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Limitations of Reporting Requirements under California's Livestock Antimicrobial Restriction Law

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Background: Antimicrobial use in livestock production is considered a key contributor to growing antimicrobial resistance in bacteria. In 2015, California became the first state to enact restrictions on routine antimicrobial use in livestock production via Senate Bill 27 (SB27). SB27 further required the California Department of Food and Agriculture (CDFA) to collect and disseminate data on antimicrobial use in livestock production.

Objective: The goal of this report is to assess whether CDFA's data release allows us to evaluate how antimicrobial use changed after the implementation of SB27.

Methods: We combine the CDFA data with feed drug concentration ranges from the Code of Federal Regulation to evaluate the spread of plausible antimicrobial use trends. We also estimate antimicrobial consumption rates using data from the National Agricultural Statistical Service (NASS) and compare these to changes in medicated feed production reported by the CDFA.

Discussion: We show that CDFA's reported data are insufficient to reliably estimate whether antimicrobial usage has increased or decreased, most notably because no information is provided about the mass of antimicrobials approved for use or medicated feed drug concentrations. After incorporating additional external data on feed drug concentrations, one can at best provide uninformative bounds on the effect of SB27. We find some evidence that antimicrobial use has decreased by incorporating data on national sales of antimicrobials for food-producing animals, but the weakness of this inference underlines the need for improved data collection and dissemination, especially as other states seek to implement similar policies. We provide recommendations on how to improve reporting and data collection under SB27. https://doi.org/10.1289/EHP13702

Introduction

The contribution of antimicrobial use in the rearing of food-producing animals to antimicrobial resistance has been the subject of great controversy. In 2009, the US Food and Drug Administration (FDA) initiated a series of regulatory guidance documents that aimed to curb the misuse of medically important antimicrobial drugs in animal production, particularly by addressing administration for purposes of growth promotion and feed conversion.[1] The FDA's approach, however, did not address use for disease prevention. In excluding such uses from consideration, concerns were raised that these drugs would be continued to be used on a routine, untargeted basis in the absence of a confirmed or suspected disease agent.[2–4]

In 2015, California became the first US state to address these uses by passing SB27,[5] which tasked the California Department of Food and Agriculture (CDFA) with the goal of addressing the potential for ongoing routine administration of medically important antimicrobials in food animals. On its face, the law appears to restrict the use of antimicrobials in a "regular pattern" (i.e., disease prevention). The law, however, also includes ambiguous language that may function as a loophole. The professional judgment of a veterinarian can allow the use of medically important drugs in some cases to prevent disease risks from a "particular disease or infection."

Recent work by Casey et al.[6] found that SB27 was associated with a reduction in resistance to extended-spectrum cephalosporins among *Escherichia coli* (*E. coli*) human urine isolates in California. Resistance to the more extensively used aminoglycoside or tetracycline classes,[7] however, did not change. These findings echo the complexity and ambiguity prevalent in the broader literature on the relationship of antimicrobial use and resistance, with some studies finding clear links[8,9] and others finding little or no relation.[10,11] More detailed animal agricultural antimicrobial usage data are needed in California to put Casey et al.'s findings in context. Specifically, are usage reductions associated with the law responsible for the reductions in resistance (or lack thereof), or are other factors driving resistance trends?

To aid in the assessment of whether SB27 met its stated goal, SB27 includes an evaluative component. Specifically, the bill *a*) directs the CDFA to "gather information on medically important antimicrobial drug sales and usage," *b*) authorizes the CDFA to collect copies of Veterinary Feed Directives (VFDs) as part of their monitoring efforts, and *c*) directs the CDFA to maintain the anonymity of any individual entity's identity in its reporting of

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the collected data.[5] In theory, these data should allow for the assessment of the implementation and success of SB27.

As the first state law to regulate agricultural antimicrobial use, the outcome and perceived success of SB27 may inform decisions in other states and even future regulatory action at the federal level. Since the passage of SB27, Maryland passed a nearly identical bill, and other states have either passed or attempted to pass similar laws.[1] One mechanism for measuring the success of SB27 is to use monitoring data to determine whether CDFA's implementation of the law led to reductions of medically important antimicrobial use in livestock production.

Here, we review the publicly available data collected and disseminated by the CDFA with the goal of assessing changes in patterns of medically important antimicrobial use following the implementation of SB27.

