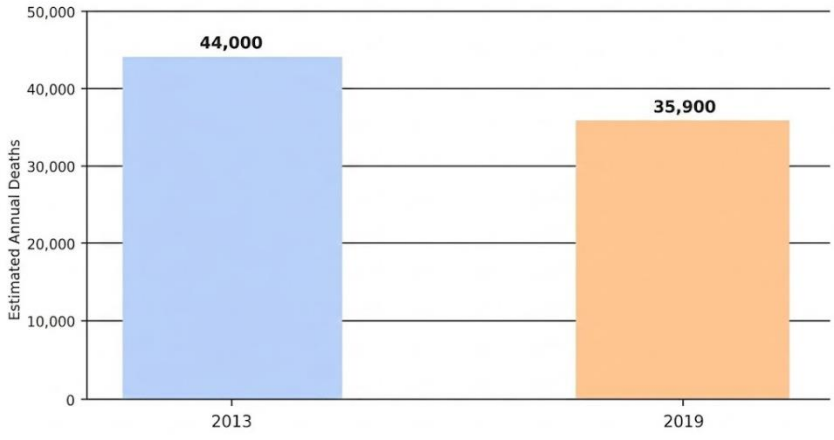
EXECUTIVE SUMMARY OF CITIZEN PETITION TO THE FOOD & DRUG ADMINISTRATION TO PROTECT PUBLIC HEALTH FROM UNSAFE USES OF ANTIBIOTICS IN LIVESTOCK & POULTRY

EXECUTIVE SUMMARY

The Routine Use of Antibiotics in Animal Feed and Water Poses a Major Public Health Threat

The routine use of antibiotics in animal feed and water for disease prevention rather than treatment or control of diagnosed bacterial diseases threatens the effectiveness of medically important antibiotics. These antibiotics are essential for surgery, chemotherapy, organ transplantation, and the care of premature human infants, not to mention the treatment of many common bacterial diseases. This overuse of antibiotics leads to the creation of antibiotic-resistant bacteria that then sicken and kill people and animals, risking the health and welfare of all Americans and people around the world. Indeed, antibiotic-resistant bacteria are already responsible for about 35,000 deaths and over two million illnesses every year in the United States alone. All of this is well known and undisputed.

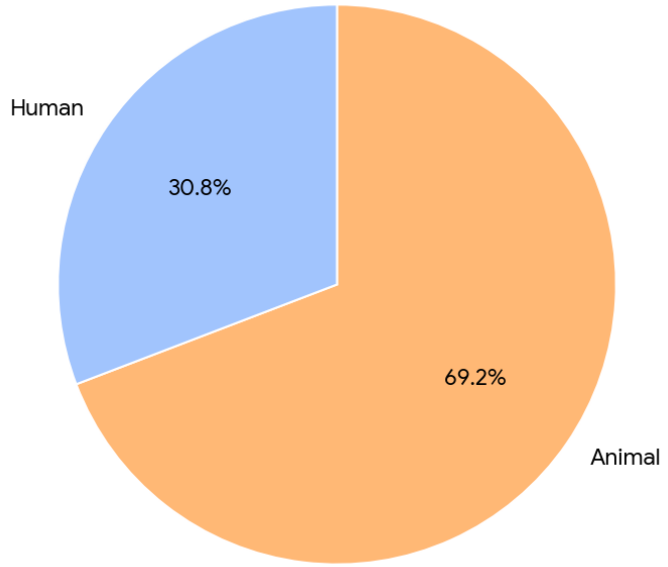
Figure 1. Estimated U.S. Deaths from Antibiotic-Resistant Infections[1]



[1] Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2019*, at 3, 6 (2019), https://www.cdc.gov/antimicrobial-resistance/data-research/threats/index.html (updating the estimated number of deaths caused by antibiotic resistance in 2013 to be nearly 44,000 deaths and estimating 35,900 deaths caused by antibiotic resistance in 2019). The 2019 figure of 35,900 AR deaths reflects an 18% reduction resulting from dedicated prevention and infection control efforts between 2013 and 2019.

While both animal agricultural use and human health use contribute to antibiotic resistance, there is far less justification for any use of antibiotics other than control or treatment of disease. Despite that widely acknowledged fact, the significant majority of antibiotics sold in the U.S. are used not to treat sick people or even sick animals. Rather, most antibiotics are given to entire herds of livestock or flocks of poultry via feed or water, often for extended periods, for disease prevention. This long-term low-level dosing creates the ideal conditions to maximize selective pressure for, and expand reservoirs of, resistant bacteria and resistance genes. This also is well known and undisputed. It is time for FDA to end this unsafe practice.

