

Economic Consequences of New Federal and State Regulations to Limit Antibiotic Use in Livestock

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Antibiotic resistance is one of the most pressing public health challenges facing the world today. In response, regulations have been put in place to limit the use of antibiotics in food-producing animals for growth promotion and to increase feed efficiency. These changes are likely to reduce productivity and have market-level impacts on output and prices.

According to the World Health Organization, antibiotic resistance is one of most substantial threats to global health and food security. The Centers for Disease Control and Prevention (CDC) report that two million people in the U.S. each year become infected with bacteria that are resistant to antibiotics, with 23,000 of those individuals dying as a result. Antibiotic resistance compromises the medical and veterinary communities' ability to effectively fight infectious diseases and manage infectious complications, which has serious health implications worldwide, while adding considerable costs to the treatment and control of disease.

Bacteria become resistant to antibiotics by mutating in a way that reduces or eliminates a given drug's effectiveness. Most health organizations cite the misuse or overuse of antibiotics in humans and animals as the primary factor contributing to the spread and increase in antibiotic resistance globally. While concerns about

resistance are paramount in both the human- and animal-health arenas, the food-producing animal segment (e.g., beef cattle, dairy cattle, poultry) of the supply chain has been widely criticized for using antibiotics for growth promotion and enhanced feed efficiency (i.e., subtherapeutic uses). Subtherapeutic antibiotic use in animals may manifest through low-levels of antibiotics administered for an extended period of time. According to the CDC, this type of long-term, low-level exposure contributes to the survival and growth of resistant bacteria.

When resistant bacteria are present in animals, they may be transmitted to humans through water and/or soil not washed off of food, improperly cooked meat, and exposure to animal feces. CDC reports 1 in 5 antibiotic-resistant infections in humans are caused by bacteria from food and animals.

In this article, I examine the new federal regulation and compare it to similar state-level regulations coming into effect in California in January 2018. I look at likely cost impacts for consumers and market-level impacts on prices, output, and competitiveness of California and U.S. producers relative to producers located elsewhere.

Regulatory Changes Governing Antibiotic Use in Food-Producing Animals

In response to these growing concerns, the Department of Health and Human Services' Food and Drug Administration (FDA) has amended the Animal Drug Availability Act of 1996 to add further structure to the distribution and administration of antibiotics to food-producing animals. Prior to this amendment, all animal drugs were regulated as either prescription or over the counter. These federal regulatory changes, which were fully implemented on January 1, 2017, defined a new avenue to

distribute antibiotics used in or on animal feed or administered through water. The regulations also defined antibiotics that are considered "medically important," an antibiotic used in both humans and animals (also referred to as shared class). Further, the FDA asked companies that produce these drugs to change their labels to eliminate any reference to or direction associated with subtherapeutic uses and to change the means of sale to eliminate any over-the-counter option.

Following these changes, it is illegal to use any medically important antibiotic for subtherapeutic treatments. Moreover, this class of drugs can only be used to treat, prevent, or control disease in animals under the supervision of a licensed veterinarian. This supervision is provided through a veterinary feed directive (VFD), which closely resembles a prescription for feed- or water-based antibiotic treatment. Prior to implementation of what has become known as the VFD rule, feed- and water-based medically important antibiotics were available over the counter and used at the discretion of farmers/ranchers without veterinarian oversight.

At roughly the same time as that VFD rule went into effect, California Governor Jerry Brown signed Senate Bill 27 ("Livestock: Use of Antimicrobial Drugs"). This bill, effective beginning January 1, 2018, implements regulations in California that are similar to the federal VFD rule with a few exceptions. Table 1 compares the federal and California regulations.

