

May 21, 2021

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

RE: **Antimicrobial Resistance: Another Global Pandemic**

Dear Secretary Becerra,

COVID-19 underscores the need for governments to prepare for and urgently respond to *all* global health crises, hopefully mitigating their worst possible impacts. Antibiotic resistance is such a crisis. The Centers for Disease Control and Prevention and the World Health Organization have long deemed it one of the world's leading health threats. Despite this, the U.S. federal response has not been nearly urgent or comprehensive enough. As you "build back better" the nation's capacity to protect public health, we respectfully ask that you prioritize actions to stem the march of the 'slow-moving' pandemic of antibiotic resistance.¹

Antibiotic overuse, in both medical and farm settings, is the most important driver of resistance. As it stands, a U.S. resident dies a superbug-related death every 15 minutes. Antibiotic resistance contributes to at least 35,000—perhaps up to 162,000—U.S. deaths per year and experts project a global toll of 10 million annual deaths by 2050.² Without more effective federal actions to curtail antibiotic overuse, the resistance toll will only continue to rise.³ Our groups, as member and colleague organizations of *Keep Antibiotics Working*⁴, have advocated since 2000 for policies aimed at curbing drug overuse, especially in livestock production. We therefore seek to meet with you and your staff to discuss opportunities for your agency to act on this critical public health threat.

Roughly two-thirds of *all* medically important antibiotics sold in the United States are for food-producing animals. These sales rose more than 11% from 2017 to 2019, driven in large part by a 28% rise in sales for use in hogs.⁵ Across Europe, overall livestock consumption of the same antibiotics has steadily declined year after year since 2010—the outcome of an EU-wide campaign to prevent disease and avoid non-essential antibiotic use through interventions that improve on-farm conditions and overall animal health. With this approach, the large and profitable hog industries in Denmark and the Netherlands curtailed antibiotic usage by 60 to 70% compared to peak usage. This suggests that if the United States were to effectively implement the following three actions, it too could succeed in reducing livestock antibiotic use and turning the tide on antibiotic resistance:

- **Set National Targets to Curtail Antibiotic Use.** HHS should set ambitious national targets for reducing antibiotic use both in agriculture and human settings. Targets allow federal agencies to maintain accountability to their public health mission and adequately track progress over time.
- **Enact New Rules to Limit Allowed Uses of Antibiotic Drugs.** Ninety-four percent of antibiotics sold for use in food animal production are put into feed or water for groups of animals⁶—often for "disease prevention" when no clinical infections are present. Current FDA rules allow many of these drugs to be fed to all animals on a farm for their entire lives. FDA approved most of these antibiotics decades ago, long before the agency's safety determination required it to consider how exposing healthy herds to antibiotics for very long durations of time would increase selection for antibiotic resistance. This changed in 2003, when FDA published new guidance recommending against long durations of use for new medically important antibiotics. In 2013, when FDA began the process to restrict the use of antibiotics for growth promotion, the agency failed to address the overuse of the same drugs for routine disease prevention and left the excessive durations for older drugs in place.⁷ In 2016, FDA, recognizing the problem of long durations in older animal antibiotics, asked for public comment on how they could set duration limits for drugs that do not have them.⁸ No action was taken until February 2021, when FDA again asked for public

comment on a “draft concept paper”—not even a draft guidance.⁹ The agency’s concept is to allow drug makers to set their own limits on how long antibiotics should be fed to (often healthy) herds. The proposed timeline also delays placing duration limits on product labels until 2030 or even later. Fourteen years will have elapsed from the year FDA identified duration limits as a priority (2016) to the year when these modest rules may go into effect (2030). Without further action, after 2030, the overuse of medically important antibiotics in livestock production will continue, largely unchanged. This is unacceptable and continues to put public health at risk. FDA needs to move much faster to curtail antibiotic overuse. Antibiotic drugs should only be allowed for use to treat sick animals, to control disease outbreaks verified by a licensed veterinarian, and in limited other circumstances on individual animals. Limits must also be set regarding the length of time antibiotics can be used.

