



PHARMING PROFITS: THE DRUGS THAT MAKE CHEAP MEAT

CONCENTRATED ANIMAL FEEDING OPERATIONS (CAFOs) have come to dominate U.S. agriculture, crowding animals into tight quarters with little or no access to the outdoors, poor sanitation, and extremely short lifespans. This intensification has coincided with dramatic increases in the use of animal drugs to promote rapid growth rates, prevent the spread of disease, and reduce the costs of production per head.

PART I: HOW LIVESTOCK PRODUCERS USE ANIMAL DRUGS

Why do animal producers give drugs to their livestock?

Many animal drugs are used to treat sick animals, but they may be approved for other purposes. Four main purposes of animal drugs are:

- ✦ **Disease treatment:** controlling a diagnosed illness in animals that show symptoms of sickness.

- ✦ **Disease control:** preventing illness from spreading to healthy animals when diseased animals are present in the herd or flock.
- ✦ **Disease prevention:** preventing disease in healthy animals, when no animals in the herd or flock display signs of disease.
- ✦ **Growth promotion and feed efficiency:** physiologically altering the animals so they gain weight at faster rates while consuming less food.

Why do producers use drugs to promote growth?

Similar to athletes taking steroids, many livestock producers give growth-promoting drugs to animals for performance enhancement: growing bigger in the right places as quickly as possible. Growth-promoting drugs differ in their modes of action, results, and risks, but they all enable cows, chickens, pigs, or other livestock to gain weight at



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unnaturally fast rates while eating less food. This saves producers feed costs per pound of marketable product and reduces the length of time that animals live in their facilities, reducing the producers' heating, lighting, cleaning, water, and labor costs. Researchers have estimated economic gains from the use of growth promoting drugs at around \$100 per animal.¹

Which approved animal drugs are used to promote growth, and how do they work?

- ✦ **Antimicrobials:** Antimicrobial agents, especially antibiotics, have been used in low doses to promote growth and feed efficiency since the 1940s. Antimicrobials are thought to promote growth by suppressing microbes that would otherwise take nutrients away from the animal.² The growth response has also been shown to be correlated to poor living conditions; animals in good housing with better hygiene, nutrition, and overall health do not respond to antibiotics with significantly increased growth.³
- ✦ **Beta-agonists:** Beta-adrenergic agonists increase growth by inhibiting fat production, increasing protein synthesis, and reducing protein breakdown in muscle.⁴ They redirect energy in an animal's body, sending less to the

organs in favor of peripheral tissues.⁵ Pigs fed ractopamine gain almost 20% more weight,⁶ produce 10% more meat,⁷ and exhibit greater leanness and "cutability."⁸ Zilpaterol results in average gains of 20-30 pounds for cattle.⁹

- ✦ **Steroid Hormones:** Most hormone drugs are administered via implant, and it is estimated that 90% of U.S. cattle receive growth-promoting implants.¹⁰ Hormone implants elevate IGF-1 concentrations and activate the steroid receptors, resulting in increased protein synthesis, reduced protein degradation, and enlarged muscle fiber.¹¹ Trenbolone acetate and 17 β -estradiol are the two most commonly used hormones in beef production.¹² Melengestrol acetate is the only hormone not implanted, but is added to feed to promote growth and feed efficiency, as well as to control the reproductive cycle of cattle.¹³ It has been reported that growth rates of treated cattle increase by 10-20%, and feed conversion improves by 5-15%.¹⁴ The economic benefits to producers are significant: compared to untreated animals, the cost savings from improved feed efficiency averages about \$40 per animal.¹⁵

Aren't drugs meant to treat illness?

Some drugs are only approved for growth promotion and feed efficiency and have no therapeutic purpose. But, many are meant to actually treat sick animals. Antimicrobials, endectocides, coccidiostats, antifungals, and nonsteroidal anti-inflammatory agents (NSAIDs) may all be used to treat, control or prevent pathogens, infections, and illness in animals.¹⁶ The use of drugs for "disease treatment" is considered therapeutic and acceptable use. "Disease control" may also be necessary on occasion to keep healthy animals from catching a contagious illness that has emerged within a group of animals living together. The overuse of many therapeutic drugs has allowed the industry to scale up production by creating an artificially sanitary and safe environment. "Disease prevention," for example, is a non-therapeutic use in which producers regularly administer drugs to healthy animals to decrease their susceptibility to the pathogens and diseases that thrive in crowded and unsanitary conditions. Drugs should be used to control disease sparingly and only during an outbreak. Illness should be prevented with improved living conditions, nutritious diets, and breeding animals for health and immunity rather than growth

PART II: HOW GOVERNMENT (FAILS TO) REGULATE ANIMAL DRUGS

How does FDA approve and regulate these drugs?