Figure 2. Estimated U.S. Antibiotic Sales for Use in Food-Producing Animals vs. Use in Human Medicine (2020)[2]



A Robust Body of Science Demonstrates that Current Uses of Antibiotics in Agriculture Are Unsafe

There is a broad consensus among public health authorities, including FDA and Centers for Disease Control and Prevention (CDC) that the use of antibiotics in livestock production significantly contributes to the development and spread of antibiotic resistance transmissible to people and animals. The mechanisms and harms are clear:

1. Antibiotic exposure selects for resistant bacteria by killing off non-resistant bacteria and leaving a population of resistant bacteria;
2. Prolonged, low-dose group administration accelerates selection, co-selection on mobile genetic elements, and horizontal gene transfer by creating ideal conditions for resistant bacteria to spread widely;

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[2] David Wallinga, *Antibiotic Use Remains Far Too Intensive in U.S. Livestock*, Nat. Res. Def. Council (Sep. 11, 2023), https://www.nrdc.org/bio/david-wallinga-md/antibiotic-use-remains-far-too-intensive-us-livestock. Human sales data was obtained by IQVIA and provided by One Health Trust. FDA does not track antibiotic use, so researchers use sales data as the best available indication of use.

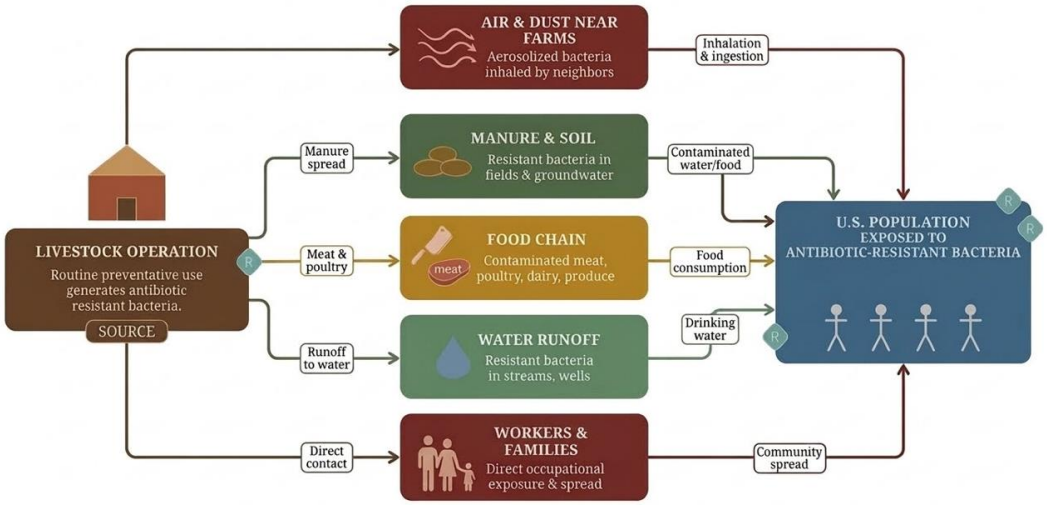
3. Resistant pathogens—including non-typhoidal *Salmonella* and *Campylobacter*—lead to increased hospitalization and more difficult-to-treat infections because standard treatments are ineffective; and
4. Opportunistic (i.e., normally harmless) pathogens such as *Escherichia coli*, *Staphylococcus aureus*, and *Enterococcus* can acquire resistance in agricultural settings and then also contribute to human illness when transmitted from those settings to vulnerable human hosts.

Dozens of expert studies confirm this, demonstrating, for example, that antibiotic use in animal agriculture results in the spread of resistant bacteria to humans by:

- Showing that bacteria exchange resistance genes not only among the same bacteria but between different bacterial species.
- Comparing genetic similarity between bacteria in animals and humans;
- Comparing high animal agriculture regions to low animal agriculture regions;
- Comparing conventional agriculture that uses antibiotics with organic agriculture that does not;
- Analyzing samples of water, air, and dust near animal factories, finding antibiotic-resistant bacteria;
- Examining the bacteria found in farm workers and neighbors of animal operations;
- Analyzing retail meat and poultry (even that deemed “antibiotic free”).

Numerous studies have also shown that multiple pathways connect on-farm use of antibiotics, and thus on-farm selection of antibiotic resistance, with human exposure. Humans are exposed through contamination of meat and poultry at slaughter and retail; consumption of meat and poultry containing antibiotic resistant bacteria; direct occupational exposure; movement of air and dust from facilities; runoff and leaching of manure-borne bacteria and resistance genes into soil and water; and transfer of resistance determinants across bacterial species.

Figure 3. Pathways by Which Antibiotic-Resistant Bacteria Travel from Food-Producing Animals to Humans[3]



This science is not new or hidden. Indeed, FDA[4] and the CDC[5] have known for many decades that the misuse and overuse of antibiotics can contribute to antibiotic resistance that transfers to humans and thus poses a human health risk. Reflecting this knowledge, in 1977, FDA proposed to take action to end the misuse of antibiotics, but heavy lobbying pressure from the pharmaceutical and livestock industries got Congress to intervene and prevented FDA from proceeding.