Data and Methods

CDFA Data Collection and Release

To investigate the informativeness of the CDFA's antimicrobial use monitoring and reporting regime, we assessed the ability to estimate the quantity of administered VFD drugs from the data they make publicly available. Under SB27's mandate, the CDFA has collected copies of VFDs from medicated feed manufacturers and distributors on a quarterly basis since 2017 ("VFD Data").[12] Among other details, VFDs specify the client's identity and location, the number and species of animals that will receive the medicated feed, and the allowed dosage (i.e., feed concentration) and duration of the feed ration. After the first round of data collection in 2017, the CDFA determined that more data were needed to characterize the quantity of medicated feed intended for use in livestock production. As such, since 2018, the CDFA has gathered and reported data on the quantity of VFD feed manufactured and sold by manufacturers and distributors ("Manufacturer Data"). SB27 only gives the CDFA authority to collect VFDs, so compliance with the CDFA's request for the Manufacturer Data is voluntary. Notably, the CDFA does not report the extent of compliance with this request.

The CDFA publishes summaries of the VFD and Manufacturer Data that maintain the anonymity of any entities represented by the data in annual or biannual reports.[12–14] Many of the data collected on VFDs, such as the number of treated animals and the approved dosages, are not reported on at all. Most importantly, the data do not specify the total masses of each antimicrobial approved for use in livestock production, which are needed to track changes in antimicrobial use. It is possible that the CDFA can estimate these metrics internally using the information gathered from the VFD data. Nevertheless, they are not included in the aforementioned reports. External parties are also unable to estimate antimicrobial masses using the Manufacturer Data because the CDFA does not release data on feed concentrations.

Characterizing Antimicrobial Use Uncertainty Using Antimicrobial Use Indications

In the absence of CDFA data on medicated feed drug concentrations, we examined alternative sources of information. To the best of our knowledge, there are no empirically grounded data that report the concentrations of medicated feed in California or the United States.

For this reason, we obtained data on feed drug concentration ranges from animal drug use indications in the Code of Federal Regulations (CFR).[15] The use indications govern how a regulated animal drug is administered to combat a given set of ailments or symptoms in a class of animals and typically specify the range of permissible drug dosages. For each drug that the CDFA reports on, we recorded the minimum and maximum allowed dosage in the drug's CFR use indications when it is expressed in units of mass of antimicrobial per kilogram or ton of feed. We did not record dosages expressed in units of antimicrobial mass per animal per day or antimicrobial mass per pound of animal mass due to lack of data. The CDFA does not release data on animal counts, animal mass, or other variables with conformable units, and we were not able to identify a methodology for reliably converting these units to grams per ton of feed. This difficulty underscores the uncertainty that we characterize in the analysis below.

Because the CFR use indications only yield drug concentration ranges and because we do not have data on how medicated feed is distributed across use indications, they cannot be used to obtain a point estimate of the mass of antimicrobials approved for administration to livestock. As a result, we instead used the indications to characterize the uncertainty permitted by the CDFA's minimal reporting. To do this, we constructed two hypothetical trends of total drug use by imputing changes in drug concentrations within the ranges stated by the use indications. For each drug, we imputed an upward trend where the feed drug concentration starts from the 25th percentile of drug concentrations found on drug labels and progresses linearly to the 75th percentile, and we imputed a downward trend where the feed drug concentration starts from the 75th percentile of drug concentrations found on drug labels and progresses linearly to the 25th percentile. These trends illustrate the uncertainty in antimicrobial use trends, given the CDFA's limited data reporting.

Comparing with National Data

In comparison with the CDFA's reporting, the FDA data[7] on national sales of antimicrobials for use in food-producing animals are more complete. Specifically, the FDA collects data on the quantity of antimicrobials sold for use in medicated feed and discloses these quantities disaggregated by drug class and the intended species of use in publicly available reports available on the agency's website.

