

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 most recent data show that sales of medically important antibiotics for use in food-producing animals were higher, not lower, than they were five years earlier. Based on these and other public data, outside experts reasonably conclude that antibiotic stewardship in U.S. food animal production overall is likely worse than it was in 2017.

Earlier this year, twenty leading medical, infectious disease, public health, animal health, food safety, and other organizations [sent a letter](#) to Congressional leaders pointing out that continued veterinary overuse of these precious medicines poses a significant public health threat. They called out the critical need for improved FDA tracking and reporting on antibiotic use and stewardship in food animal production as a prerequisite for reducing their overuse. 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. By contrast, the FDA has done almost nothing to date to measure and verify improved veterinary antibiotic stewardship. Roughly twice as many antibiotics of medical importance (by weight) continue to be sold for food-producing animals as for human medicine.

With this letter, the undersigned groups reiterate an urgent call for Senate leaders to exercise public health and food safety leadership, and address these data gaps, as part of their once-every-five-year reauthorization of the Animal Drug User Fee Act (ADUFA). We urge 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. The House already passed its ADUFA bill that fails to bring about these public health imperatives; the Senate bill under discussion would do the same.

If these bills become law, the FDA would continue reporting each year only on certain stewardship-related activities, not on stewardship outcomes. This is already the case with the FDA’s current five-year veterinary antibiotic stewardship “action plan”, which expires at the end of 2023. That flawed plan at its outset failed to establish any consistent indicators for measuring stewardship from one year to the next, nor does it include any quantifiable goals for improving stewardship over time. Absent both stewardship indicators and goals, this plan has left the FDA lacking the fundamental ability to demonstrate whether antibiotic stewardship in animals today is better, worse, or the same as it was in 2017, before the current plan was initiated. Unless Congress requires it to do so, the FDA will continue reporting completion of certain activities alone, while more meaningful public health data—such as actual changes in antibiotic stewardship—likely will remain unreported.

Antibiotics save lives but also are the lynchpin of modern medicine. Without effective stewardship, our children will see a future where organ transplants, kidney dialysis, Cæsarian sections and other lifesaving procedures are far riskier—perhaps too risky to remain viable treatments. Congress is long overdue for prioritizing stewardship of animal antibiotics. Action forestalled another five years, until the next ADUFA gets crafted, 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,

Pediatric Infectious Diseases Society (PIDS)  
One Health Trust  
Alliance of Nurses for a Healthy Environment  
Secretariat of the Preventing Pandemics at the Source Coalition  
Food Animal Concerns Trust  
Humane Society Legislative Fund  
Center for Food Safety  
Earthjustice  
Health Care Without Harm  
Antibiotic Resistance Action Center,  
the George Washington University  
Society for Healthcare Epidemiology of America (SHEA)

Natural Resources Defense Council  
U.S. PIRG  
Florida Clinicians for Climate Action  
Society of Infectious Disease Pharmacists  
Re: Wild  
Andrew Weil Center for Integrative Medicine  
University of Arizona  
Sharing Antimicrobial Reports for Pediatric Stewardship (SHARPS), Department of Pediatrics/Infectious Disease, Washington University School of Medicine in St. Louis  
Association for Professionals in Infection Control and Epidemiology (APIC)

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