More recently, Martin Makary, who recently resigned as FDA Commissioner, urged physicians to "draw attention to the association between routine antibiotic use in animals and the declining efficacy of antibiotics in treating human infections," acknowledged "the health and economic consequences of antibiotic misuse in animal production," and explained that "we have created this massive public health problem that affects children" and others who are vulnerable.[6]

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[3] CDC, *Antibiotic Resistance Threats in the United States 2019*, at vii (2019), https://www.cdc.gov/antimicrobial-resistance/data-research/threats/index.html.

[4] *Antimicrobial Resistance*, FDA, https://www.fda.gov/animal-veterinary/safety-health/antimicrobial-resistance (last updated Dec. 5, 2025); *Know When and How to Use Antibiotics, and When to Skip Them*, FDA, https://www.fda.gov/consumers/consumer-updates/know-when-and-how-use-antibiotics-and-when-skip-them (last updated Nov. 18, 2024).

[5] *Antimicrobial Resistance: Causes and How It* Spreads, CDC (Sep. 25, 2025), https://www.cdc.gov/antimicrobial-resistance/causes/index.html; *U.S. Actions & Events to Combat Antimicrobial Resistance*, CDC (Dec. 19, 2024), https://www.cdc.gov/antimicrobial-resistance/programs/AR-actions-events.html.

[6] Curt Chaffin, The Good Food Institute, *The Same Entities that Helped Create Antibiotics Are Advancing Alternative Proteins*, Alt Protein Planet (Apr. 18, 2025), https://thegoodfoodinstitute.substack.com/p/the-same-

Makary added that, although it was believed that the use of antibiotics in food animals "could prevent disease before it happens . . . we've learned [] that the routine use of antibiotics in agriculture has some disastrous implications for public health in humans."[7]

Citizen groups have also sounded the alarm. For example, an Environmental Working Group (EWG) analysis of more than 47,000 lab tests of bacteria found on supermarket meat detected antibiotic resistant bacteria on the majority of turkey, pork chop, and ground beef samples tested.[8]

There is also growing public awareness of the dangers posed by using antibiotics in animal feed and water. One national poll found that the vast majority of Americans believe antibiotic use on dairy farms threatens human health, and that most would be willing to pay more for milk from cows that were not given antibiotics.[9] In another national poll, two-thirds of Americans said that antibiotic-free labels were important to them when purchasing meat, and 75% said that they would be willing to pay more for meat that was antibiotic-free.[10]

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entities-that-helped-create ("Dr. Makary has dedicated significant attention to the role agriculture plays in antimicrobial resistance."); Martin A. Makary, Katerina Kaczmarski & Keeve Nachman, *A Call for Doctors to Recommend Antibiotic-Free Foods: Agricultural Antibiotics and the Public Health Crisis of Antimicrobial Resistance*, 71 J. Antibiotics 685 (2018); Tedx Talks, *The Next Pandemic | Marty Makary | TedxPearlStreet*, at 13:26 (YouTube, Oct. 1, 2020), https://www.youtube.com/watch?v=8rp3dSMaz4Q ("Antibiotics in livestock is a major driver of antibiotic resistance. . . . 70 to 80 percent of all the antibiotics produced are used in animals. Why? For no good reason. It's so the animals can be crowded and used in factory farming techniques and sometimes cruel conditions ."); *A Call for Doctors to Lead the Charge for Antibiotic-Free Foods*, Johns Hopkins Medicine (June 1, 2018), https://www.hopkinsmedicine.org/news/newsroom/news-releases/2018/06/a-call-for-doctors-to-lead-the-charge-for-antibiotic-free-foods. Makary also stated that "about 20 percent, now, of all the antimicrobial-resistant infections that we see in the hospital probably originated from agriculture and from the overuse of antibiotics in agriculture." In fact, around 20% of resistant infections are associated with *Campylobacter* and non-typhoidal *Salmonella* alone. *See* CDC, *Antibiotic Resistance Threats in the United States 2019*, at 17 (2019), https://www.cdc.gov/antimicrobial-resistance/data-research/threats/index.html. The figure Makary cited does not include the many other resistant pathogens originating in the use of antibiotics in agriculture. *See*, *e.g.*, Maliha Aziz et al., *Zoonotic Escherichia coli and Urinary Tract Infections in Southern California*, 16 Clinical Microbiology (2025); Vanessa Silva et al., *Staphylococcus aureus and MRSA in Livestock: Antimicrobial Resistance and Genetic Lineages*, 11 Microorganisms (2023). In other words, it is likely that significantly more than 20% of anti-microbial resistant infections in hospitals originated from the overuse of antibiotics in agriculture.

[7] PIRGvideos, *Dr. Marty Makary Addresses Antibiotic Resistance – 4 Minutes*, at 1:15 (YouTube, July 11, 2018), https://www.youtube.com/watch?v=VdygxfL9iFc; *This Infection Is Resistant to Everything We Have*, PIRG (Oct. 4, 2018), https://pirg.org/articles/this-infection-is-resistant-to-everything-we-have/.