The U.S. Food and Drug Administration (FDA) has authority to regulate animal drugs under the Federal Food, Drug, and Cosmetic Act to ensure effectiveness for their intended use and safety for animals and consumers.¹⁷ To get a drug on the market, the manufacturer (or “sponsor”) submits a “New Animal Drug Application” to FDA that must include certain specific information.¹⁸ FDA must then independently evaluate the safety of the drug before granting approval, though in reality it performs a cost-benefit analysis to determine if a drug’s benefits outweigh its potential harms.¹⁹ Once FDA approves an animal drug, it issues regulations governing its lawful use, labeling, distribution, and conditions of use.²⁰ FDA can also establish tolerance levels for animal drug residues if it finds there is a “reasonable probability” that the drug presents a risk to public health.²¹ As long as the drug is used in compliance with FDA regulations for conditions of use and does not exceed FDA’s tolerance levels, it is considered safe.²² FDA’s involvement in the oversight of approved animal drugs is generally minimal unless or until questions arise about a drug’s safety.

Does FDA monitor drug use?

FDA only collects sales data about drugs with antimicrobial active ingredients. The sponsor of an antimicrobial drug must submit an annual report to FDA on the quantity of each microbial active ingredient in the drug that is sold or distributed for use in food-producing animals domestically and abroad. The report must be broken down by month and must specify the amount of each antimicrobial active ingredient by container size, strength, and dosage form. The dosage form information must include a listing of the target animals, indications, and production classes that are specified on the approved label of the product.²³ Aside from this, FDA does not currently collect data on animal drug usage.

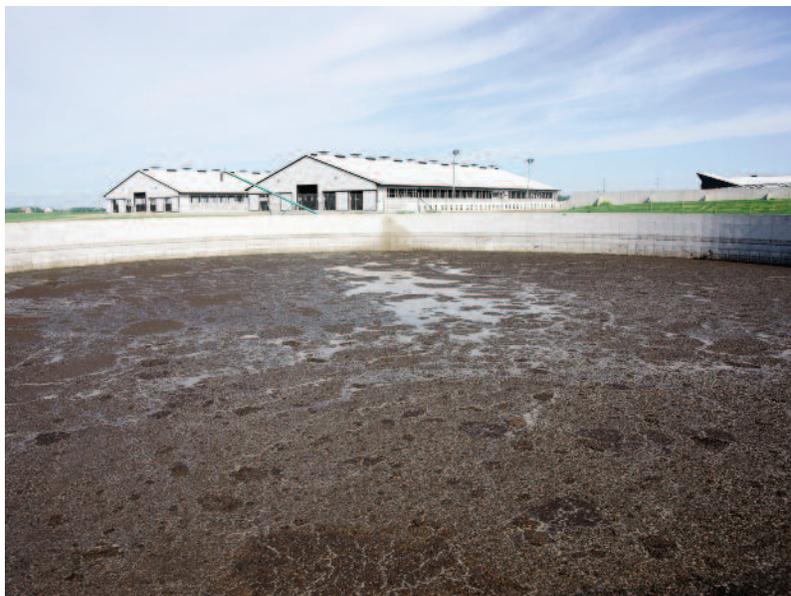
Can FDA take a drug off the market?

Though FDA has the authority—and duty—to withdraw approval for a drug that has proven to be unsafe²⁴, it does not routinely monitor emerging data on approved drugs

and rarely takes action on its own. Instead, it relies on others to bring data to its attention showing that the drug is unsafe for use under the conditions that FDA authorized, or that the drug will not have the intended effect for which it was approved.²⁵ The full withdrawal process can be lengthy, but FDA can take a drug off the market immediately by suspending approval if the drug presents an “imminent hazard” to human or animal health.²⁶ FDA can reverse its decision and allow a drug back on the market whenever it determines that such a reversal is required.²⁷



Animals drugs are present in the manure of treated animals, and enter the environment as a result of manure storage leaks, runoff into waterways, accumulation in soils, and transmission via vermin, wildlife, workers, and even on meat.