Understanding the evolution of medicated feed drug concentrations at the national level may provide some insight into antimicrobial use trends in California livestock production. Although national data also cannot be used to estimate average drug concentrations, they allow for the estimation of a closely related quantity: the biomass-adjusted Antimicrobial Consumption Rate (henceforth ACR).[16] The ACR in year t is defined as:

$$r_t = \frac{\text{Total mass of antimicrobial administered in year } r}{\text{Total mass of animals in year } t}.$$

The ACR measures the average intake of antimicrobial (class) per kilogram of livestock and is useful for comparing antimicrobial use intensities across regions with different livestock compositions. In our case, it is useful because the average feed drug concentration (x_t) can be written as a function of the ACR and the average feed consumption per kilogram livestock in a year (c_t):

$$x_t = \frac{r_t}{c_t}.$$

This equation tells us that if we assume that the average amount of feed eaten per kilogram of livestock remains constant over time, the average drug concentration of feed varies proportionally to the biomass-adjusted antimicrobial consumption rate. We consider this assumption plausible for the national ACR because the share of total US livestock mass across species has not changed substantially during the CDFA's reporting time frame (see Figure 1). Furthermore, although we do not possess

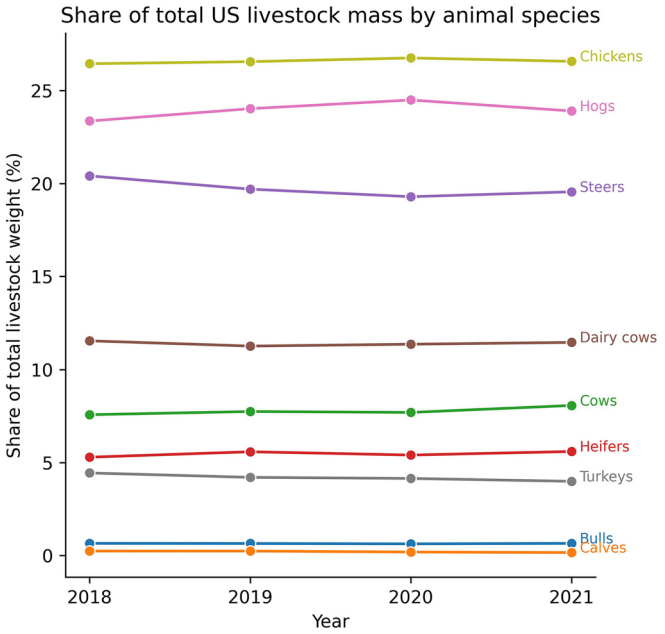

Figure 1. Share of total livestock mass by animal species between 2018 and 2021. Source: Data on US livestock Counts from the National Agricultural Statistics Service.[18] See "data_directory.xlsx" in the "data" folder of the Supplementary Material for more information on the animal count data series used.

evidence to support the following claim, we are not aware of strong reasons to believe that feed consumption per animal of a given species has changed substantially in the same period.

Because the relationship between the ACR and average feed drug concentration is only modulated by average livestock feed consumption, we can compare the two quantities to make weak inferences about changes in feed drug concentrations under the assumption that average livestock feed consumption did not change. To make these comparisons, we computed the national US ACR for 2018, 2019 and 2020. We obtained data on antimicrobial sales from the 2021 FDA report on antibiotic use for food-producing animals.[7] To estimate the total mass of animals, we multiplied annual animal counts for FDA-defined major food-producing animals—cattle, pigs, chickens, and turkeys[17]—from the National Agricultural Statistics Service[18] by average animal mass factors from European Medicines Agency[16] and summed the total mass for each animal species.

Discussion

Limitations of CDFA Reporting

The majority of antimicrobials used in animal agriculture belong to drug classes that are also important for treatment of infections in human clinical medicine.[19] According to the World Health Organization, the use of clinically important antimicrobials such tetracyclines, glycopeptides, and macrolides for livestock growth promotion has selected for resistance to these and other related drugs.[20] Careful stewardship of their administration is therefore critical to preserving their effectiveness for public health.

California was the first US state to implement a law regulating routine antimicrobial use for livestock production. As such, understanding the impact of SB27 is of great scientific and policy interest. The only publicly available data with the potential to characterize the effect of the law's implementation on antimicrobial use specifically are the VFD and Manufacturer Data. However, the inability to derive antimicrobial quantities from these data means that they cannot be used to describe changes in antimicrobial use patterns. The lack of specific instruction to "report total quantities of antimicrobials used" in the bill was raised by concerned parties during the legislative process but was not addressed in the final regulation.[21]

As a result, the best proxy for overall antimicrobial use in the data is the Manufacturer Data representing the quantity of medicated feed sold and manufactured in California between 2018 and 2021. Figure 2 plots these quantities for drugs with a complete time series and shows that the amount of feed containing chlortetracycline and neomycin/oxytetracycline appears to have decreased between 2018 and 2020, whereas the quantity of feed containing chlortetracycline/sulfamethazine appears to have increased over the same period.