[8] *See* Aurora Meadows, *Supermarket Meat Still Superbugged, Federal Data Show*, Env't Working Grp. (June 28, 2018), https://www.ewg.org/research/superbugs; *see also* Zen Honeycutt, *Contraceptive and Harmful Antibiotics Found in Top Ten Fast Food Samples*, Moms Across Am. (Oct. 9, 2023), https://www.momsacrossamerica.com/blog/harmful_antibiotics_and_a_contraceptive_found_in_top_ten_fast_food_samples (testing foods from the top U.S. restaurant chains, finding antibiotic residues in food from seven out of the top ten chains, and concluding, "[o]ne thing is certain: long-term exposure to antibiotics . . . in foods can cause serious health problems like antibiotic resistance.").

[9] M. Wemette et al., *Public Perceptions of Antibiotic Use on Dairy Farms in the United States*, 104 J. Dairy Sci. 2807 (2021).

[10] John Zogby, *Antibiotic-Free Labels Are Important to Two-Thirds of Americans when Buying Meat – and Data to Back-Up Claims Is Paramount, a New Poll Shows*, Forbes (Feb. 11, 2021), https://www.forbes.com/sites/johnzogby/2021/02/11/antibiotic-free-labels-are-important-to-two-thirds-of-americans-when-buying-meat---and-data-to-back-up-claims-is-paramount-a-new-poll-shows/.

And here, petitioners, representing millions of people threatened or already harmed by unsafe use of antibiotics are demanding that FDA finally act. Petitioners include health care workers, threatened when patients have antibiotic resistant infections; animal agriculture workers who are especially threatened by antibiotic resistant bacteria, which is found in higher concentrations at and near animal facilities; people downwind or downstream of animal production facilities, also at increased risk; and just average Americans who are at risk from antibiotic resistant bacteria that are all around us.

Antibiotic resistance resulting from antibiotic use in food-producing animals is particularly pernicious because individuals can do little to protect themselves from it. Antibiotic-resistant bacteria are in the air we breathe, the water we drink, and the food we eat, even if we only buy meat and poultry raised without antibiotics or live far from farming operations. The only way Americans will be safe is for FDA to comply with its legal obligation to end the routine use of antibiotics in animal feed and water other than for treating or controlling diagnosed disease.

The Routine Preventive Use of Antibiotics in Animal Feed and Water Is Not Necessary for Raising Livestock and Poultry

The animal agriculture and pharmaceutical industries have pressed hard to stop FDA from withdrawing approval for the use of antibiotics in disease prevention and for long durations. However, the routine use of antibiotics in agriculture for disease prevention and for long durations is not only dangerous, but it is also entirely unnecessary.

Indeed, the routine use of antibiotics in food animals did not start to solve a pressing agricultural need. Rather, the practice started because the pharmaceutical industry hoped to establish a larger market for antibiotics. The pharmaceutical industry sought long-term, rather than episodic, uses and heavily promoted the use of antibiotics for growth promotion and to enable less costly animal maintenance practices. Since then, the industry has continued to extensively market this long-term use.

According to industry analysis, the U.S. market for production animal medicines is about $8 billion per year, and the U.S. animal drug industry is growing at over 7.5%-per year.[11] The global market for farm animal drugs is almost three times that.[12] One analysis notes that "growth [in the U.S. veterinary medicine market] is being fueled by the widespread use of medications in livestock, the increasing focus on preventing and controlling diseases, and more intensive farming practices."[13]