- **Track Actual Antibiotic Use.** Food animals are the biggest consumers of medically important antibiotics in the United States. Surveillance systems are desperately needed that describe what, when, where and how these precious medicines are actually used on U.S. farms and feedlots. Over the past two decades, members of Congress, numerous GAO reports, FDA advisors, and other infectious disease experts have all recognized the critical public interest in collecting and reporting national data on farm usage of antibiotics. New legislation in California and Maryland has shown the feasibility of collecting farm-level data on antibiotic use, with reporting under the Maryland law in particular showing the public benefit of that approach.¹⁰ But we remain no closer to having a national surveillance system today than was the case under the Clinton Administration. Strong, sustained leadership is urgently needed to overcome opposition to this accountability measure.

As Secretary, you have heard expert warnings that the next pandemic is never a question of “if”, but rather “when”. The “when” for antibiotic resistance is now, unfortunately. Like COVID-19, antibiotic resistance is a threat that will defy quick or easy solutions. Our stockpile of dependable antibiotics is rapidly shrinking and with it the viability of surgical procedures which rely on these life-saving drugs. Conserving existing antibiotics is especially critical given that our efforts to develop new antibiotics are enormously expensive and fraught with uncertainty. At the same time, the lack of forward progress demonstrated by previous administrations must be urgently remedied. Strong federal leadership is both a necessity, and overdue.

We look forward to meeting and sharing our recommendations with you and your staff. To arrange, please respond to Steven Roach, sroach@foodanimalconcerns.org, longtime coordinator of *Keep Antibiotics Working*.

Sincerely,

Animal Legal Defense Fund
Antibiotic Resistance Action Center, George
Washington University
Center for Biological Diversity
Center for Food Safety
Consumer Federation of America
Consumer Reports
Earthjustice
Food Animal Concerns Trust
Government Accountability Project Food Integrity
Campaign

Health Care Without Harm
Humane Society Legislative Fund
Humane Society Veterinary Medical Association
Interfaith Center on Corporate Responsibility
Johns Hopkins Center for a Livable Future
Natural Resources Defense Council
San Francisco Bay Physicians for Social
Responsibility
The Humane Society of the United States
U.S. PIRG
World Animal Protection

¹ Jinks T. “Drug-resistant infections: what we’re doing now to tackle this slow-moving pandemic,” Wellcome Trust, November 10, 2020 ; Makary M. et al, *The Next Pandemic is Already Here*, MedPage Today, January 20, 2021.

² <https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>

³ CDC, *Antibiotic Resistance Threats in the United States*, 2019, US Department of Health and Human Service, 2019.

⁴ Keep Antibiotics Working is a coalition of 20 public health, consumer, animal protection and other non-profit organizations, that has advocated for smarter usage on farms of the antibiotics most precious to people.

⁵ US Food and Drug Administration, 2019 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, December 2020.

⁶ US Food and Drug Administration, 2019 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, December 2020.

⁷ Center for Veterinary Medicine | FDA. “CVM GFI #213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209.” U.S. Food and Drug Administration. FDA, April 16, 2019. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed>.

⁸ Center for Veterinary Medicine | FDA. “CVM Updates - FDA Seeks Public Input on Next Steps to Help Ensure Judicious Use of Antimicrobials in Animal Agriculture.” WebContent. Center for Veterinary Medicine, September 12, 2016. <https://wayback.archive-it.org/7993/20190207232109/https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm520110.htm>.

⁹ Center for Veterinary Medicine | FDA. “FDA Seeks Public Comment on Potential Approach for Defining Durations of Use for Certain Medically Important Antimicrobial Drugs for Food Animals.” FDA, February 22, 2021. <https://www.fda.gov/animal-veterinary/cvm-updates/fda-seeks-public-comment-potential-approach-defining-durations-use-certain-medically-important>.

¹⁰ California Legislature. 2015. California Senate Bill 27, Assembly Floor Analysis.

Available: https://leginfo.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201520160SB27;

California Legislature. 2015. Food and agricultural code - fac, division 7. Agricultural chemicals, livestock remedies, and commercial feeds [12500 - 15340] chapter 4.5. Livestock: Use of antimicrobial drugs [14400 - 14408].

Available: https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=FAC&division=7.&title=&part=&chapter=4.5.&article=;

Maryland General Assembly. 2019a. Senate Bill 471.

Available: <https://mgaleg.maryland.gov/2019RS/bills/sb/sb0471e.pdf>;

Maryland General Assembly. 2019b. Senate Bill 471 Fiscal and Policy Note Enrolled - revised.

Available: http://mgaleg.maryland.gov/2019RS/fnotes/bil_0001/sb0471.pdf.