It is tempting to conclude from these data that chlortetracycline and neomycin/oxytetracycline use has fallen over time and

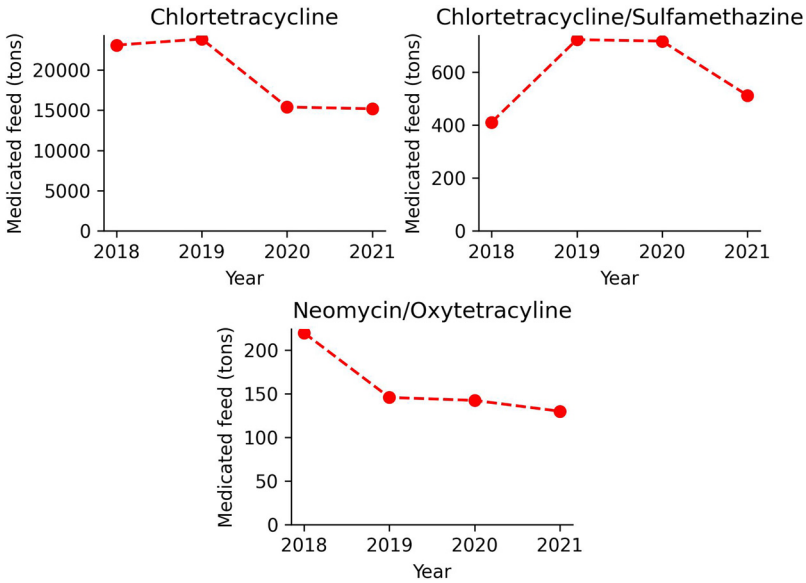

Figure 2. Tons of medicated feed sold and manufactured in California for drug/drug combinations with complete time series between 2018 and 2021. Source: 2020–2021 California Department of Food and Agriculture Veterinary Feed Directive Summary Report.[14]

Table 1. Summary of feed drug concentrations obtained Code of Federal Regulations use indications.

Drug	Number of concentration records obtained from use indications	Feed drug concentration (g/ton feed)					
		Mean	Min	25%	50%	75%	Max
Chlortetracycline/sulfamethazine	4	51.3	35	35	35	51.3	100
Chlortetracycline	65	434.9	5.83	25	100	500	4,000
Neomycin/oxytetracycline	5	260	100	100	200	400	500
Tylosin	30	27.9	8	8	8	40	100

Note: Summary of the drug concentrations found in the Code of Federal Regulations use indications, Title 21, Chapter I, Subchapter E, Part 558.[15] Note that we only record antimicrobial concentrations provided in units of grams per ton of feed, as concentrations provided in other units could not easily be compared to the VFD data. Max, maximum; min, minimum.

that chlortetracycline/sulfamethazine use has increased. However, temporal variation in the drug concentration of medicated feed, which is not reported by the CDFA, could mean that antimicrobial use trends do not correspond to trends in the quantity of medicated feed sold. Table 1 shows that feed drug concentrations from the CFR use indications vary significantly.[15] This results in high levels of uncertainty about overall antimicrobial use. We show this quantitatively by multiplying the Manufacturer Data on medicated feed