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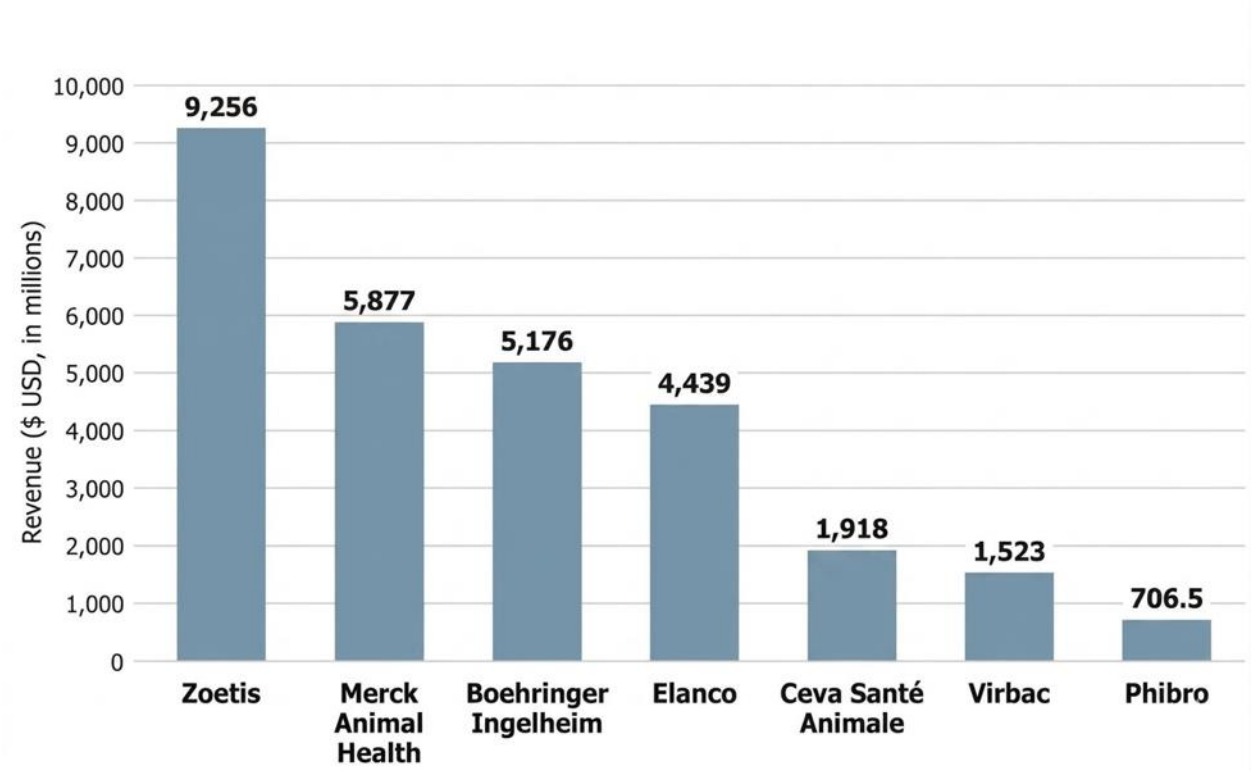
[11] *U.S. Veterinary Medicine Market (2025 - 2033)*, Grand View Rsch., https://www.grandviewresearch.com/industry-analysis/us-veterinary-medicine-market-report (last updated Sep. 2025) (including other medicines, diagnostics and non-drug additives, in addition to antibiotics).

[12] *Farm Animal Drug Market: Global Industry Analysis 2015 - 2024 and Opportunity Assessment 2025 – 2035*, Future Mkt. Insights Inc., https://www.futuremarketinsights.com/reports/farm-animal-drugs-market (last updated Oct. 7, 2025).

[13] *U.S. Veterinary Medicine Market (2025 - 2033)*, Grand View Rsch., https://www.grandviewresearch.com/industry-analysis/us-veterinary-medicine-market-report (last updated Sep. 2025).

Figure 4. Estimated Global Sales of Seven Major Animal Health Companies (2024, Net Manufacturer Revenue for Animal Health)[14]



Despite claims as to the need for disease prevention use, improved animal husbandry can largely eliminate this need. This is made clear, first and foremost, by the work of thousands of farmers who raise livestock and poultry with very infrequent use of antibiotics (such as if the antibiotics are needed to treat illness) or not at all. Indeed, the chicken industry uses ten times less antibiotics per pound of meat produced than the cattle and swine industries.

