorization package.

Federal health agencies like the FDA need Congress to provide them with clear direction and authority, along with permanent resources, to closely track antibiotic use, identify patterns of overuse, and mount effective reform efforts. These actions represent the nation's best opportunity to slow the spread of antibiotic-resistant bacteria before it is too late.

Sincerely,

| Infectious Diseases Society of America | American Public Health Association |
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| Humane Society of the United States | Humane Society Veterinary Medical Association |
| Natural Resources Defense Council (NRDC) | Pediatric Infectious Diseases Society |
| Antibiotic Resistance Action Center, | Health Care Without Harm |
| the George Washington University Food Animal Concerns Trust (FACT) | Andrew Weil Center for Integrative Medicine, University of Arizona |
| Humane Society Legislative Fund | Johns Hopkins Center for a Livable Future |
| The Alliance of Nurses for Healthy | Lymphoma Foundation of America |
| Environments (ANHE) | U.S. Public Interest Research Group (PIRG) |
| Society of Infectious Disease Pharmacists | Sharing Antimicrobial Reports for Pediatric |
| Association for Professionals in Infection | Stewardship (SHARPS), Department of |
| Control and Epidemiology (APIC) | Pediatrics/Infectious Disease, Washington University School of Medicine in St. Louis |
| | University School of Medicine in St. Louis |

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