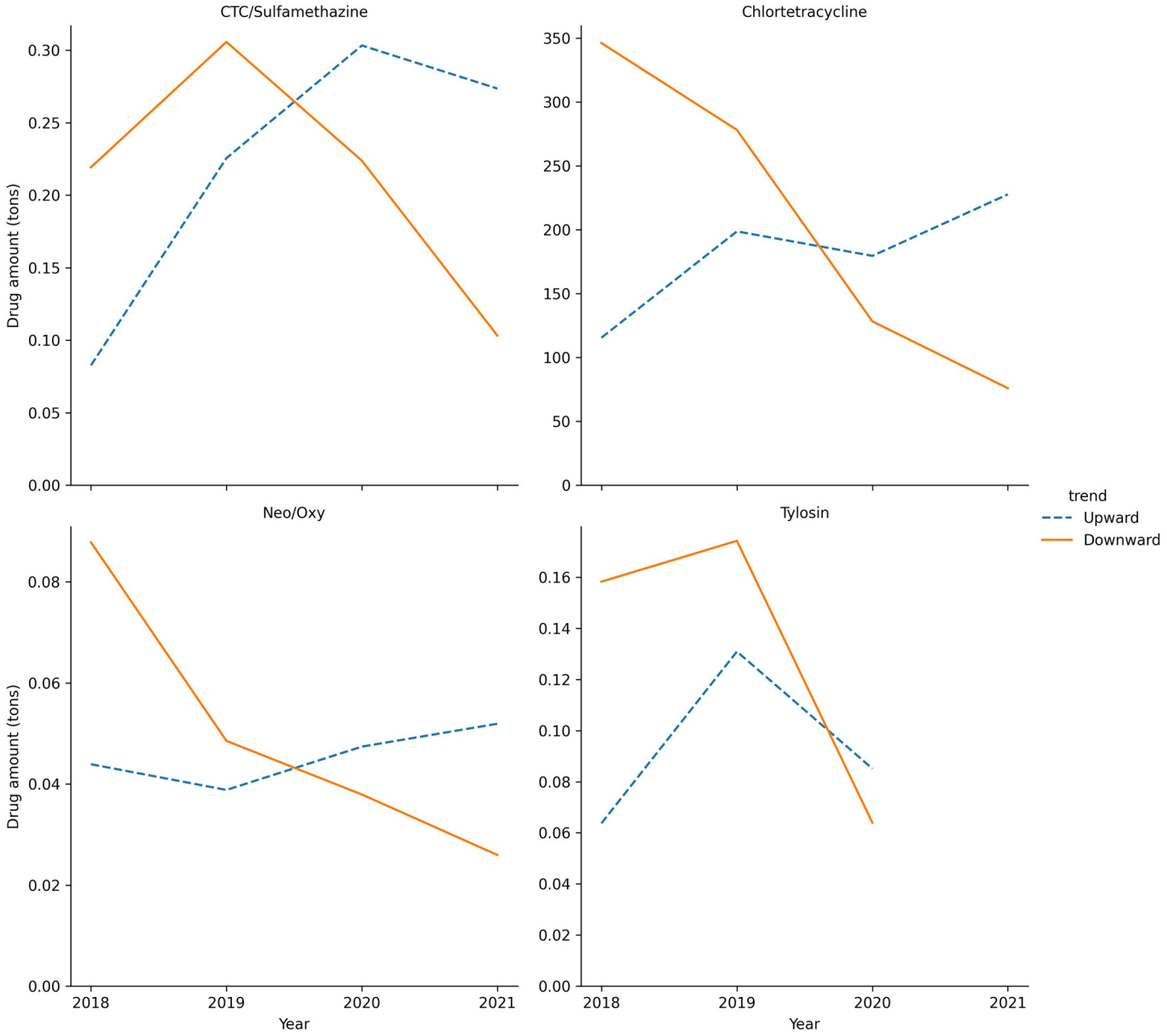

Figure 3. Plausible trajectories of overall veterinary feed directive drugs manufactured and sold in California as inferred from drug use indications. Trend lines represent the medicated feed amounts reported in the Manufacturer Data by the CDFA[14] multiplied by upward or downward trends in underlying feed drug concentrations. The upward feed drug concentration trend starts from the 25th percentile of drug concentrations found on drug labels and progresses linearly to the 75th percentile, whereas the downward trend where the drug feed concentration starts from the 75th percentile of drug concentrations found on drug labels and progresses linearly to the 25th percentile. Feed drug concentrations are obtained from the US Code of Federal Regulations[15] and can be found in the "CFR Use Indications" sheet of the "drug_data.xlsx" Excel file located in the raw data folder of the Supplementary Material.