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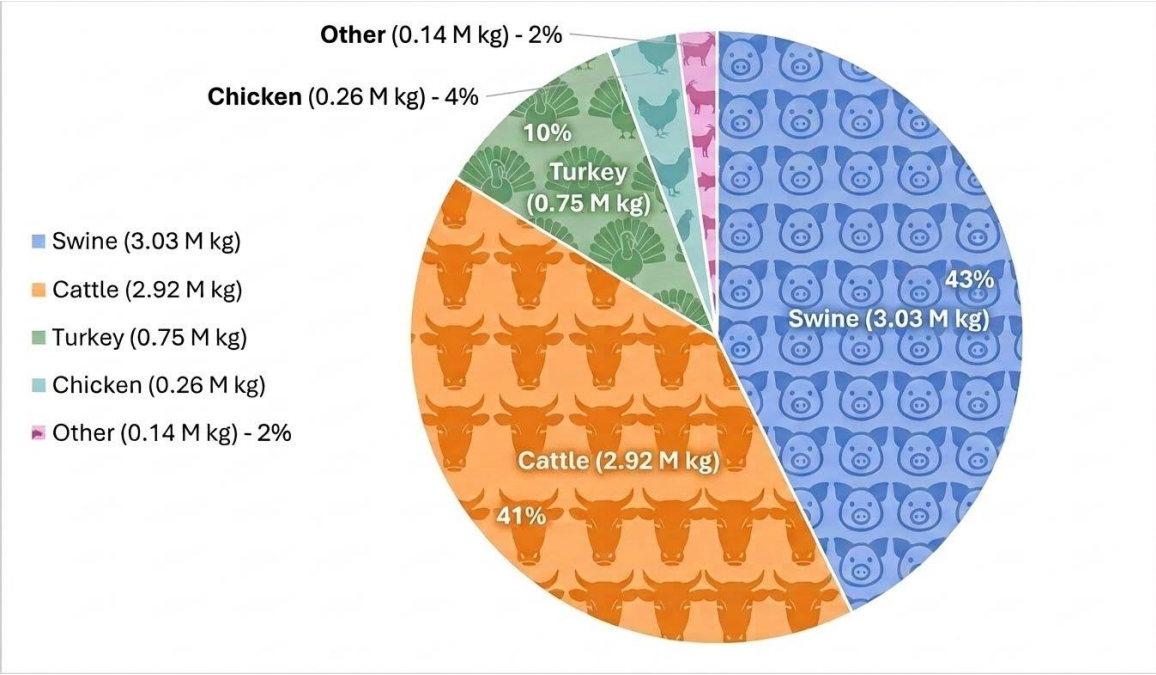
[14] All revenue figures are for the calendar year ended December 31, 2024, except Phibro Animal Health, which reports on a fiscal year ending June 30. All figures represent manufacturer net revenue and are not directly comparable to end-market or retail-level market size estimates. Currency conversions from EUR to USD use approximate 2024 average exchange rates (~1.09 USD/EUR). *See* Zoetis, *2024 Annual Report* (2025), https://s203.q4cdn.com/620628704/files/doc_downloads/2025/Zoetis-2024-Annual-Report.pdf; *Merck Announces Fourth-Quarter and Full-Year 2024 Financial Results*, Merck (Feb. 4, 2025), https://www.merck.com/news/merck-announces-fourth-quarter-and-full-year-2024-financial-results/; Boehringer Ingelheim, *2024 Highlights: Think Beyond* (2025), https://www.boehringer-ingelheim.com/annualreport/2024/files/downloads-and-archive/highlights-2024/BOE_Highlights_2024_EN.pdf (reporting 4,749 million euros in total revenue for animal health in 2024); Elanco, *2024 Annual Report* (2025), https://assets.elanco.com/63faca97-0277-00f3-7b39-47b486080a51/99e38b60-2f28-4a0f-9254-8e23b06e3f9f/AR_601875.pdf; Ceva Santé Animale, *Non-Financial Performance Statement 2024* (2025), https://www.ceva.com/wp-content/uploads/2025/10/EN-CEVA_DPEF_24_WEB.pdf (reporting 1.76 billion euros in total revenue for animal health in 2024); Virbac, *Annual Report 2024* (2025), https://corporate.virbac.com/files/live/sites/virbac-corporate/files/contributed/RA2024/PDF/Annual_report_Virbac_2024.pdf (reporting 1,397 million euros in total revenue for animal health in 2024); *Phibro Animal Health Corporation Reports Fourth Quarter and Fiscal Year Results, Provides Financial Guidance*, Phibro Animal Health Corp. (Aug. 28, 2024), https://investors.pahc.com/press-releases/press-release-details/2024/Phibro-Animal-Health-Corporation-Reports-Fourth-Quarter-and-Fiscal-Year-Results-Provides-Financial-Guidance/default.aspx.

While the beef industry as a whole uses much more antibiotics than the chicken industry, a recent United States Department of Agriculture (USDA) study found that over half of all feedlots gave no antibiotics in feed (the primary delivery mechanism), including over 30% of the largest feedlots.[15] Similarly, USDA data show that more than 20% of sites raising nursery pigs in traditional systems reported no antibiotic use in feed,[16] and over 30% reported no use in water.[17] So, even in the sectors with heavy use many producers have found ways to use much lower levels of antibiotics.

Figure 5. U.S. Medically Important Antibiotic Sales by Animal Species: Distribution (2024)[18]



In addition, extensive evidence from multiple European countries indicates that it is possible to profitably raise pigs and cattle with much lower levels of antibiotic use than what is used on average U.S. farms and feedlots.[19]

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[15] USDA, *Management Practices on U.S. Feedlots, 2021*, at 54 tbl. G.5.a (2024), https://www.aphis.usda.gov/sites/default/files/feedlot-health-2021-mgmt-practice-dr1.pdf.

[16] USDA, *Swine Part II: NAHMS 2021 – Reference of Management Practices on Large-Enterprise Swine Operations in the United States* tbl. C.5.f. (2021), https://www.aphis.usda.gov/livestock-poultry-disease/nahms/swine/swine-2021-part-ii-reference-management-practices-large.

[17] *Id.* at tbl. C.5.c.

[18] FDA, *2024 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals* tbl. 4a (2025), https://www.fda.gov/animal-veterinary/antimicrobial-resistance/2024-summary-report-antimicrobials-sold-or-distributed-use-food-producing-animals.