Beyond increasing the limitations on use of medically important antibiotics, relative to the federal rules, SB 27 also mandates that the California Department of Food and Agriculture (CDFA) develops and distributes stewardship guidelines for judicious use of antibiotics, puts in place requirements for data collection on the use of

Table 1. Comparison of the Federal VFD Rule and California SB 27

	Federal VFD Rule	California SB 27
What products are regulated?	Medically-important antimicrobials	Medically-important antimicrobials
What product forms are regulated?	Feed- and water-based antimicrobials	All forms, including but not limited to, feed- and water-based antimicrobials, injectable, and intra-mammary
When can medically important antimicrobials be used?	Treatment, control, and prevention of disease	Treatment, control, and prevention of disease
When can medically important antimicrobials NOT be used?	Subtherapeutically (i.e., growth promotion, feed efficiency, etc.)	Subtherapeutically (i.e., growth promotion, feed efficiency, etc.) and cannot be used for prevention in a “regular pattern”

antibiotics, conducts surveillance for antimicrobial resistance, and surveys management practices and associated health outcomes.

Antibiotic Use Prior to Regulation

Each year the FDA reports on antimicrobials with antibacterial properties sold or distributed for use in food-producing animals. Although these data are the best that are currently available, they have inherent limitations, namely that they are sales to distributors and thereby do not necessarily account for volume of product purchased and used on animals. Further, many of these drugs are approved for both food- and non-food producing (i.e., companion) animals, such that an unknown quantity of these drugs are not entering the food-producing animal system. Figure 1 shows the total quantity of medically important antimicrobials sold and distributed for use in food-producing animals in the U.S. for the most recent five years.

According to the FDA, 97% of medically important antimicrobials sold and distributed for use in food-producing animals were available for sale over the counter in 2015. In the same

year, medically important antimicrobials accounted for 62% of total antimicrobial sales in the U.S., with tetracyclines and penicillins accounting for 71% and 10% of sales in this category, respectively. On a global scale, tetracyclines are also the most frequently reported class of antimicrobials used in animals. The World Organisation for Animal Health’s (OIE) 2016 Report on Antimicrobial Agents in Animals reports that 48% of sales in 89 member countries were in the tetracycline drug class.

Potential Economic Impacts of Antimicrobial Regulations

Restricting the use of antibiotics through regulations such as the federal VFD rule or SB 27 are likely to have economic ramifications in many segments of animal agriculture. And, while different species and life-stage-specific segments of the supply chain will be affected differently, farm-level production costs are predicted to increase. The costs associated with veterinary consults to facilitate the use of feed- or water-based antibiotic treatments will be borne by producers, with small operations likely experiencing higher costs on a per-unit basis. Further, the cost of feed-based

antibiotic treatment is likely to rise as feed mills and feed distributors are required to mix and sell medicated feeds in compliance with regulations, while engaging in more stringent record-keeping obligations. As producers substitute away from medically important antibiotics to unregulated alternatives, prices for these drugs may be driven up by increased demand.