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PART III: HOW ANIMAL DRUGS IMPACT THE ENVIRONMENT, PUBLIC HEALTH, AND ANIMAL WELLBEING

What impacts do approved animal drugs have?

Unfortunately, the impacts of many of the animal drugs approved for use today have been understudied. Much of the research on animal drugs focuses on their efficacy, such as studies of the dosage levels that optimize growth rate. The limited existing literature on impacts has shown that animal drugs have direct impacts on the animals receiving the drugs, not only affecting their growth and living conditions, but their health and wellbeing. Animal drugs and their residues also enter the environment, reaching other animals and humans through multiple pathways. This residue leakage is a result of manure storage

leaks, runoff into waterways, accumulation in soil, and transmission via vermin and other wildlife, workers, and even residues in foods, among other means.

How do animal drugs impact animal wellbeing?

- ✘ Overuse of antimicrobials has supported intensification, allowing producers to overcrowd animals in confined spaces. Without the drugs, disease and infection would be unmanageable in such conditions.
- ✘ Hormone implants in steers have negative side effects such as feminization, increased aggression, and behavior problems.^{28,29,30}
- ✘ Heifers fed the synthetic hormone melengestrol acetate are more than 3 times more likely to be diagnosed with acute interstitial pneumonia that led to emergency slaughter.³¹
- ✘ Lambs implanted with the synthetic hormone zeranol had greater incidence of displaced or protruding organs and mortality.³²
- ✘ The beta-agonist, ractopamine, is linked to cardiovascular stress, tremors, increased aggression, hyperactivity, acute toxicity, and genotoxicity.³³ Some reports indicate animals on ractopamine become so aggressive they must be additionally medicated to calm them down for transport.³⁴
- ✘ Cattle fed beta-agonists spend 31% more time lying on their side with legs extended,³⁵ a sign of fatigue and illness; are more likely to engage in agonistic behavior;³⁶ and have higher rates of death.³⁷
- ✘ Horses fed small amounts of zilpaterol developed skeletal muscle tremors and increased heart rates in under an hour, and exhibited restlessness and profuse sweating.³⁸

How do animal drugs impact the environment?

- ✘ Animals excrete 60-80% of antibiotics they ingest.³⁹ As a result, low levels of antibiotics are present in soil and water.^{40,41} Nine common veterinary antibiotics have acute and chronic toxicity on freshwater crustaceans.⁴²
- ✘ Animals excrete approximately 95% of ractopamine in the first three days after ingestion.⁴³ Ractopamine has been detected in water samples downstream from swine facilities.⁴⁴

- ✘ After two weeks, manure from animals fed ractopamine has higher nitrogen, phosphorous, and sulfur levels than prior to feeding ractopamine,⁴⁵ increasing the nutrient burden on soils and waterways when manure is applied to fields.
- ✘ Over 4 tons of total androgens were estimated to be excreted into the environment by cattle, pigs, sheep and chickens in 2000 alone.⁴⁶ Steroid compounds have endocrine disrupting effects on wildlife, such as abnormal blood hormone levels, masculinization of females, feminization of males, altered sex ratios, intersexuality, and reduced fertility in fish.⁴⁷ Altered reproductive function in fish⁴⁸ and effects on amphibian development, sexual differentiation, and survival has been observed in aquatic systems.⁴⁹
- ✘ Steroid exposure among avian species alters reproductive function.⁵⁰ Studies in rabbits have demonstrated that all three synthetic hormones can pass through the placental wall, posing a risk to fetuses.⁵¹

How do animal drugs impact public health?

- ✘ Harmful bacteria like *Salmonella* and *E. coli* originating in large animal factories frequently develop resistance to antibiotics, diminishing their effectiveness when used to treat even common infections in people.
- ✘ In 2012, 40% of *Salmonella* isolates on ground turkey were resistant to 3 or more classes of antibiotics, and 24% of isolates on chicken were resistant to 5 or more classes.⁵²
- ✘ Livestock workers and farmers are at particularly high risk of exposure to drug-resistant organisms, especially multi-drug resistant Methicillin Resistant Staphylococcus aureus (LAMRSA).⁵³
- ✘ In one study, ractopamine residues were found on roughly 1/5 of the U.S. pork products sampled.⁵⁴ There is evidence that ractopamine may be harmful to humans,⁵⁵ and it is estimated that 1,700 people in China were poisoned from eating ractopamine-finished pork between 1998 and 2010.⁵⁶
- ✘ The American Public Health Association acknowledges that “[t]here is clear evidence that hormones originating outside the body can interfere with our own hormone function.”⁵⁷ The presence of hormones, particularly

synthetic hormones, in waterways near CAFOs represents possible exposure pathways for humans, especially communities near CAFOS. Meat from cattle treated with hormone implants also has higher concentrations of hormones than meat from untreated cattle.⁵⁸