[19] David Wallinga & Avinash Kar, *Very High Livestock Antibiotic Use Undercuts Effective Drugs: Beef and Pork Industries Must Do Better to Help Curb Antibiotic Resistance*, Nat. Res. Def. Council (Dec. 12, 2019), https://www.nrdc.org/bio/david-wallinga-md/very-high-livestock-antibiotic-use-undercuts-effective-drugs; *see also* Marcel van Asseldonk et al., *Antibiotics Use Versus Profitability on Sow Farms in the Netherlands*, 178 Preventive Veterinary Med. (2020); L. Collineau et al., *Herd-Specific Interventions to Reduce Antimicrobial Usage in Pig Production Without Jeopardising Technical and Economic Performance*, 144 Preventive Veterinary Med. 167 (2017); M. Postma et al., *Reducing Antimicrobial Usage in Pig Production Without Jeopardizing Production*

This evidence, coupled with the growing market success of organic and "raised without antibiotics" meat and poultry, makes clear that the routine use of antibiotics in feed and water for disease prevention is simply unnecessary for successful production or disease prevention. And in addition to being economically feasible, substantial reductions in antibiotic use would result in measurable benefits to public health. As detailed later in this Petition, study after study has shown that by sufficiently reducing antibiotic use in livestock, FDA would drive significant corresponding reduction in antibiotic resistance.

The Law Is Clear that FDA Must Take Sufficient Action to End Unsafe Uses of Antibiotics

Under the FFDCA, FDA must initiate a process to withdraw approval of any animal drug use that is "not shown to be safe" for human or animal health.[20] In other words, if a drug may pose "harm to human health," FDA must find it to be unsafe.[21] FDA must look to the probable consumption of the drug, the cumulative impact of the drug and related substances, a margin of safety, and the real-world use conditions and will – indeed it must – find a drug use unsafe unless that use poses a "reasonable certainty of no harm."[22]

Despite the overwhelming evidence that the routine use of antibiotics for disease prevention and for long durations harms human health, FDA, perhaps cowed by the pharmaceutical and animal agriculture industries' lobbies, has never tried to take sufficient action stop this misuse. To the contrary, FDA continues to allow antibiotics to be used in food producing animals not diagnosed with any disease and for long durations. Moreover, in addition to licensing these misuses of antibiotics, FDA has failed even to collect and disseminate data germane to the misuse of antibiotics, clouding the public's view into the extent of the problem. And over the decades industry marketing campaigns have driven massive sales of antibiotics for use in animal agriculture by both encouraging overuse and by downplaying risks to public health.

Consumer, health, and environmental groups sued FDA for this inaction in 2012. After the groups won in district court, the appellate court ruled for FDA, upholding as rational FDA's decision to encourage voluntary compliance with medically appropriate animal antibiotic use rather than revoke approvals of inappropriate uses.[23] FDA made much of the fact that, apparently in response to the lawsuit, the agency limited the use of antibiotics for growth promotion. Unfortunately, FDA still allowed the largely overlapping use in animals without diagnosed

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Parameters, 64 Zoonoses & Pub. Health 63 (2017); Cristina Rojo-Gimeno et al., *Farm-Economic Analysis of Reducing Antimicrobial Use Whilst Adopting Improved Management Strategies on Farrow-to-Finish Pig Farms*, 129 Preventive Veterinary Med. 74 (2016); David Wallinga, Nat. Res. Def. Council (NRDC), *U.S. Livestock Industries Persist in High-Intensity Antibiotic Use: Curbing Overuse Is Critical to Slow the Spread of Antibiotic Resistance* (2022), https://www.nrdc.org/sites/default/files/us-livestock-industries-persist-high-intensity-antibiotic-use-ib.pdf.

[20] *See* 21 C.F.R. § 514.115(b) (2025).

[21] *See* FDA, *Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* 18 (2012) (GFI #209), https://www.fda.gov/media/79140/download (noting that the standard applies even "after approval" of a drug); FDA, *Final Decision of the Commissioner: Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry* 93–94 (July 27, 2005), https://www.regulations.gov/document/FDA-2000-N-0109-0137.

[22] *Id.*; 21 U.S.C. § 360b(d)(2).

[23] *See NRDC v. FDA*, 760 F.3d 151, 175 (2d Cir. 2014).

disease for disease prevention. Moreover, FDA continued to issue only "nonbinding recommendations" to drug manufacturers, rather than enforceable mandates.[24]

Advocates petitioned FDA to act to stop the misuse of antibiotics in animal agriculture again in 2016 and FDA denied that petition, again relying on the measures it had pushed the industry to voluntarily adopt instead. While these measures briefly reduced animal agriculture antibiotic sales (a proxy for use since – again to due industry lobbying – FDA does not have the authority to mandate reporting of animal agriculture antibiotic use), recent evidence shows sales of antibiotics for use in agriculture are now again dangerously increasing. Moreover, a substantial—and still growing—body of scientific evidence since that time demonstrate that the use of antibiotics for disease prevention contributes to antibiotic resistance that is transferred to humans at unsafe levels. Accordingly, this Petition is supported by ample new scientific evidence including 89 studies since June 10, 2021, when FDA issued Guidance for Industry (GFI) #263; and another 84 since December 12, 2013, when FDA adopted GFI #213. As explained further below, these two dates are notable because they are milestones in the implementation of FDA's unsuccessful effort to deal with the problem of antibiotic overuse in animal agriculture through the adoption of non-binding guidance for industry and the promotion of voluntary industry compliance.