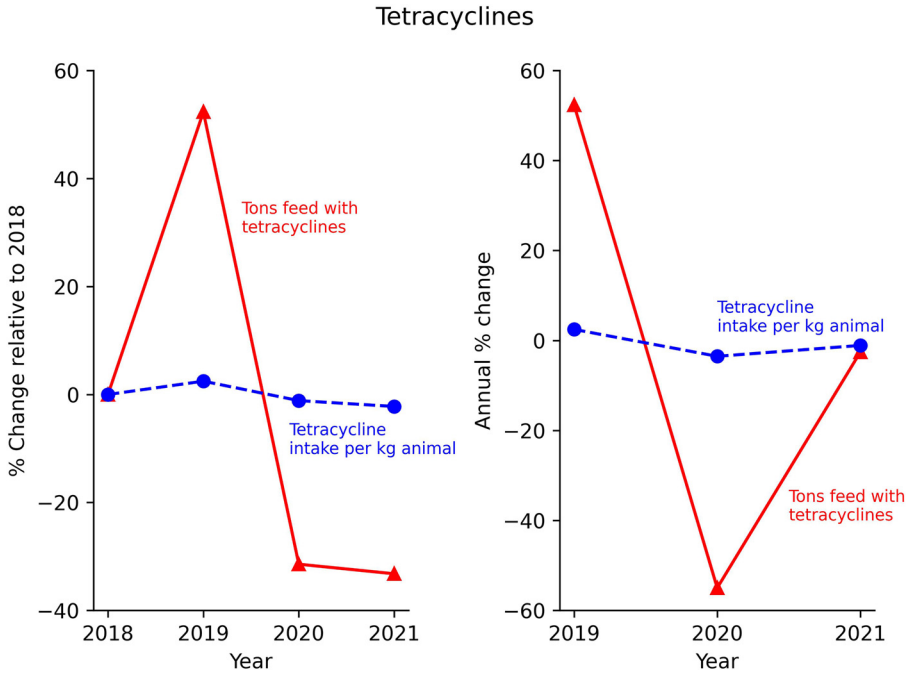

Figure 4. Changes in tons of tetracycline feed sold and manufactured in California alongside changes in biomass-adjusted tetracycline consumption rates. Sources: Tons of feed with tetracycline sold and manufactured in California is obtained from California Department of Food and Agriculture's 2020–2021 Veterinary Feed Directive summary report.[14] National tetracycline intake per kilogram animal is calculated using data from the FDA's 2020 report[7] on antimicrobial use in US livestock production, data on California livestock counts from the National Agricultural Statistics Service,[18] and average animal mass at time of antibiotic administration from the European Medicines Agency.[16]

amounts by hypothetical drug concentration trends that fall within the ranges specified in the CFR use indications to obtain drug quantity estimates that are plausible, given the reporting regimen (see the "Data and Methods" section for more information on the construction of the trends). As seen in Figure 3, feed drug concentrations rendered plausible by the CDFA's reporting are consistent with both increases and decreases in antimicrobial use during the CDFA's reporting period. The fact that both of these trends are plausible, given available data, indicates that the CDFA's current monitoring and reporting are insufficient to draw reliable conclusions about overall changes in antimicrobial use in California livestock production.

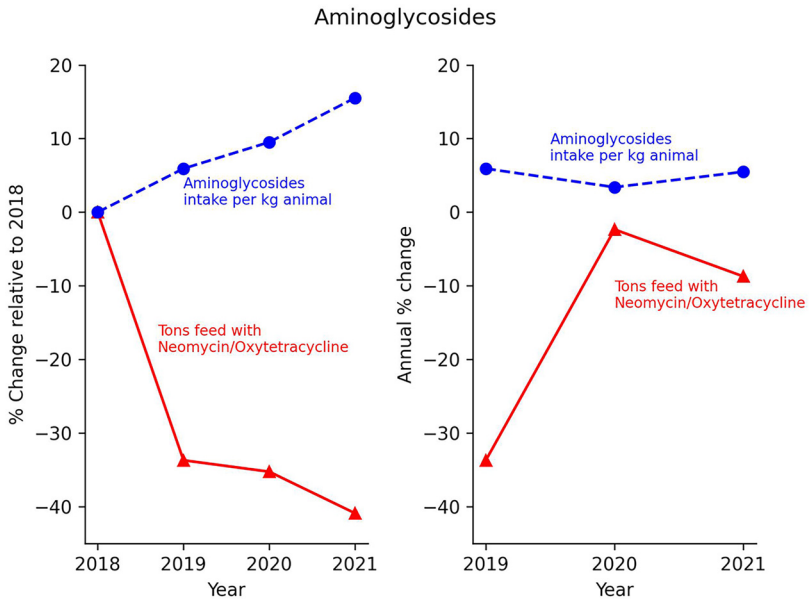

Figure 5. Changes in tons of neomycin/oxytetracycline feed sold and manufactured in California alongside changes in biomass-adjusted aminoglycosides consumption rates. Sources: Tons of feed with neomycin/oxytetracycline sold and manufactured in California are obtained from California Department of Food and Agriculture's 2020–2021 Veterinary Feed Directive summary report.[14] National aminoglycoside intake per kilogram animal is calculated using data from the FDA's 2020 report[7] on antimicrobial use in US livestock production, data on California livestock counts from the National Agricultural Statistics Service,[18] and data on average animal masses at the time of antibiotic administration from the European Medicines Agency.[16] Note that neomycin/oxytetracycline is compared with aminoglycosides despite the fact that oxytetracycline is a tetracycline. This comparison is valid because all drug use indications specify neomycin and oxytetracycline, when combined, should be administered in a 1:1 ratio.