- ✘ The European Union Scientific Committee on Veterinary Measures confirmed that estradiol has mutagenic and genotoxic effects on humans.⁵⁹ Continuous exposure to low concentrations of hormones has been linked to increased incidence of human cancers.⁶⁰



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Steroid compounds have endocrine disrupting effects on wildlife . . . altered reproductive function in fish and effects on amphibian development, sexual differentiation, and survival has been observed in aquatic systems.





While regulatory reform is critical, market-based actions can be an important driver of change. Consumers can influence the market by purchasing drug-free meat (such as USDA certified organic or humane product labels) or participating in campaigns to demand that food retailers and drug manufacturers act to reduce the use of all animal drugs.

PART IV: HOW TO GET DRUGS OUT OF OUR MEAT SUPPLY

What can the federal government do to reduce the use of animal drugs?

- ✘ **FDA should increase transparency:** FDA has informally placed the burden on the public to uncover new data on the safety of animal drugs. The public cannot serve as a watchdog without knowing what information the Agency has or needs to update its safety evaluations. FDA should make scientific data on the health and safety of animal drugs within its possession publicly available by publishing the data on its website.
- ✘ **FDA should systematically re-review the safety of approved drugs, with the burden placed on industry:** FDA has authority to review the safety of animal drugs that are already on the market. The Agency should use its existing authority under the Federal Food, Drug, and Cosmetics Act (FFDCA) to conduct regular, systematic reviews of the safety of animal drugs to ensure that they are still safe to be marketed. To bolster FDA's

duty to do so, the FFDCA should be amended to provide for specific re-review procedures, similar to those EPA must follow with regard to the safety of pesticides.

- ✘ **FDA should take prompt action on drugs with compelling safety concerns:** FDA has authority to immediately suspend approval for any drug that presents an imminent hazard to animal or human health, and a duty to withdraw approval for drugs that are shown to be unsafe. The available information on beta-agonists and steroid hormones raises serious questions about their safety. FDA should immediately evaluate these data and consider initiating procedures to withdraw approval for these drugs.
- ✘ **FDA should collaborate with USDA to collect producer-level drug usage data:** In collaboration with CDC and USDA, FDA has indicated that it intends to identify strategies for collecting producer-level data for medically important antibiotics. In addition to engaging seriously and moving forward in a timely manner in this effort, FDA should expand this commitment to include collecting usage data for all animal drugs. While antimicrobials have gained particular notoriety due to their likely role in the rise in drug-resistant infections among humans, they are not the only group of animal drugs that pose a threat to humans, animals, or the environment.

What can state or local governments do to reduce the use of animal drugs?

States, counties, and cities do not have to wait for FDA to protect the health of their citizens, their environment, and the animals raised for food within their jurisdictions. The FFDCA leaves room for states to regulate in the absence of effective federal legislation. Six states—California, Maryland, Minnesota, New York, Pennsylvania, and Vermont—have proposed legislation that would regulate the nontherapeutic use of antibiotics in livestock. Maryland succeeded in passing legislation that banned arsenic-based drugs in chicken feed before FDA took action. In 2015, California banned the use of medically important antimicrobial drugs to livestock solely for purposes of promoting weight gain or improving feed efficiency. Cities and counties across the country have also passed resolutions supporting state and national bans on nontherapeutic uses of antibiotics in livestock production.

What can individuals do to address the use of animal drugs?

Consumer demand and attention has already pushed many large restaurant chains to make public commitments to reduce or eliminate nontherapeutic uses of antibiotics by their meat suppliers. Drug manufacturers have also voluntarily taken animal drugs off the market in response to public pressure. While regulatory reform is critical, market-based actions can be an important driver of change. Consumers can influence the market by purchasing drug-free meat (such as USDA certified organic or humane product labels) or participating in campaigns to demand that food retailers and drug manufacturers act to reduce the use of all animal drugs.



States, counties, and cities do not have to wait for FDA to protect the health of their citizens, their environment, and the animals raised for food within their jurisdictions.

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