Thus, the 2014 court's finding that FDA's reliance on partial, voluntary measures is sufficient to meet the agency's mandate under the FFDCA is simply out of date. Courts are clear that "[d]ecisions which are not arbitrary and capricious in the light of existing knowledge may become so by the dint of scientific advances."[25] That is the case here. The horrifying reality is that antibiotic-resistant disease now kills 35,000 Americans every year, and sickens over 2 million others – it should be inconceivable that FDA still asserts that this is safe.

Given the many pathways – food, air, water, or contact – that link antibiotic use in animal production to human exposure to antibiotic resistant bacteria and resistance genes, individuals cannot insulate themselves from these antibiotic-resistant bacteria. For example, consumers avoiding the consumption of certain animal products may still be exposed by air, water, or other food consumers. However, policy interventions to reduce antibiotic use can help protect the public from resistant bacteria. Indeed, multiple studies show that restricting certain antibiotic uses in food animals is followed by measurable declines in resistance—thus confirming that policy interventions to reduce system use and exposure work.[26]

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[24] *See, e.g.,* GFI #213.
[25] *Ala. Power Co. v. Costle*, 636 F.2d 323, 388 n.116 (D.C. Cir. 1979) (quoting *Texas v. EPA*, 499 F.2d 289, 301 n.16 (5th Cir. 1974)).
[26] *See* infra Section B.VI.

FDA Must Take the Following Actions to Ensure that the Use of Antibiotics in Animal Agriculture is Safe

Petitioners request that FDA take the following actions to ensure that the use of antibiotics in animal agriculture is safe as required by Congress.

- FDA must find that the current routine use of antibiotics in animal feed and water when not associated with diagnosed illness does not meet the mandated standard of presenting a "reasonable certainty of no harm."
- FDA must withdraw approval of antibiotics administered in feed or water when not associated with diagnosed illness—including "disease prevention" or "technical purposes"— and for the non-medical purpose of "maintenance of growth."
- FDA should use the regulatory tools at its disposal to expedite and streamline these withdrawal proceedings.
- FDA should prohibit labeled durations that constitute high extent of use – group administration beyond 21 days – consistent with FDA's risk-management framework in GFI #152.[27]
- FDA should begin systematic collection and reporting of species- and sector-specific antibiotic use data by leveraging existing feed-distribution records and Veterinary Feed Directives (VFDs).

FDA should set public-health-based reduction targets for antibiotic use by livestock sector (e.g., poultry, swine, dairy cattle, beef cattle) to drive to drive greater transparency and measurable improvements in antibiotic stewardship" in animal agriculture, as HHS is already pursuing for antibiotic use in human medicine.

[27] FDA, *Draft Guidance for Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* 20 tbl. 7 (2023) (Draft GFI #152), https://www.fda.gov/media/69949/download.

Petitioners:

Agri-Cultura Cooperative Network

Alliance for Humane Biotechnology

Alliance of Nurses for Healthy Environments

American Regeneration

Animal Legal Defense Fund

Animal Outlook

Animal Partisan

Antibiotic Resistance Action Center, George Washington University

Anura Capital

Beyond Pesticides

Buffalo River Watershed Alliance

Center for Biological Diversity

Center for Food Safety

Committee on the Middle Fork Vermilion River

Compassion in World Farming

Consumer Reports

California Rural Legal Assistance Foundation

Cultivate Charlottesville

Farm Forward

Farm Sanctuary

FarmSTAND

Farmworker and Landscaper Advocacy Project

Farmworker Association of Florida

Food & Water Watch

Food Animal Concerns Trust

Foodwise

FOUR PAWS

Friends of the Earth

Public Citizen

Green America

HEAL (Health, Environment, Agriculture, Labor) Food Alliance

Health Care Without Harm

Hudson Riverkeeper

Jefferson County Farmers & Neighbors, Inc.

Latino Farmers & Ranchers International, Inc.

Lymphoma Foundation of America

Mercy For Animals

Northeast Organic Farming Association of New York

Nutrient Density Initiative

Pasa Sustainable Agriculture

Pediatric Infectious Diseases Society

Pesticide Action and Agroecology Network

Regenerative Agriculture Coalition

Rural Coalition

Science and Environmental Health Network

Sierra Club

Socially Responsible Agriculture Project

Soul Fire Farm

The Non-GMO Project / Food Integrity Collective

Unitarian Universalist Animal Ministry

United We Eat

Urban Tilth

Western Nebraska Resources Council

Women’s International League for Peace and Freedom, U.S. Section

Waterkeeper Alliance

Delaware Riverkeeper Network

Environmental Working Group

Farm Aid

Minnesota Center for Environmental Advocacy

Moms Across America

Non-Toxic Neighborhoods

Northeast Organic Farming Association of New Hampshire

National Consumers League

San Francisco Bay Physicians for Social Responsibility