Comparing with National Data

Using national livestock antimicrobial sales data provided by the FDA (see the "Data and Methods" section for more detail), Figures 4 and 5 plot the percentage changes in national ACRs alongside percentage changes in tons of medicated feed produced for tetracyclines and aminoglycosides. For both tetracyclines and aminoglycosides, changes in the quantity of medicated feed used are larger than changes in the ACR. For instance, the amount of feed consumed containing aminoglycosides fell by 35% between 2018 and 2020, whereas the national sales rate rose by 10% in the same period. In other words, California's antimicrobial consumption rate for aminoglycosides would have to be three times larger than the national average to be consistent with an increase in the amount of neomycin/oxytetracycline administered between 2018 and 2020. For tetracyclines, the changes in the national ACR are an order of magnitude smaller than the changes in tetracycline feed quantities.

Overall, assuming that national antimicrobial sales mirror California's, California's trends are consistent with declines in livestock antimicrobial use for tetracyclines and neomycin/oxytetracycline. We stress that this evidence is far from conclusive, because it is possible that California's antimicrobial consumption rates differ from the national averages. California raises a different composition of livestock in comparison with that of the rest of the country, which likely results in different antimicrobial use patterns. However, changes in California's antimicrobial consumption rates would need to be many multiples larger than the changes observed at the national level to negate the naive antimicrobial use trends (i.e., the decline in use) inferred from medicated feed quantities.

Conclusion and Recommendations

California's SB27 represents the first legislative intervention addressing the disease prevention loophole left open by FDA guidance; implementation of the law has critical implications for agriculture's contribution to the persistent problem of antimicrobial resistance. Recognizing the importance of effective data collection to the bill's success, SB27 specifically directed the CDFA to "advise the Legislature as to whether or not participation [in monitoring efforts] is sufficient to provide statistically relevant data."[5] In its 2019 report, the CDFA concluded that its monitoring program "aligns with the intent of the Law."[22]

Our findings call this conclusion into question. The CDFA's data collection and reporting make drawing meaningful inferences about livestock antimicrobial use trends very challenging, thereby undermining assessments of the bill's public benefit. As the first bill of its kind, SB27 is likely to serve as a model for other state and national regulators seeking to address antimicrobial overuse. Unfortunately, the antimicrobial usage data gathered under SB27 provide little useful information in that regard.

We conclude with recommendations to improve reporting and data collection under SB27. First, state law should grant the CDFA explicit authority to collect the Manufacturer Data. Relying on voluntary submissions from antimicrobial manufacturers and distributors unnecessarily encumbers the CDFA when gathering useful information for antimicrobial governance.

Second, Maryland's SB471 provides a model for improved reporting.[23] Maryland's Department of Agriculture must annually report VFD data on the total mass of antimicrobials approved for use, the number of animals approved for antimicrobial administration, the antimicrobial use indications, and their approved pattern of use. Data on antimicrobial masses are publicized alongside information that contextualizes the causes and extent of antimicrobial use. Maryland is also required to disaggregate data at the county level whenever at least three farms in a county report data. In contrast, California declared that all reported information is not a "public record," making such data reporting and sharing with researchers difficult.[5] Maryland's reports manifest much more robust reporting, providing an example for California and other states.[24]

Third, although SB27 requires the CDFA to consult with the California Department of Public Health for antimicrobial stewardship guidelines, such consultation should be extended to the reporting framework as well.[5] Antimicrobial use regulation is largely motivated by public health, and input from such stakeholders could reveal reporting gaps at earlier stages.

Finally, the CDFA should release its antimicrobial use data in microdata formats, such as comma separated value (.csv) files that are ready for statistical analysis. The CDFA currently publishes data in tables inside .pdf documents. This publishing format impedes the ability of researchers and other stakeholders to study the implementation of SB27.

As the first state-level measure of its kind, SB27 sets important precedent for the regulation of livestock antimicrobial use across the country. At the same time, the law's limitations call attention to the importance of ensuring that monitoring programs allow for unambiguous evaluations of changes in antimicrobial use trends. Careful design, reform, and implementation of reporting requirements will be critical to ensure that the law furthers its objectives.

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