

September 6, 2023

Hon. Charles Schumer  
Senate Majority Leader  
322 Hart SOB  
Washington, DC 20510

Hon. Mitch McConnell  
Senate Minority Leader  
317 Russell SOB  
Washington, DC 20510

**Re: Improving Antibiotic Stewardship in Food-Producing Animals**

Dear Leader Schumer and Minority Leader McConnell,

Effective antibiotics save lives. The efficacy of long-reliable antibiotics has waned with their continued overuse, however. Even common infections are more dangerous today because the bacteria causing them are now resistant to treatment with more antibiotics. Every 15 minutes someone in the U.S. dies from a drug-resistant infection. Experts predict by 2050 there could be 10 million worldwide deaths each year from these so-called superbug infections unless policymakers take urgent action to more effectively curb overuse and thereby slow the spread of resistance.

Antibiotic overuse, meaning use that is unnecessary or avoidable, persists in human medicine and especially in food animal production in the U.S. The only information the FDA regularly reports that pertains to stewardship and use of animal antibiotics are national sales data, which Congress directed as part of its 2008 amendments to the Animal Drug User Fee Act (ADUFA). The latest FDA data clearly show that 2021 sales of medically important antibiotics for use in food-producing animals were higher, not lower, than they were five years earlier. Outside experts, based on these and other public data, reasonably conclude that antibiotic stewardship in U.S. food animals overall is likely worse than it was in 2017.

Recently, twenty leading medical, infectious disease, public health, animal health, food safety, and other organizations signed a letter to Congress (linked [here](#)) pointing out the public health threat posed by continued veterinary overuse of these precious medicines. Specifically, the letter called out the acute need for improved FDA tracking and reporting on antibiotic use and stewardship in food animal production as a prerequisite for reducing the ongoing overuse of these precious medicines. Roughly twice as many medically important antibiotics (by weight) are sold for use on food-producing animals as for human medicine. Despite this fact, the FDA has done almost nothing to measure and verify improved stewardship. By contrast, the CDC has made significant efforts to track and improve antibiotic use and stewardship in human settings; all U.S. hospitals are required to report on both antibiotic resistance and use, starting in 2024.

The same letter called on Congress to exercise public health and food safety leadership to address these data gaps as part of its once-every-five-year reauthorization of the Animal Drug User Fee Act (ADUFA). It urged specific changes to ADUFA to create FDA accountability for measuring veterinary antibiotic stewardship, as well as improving it. FDA also should be held accountable for critically reviewing maximum durations of use for already-approved antibiotics and taking timely action to bring them into alignment with the agency's own stewardship principles.

By contrast, the House and Senate are poised to approve reauthorized ADUFA legislation that would require the FDA to report each year on certain stewardship-related activities, but not stewardship outcomes. FDA-reported activities, for example, would be those listed under the agency’s first five-year veterinary antibiotics stewardship “action plan”, which expires at the end of 2023. However, that same plan fails to include quantifiable goals for improved stewardship over time, or even the establishment of consistent indicators for measuring stewardship from one year to the next. As such, the FDA today lacks the fundamental ability to demonstrate whether antibiotic stewardship in animals is better, worse, or the same as in 2018, before its stewardship action plan began. Unless Congress requires it to do so, the FDA will continue to report on its completion of certain activities, while more meaningful public health information—such as actual changes in antibiotic stewardship—likely will remain unreported.

Antibiotics do not simply save lives; they are the lynchpin of modern medicine. Without more effective stewardship, the next generation will experience a future where lifesaving procedures such as organ transplants, kidney dialysis, and Cesarean sections are far riskier—perhaps too risky to be viable treatments. It is long past time for Congress to prioritize stewardship of these precious medicines. Action forestalled for another five years, or until the next ADUFA reauthorization, could be action taken too late.

We urge you to reject the current ADUFA draft and make meaningful changes to begin addressing antibiotic stewardship in food-producing animals before it is brought for a vote before the Senate.

Sincerely,

One Health Trust

Secretariat of the Preventing Pandemics at the Source Coalition

Sharing Antimicrobial Reports for Pediatric Stewardship (SHARPS), Department of Pediatrics/Infectious Disease, Washington University School of Medicine in St. Louis

Health Care Without Harm

Food Animal Concerns Trust

Andrew Weil Center for Integrative Medicine University of Arizona

Humane Society Legislative Fund

Society for Healthcare Epidemiology of America (SHEA)

Pediatric Infectious Diseases Society (PIDS)

Alliance of Nurses for a Healthy Environment

Natural Resources Defense Council

Re: Wild

Center for Food Safety

Earthjustice

U.S. PIRG

Antibiotic Resistance Action Center, the George Washington University

Association for Professionals in Infection Control and Epidemiology (APIC)

Florida Clinicians for Climate Action

Society of Infectious Disease Pharmacists

cc: Senator Bernie Sanders, Chairman, Senate HELP Committee  
Senator Bill Cassidy, M.D., Ranking Member, Senate HELP Committee