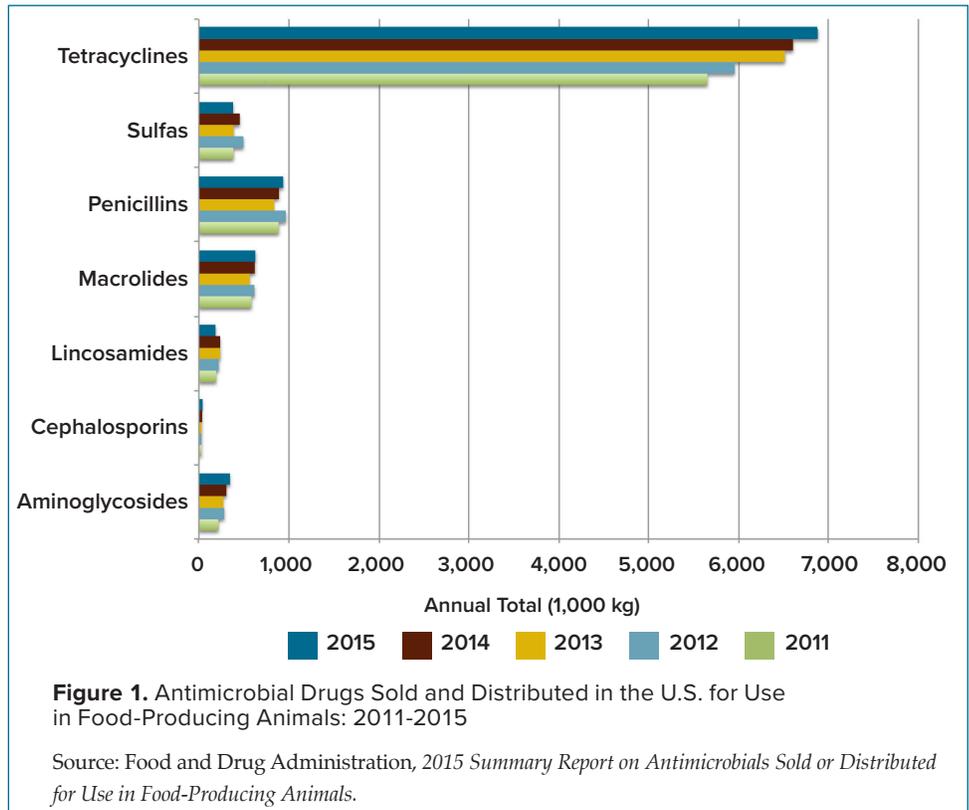
Further, producers with operations in remote locales may experience significant impediments when attempting to access veterinary services. Both the VFD Rule and SB 27 stipulate that for a veterinarian to provide a farmer/rancher with a VFD, they must have a veterinary-client-patient relationship (VCPR). FDA guidance indicates that a valid VCPR would require: i) that the veterinarian engage with the client (i.e., the animal producer) to assume responsibility for making clinical judgments about patient (i.e., animal) health, ii) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and iii) provide for any necessary follow-up evaluation or care. Limited access to veterinary services was a concern among many farmers and ranchers prior to these regulatory changes. In light of these new requirements, the demand for veterinarians with expertise in food-producing animal segments will likely rise, exacerbating shortages.

Antibiotics employed for growth promotion and to enhance feed efficiency are used in agricultural operations in order to reduce production costs per unit of meat and/or milk. Estimates based on the USDA Agricultural Resource Management Survey, analyzed by Sneeringer et al. (2015), suggest that producers using antibiotics in subtherapeutic settings will experience production cost increases of 1–2% if their access to antibiotics is restricted.

Further observational studies suggest that farmers will adopt alternative production practices in order to compensate for reductions in productivity resulting from restrictions placed on the use of antibiotics. For example, in production settings where animals are relatively confined (i.e., more animals per square foot of space), adopting enhanced sanitation practices may offset some of the production losses caused by eliminating the use of subtherapeutic antibiotics. These types of investments increase capital expenditures of these operations.

Finally, small market-level impacts should be anticipated as costs of production rise and some producers reduce production levels or exit the industry. Sneeringer et al. (2015) estimate that a 1–3% increase in production costs will increase wholesale prices by roughly 1% for a given level of output. These estimates are relatively small as not all producers or species at various life stages employ subtherapeutic antibiotic treatments.

Like other state-specific regulations that increase the regulatory burden and production costs of California farmers and ranchers, SB 27 will place those engaged in animal production in the state at a disadvantage relative to the rest of the U.S. if the use of subtherapeutic antibiotics was part of their production protocols. This is also likely true for the U.S. when competing with global trading partners. According to the World Organisation for Animal Health’s 2016 report, 74% of OIE member countries surveyed did not authorize the use of antimicrobials for growth promotion in animals. Yet, this report is silent on the identities of OIE members and so it is not possible to ascertain the strengths or weaknesses of those entities to determine likely trade impacts. Countries with high-profile antimicrobial regulations in place include Canada, the Netherlands, Denmark, and the



European Union broadly. To the extent that major U.S. trade competitors do not face similar restrictions on antimicrobial use in food-producing animals, the U.S. will be placed at a cost disadvantage in global markets.

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For additional information, the author recommends:

Sneeringer, S., J. MacDonald, N. Key, W. McBride, and K. Mathews. 2015. *Economics of Antibiotic Use in U.S. Livestock Production*. U.S. Dept. of Agriculture, Economic Research Service, Economic Research Report No. 200.

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