Recent government regulations in the United States seek to ensure the effectiveness of antibiotics by limiting their agricultural use

1. Introduction

Legislators, governmental officials, health advocates, and consumers are concerned about the rapid development of antibiotic-resistant bacteria and the potential emergence of a post-antibiotic era (McKenna, 2013). The concerns are related to the overuse of veterinary drugs in food animals which research suggests contributes to a bacterium's mutation and acquired resistance (Gilchrist et al., 2007; Holmes et al., 2015). In the absence of regulatory action, the use of antimicrobials in animals raised for food might increase by 67 percent with a corresponding increase in the development of antimicrobial resistance (Van Boeckel et al., 2015).

The US Centers for Disease Control and Prevention (CDC) consider antimicrobial resistance to be one of the nation's most serious health threats. Two million illnesses in the United States result from drug-resistant bacteria each year (CDC, 2013), and an estimated 700,000 deaths around the world (O'Neill, 2014). In a 2013 report, the CDC noted that “[a]ntibiotic use in food animals can result in resistant Campylobacter that can spread to humans” (CDC, 2013, p. 62). The European Food Safety Authority has concluded that uses of antibiotics in animals results in the continuous positive selection of resistant bacterial clones (EFSA, 2014). Given the costs of these illnesses and deaths, President Obama issued an executive order in 2014 calling for the implementation of measures to reduce the emergence and spread of antibiotic-resistant bacteria (President of the United States, 2014). The President created an
advisory council and task force for combating antibiotic-resistant bacteria. Other provisions of the executive order called for reviewing existing regulations, proposing new regulations, strengthening surveillance efforts, responding to antibiotic-resistance outbreaks, and promoting the discovery of new antibiotics.

In 2015, the White House issued a National Action Plan for Combating Antibiotic-Resistant Bacteria enumerating five goals: “to strengthen healthcare, public health, veterinary medicine, agriculture, food safety, and research and manufacturing” (White House, 2015). With respect to limiting the use of antibiotics in animal production, two categories of antibiotic usage were identified: therapeutic and nontherapeutic. Greater veterinary oversight was recommended to reduce therapeutic usages for treating, controlling, and preventing disease. Nontherapeutic antibiotics administered to animals to increase rates of weight gain or improve feed efficiency were labeled “production uses” which should be eliminated to slacken the development of resistant bacteria (FDA, 2012, 2013).

To address agriculture’s contribution to the emergence of resistant bacteria, the Federal Food and Drug Administration (FDA) issued veterinary feed directive (VFD) regulations in 2015. These regulations alter the classification of selected over-the-counter antimicrobial drugs and prohibit animal production uses of VFD drugs (CFR, 2015; FDA, 2015). Under US federal law, drugs intended for use in or on animal feed meeting certain criteria are VFD drugs (United States Code, 2012, § 354). VFD drugs can only be fed to animals based on a VFD order “issued by a licensed veterinarian in the course of the veterinarian's professional practice” (FDA, 2015). The effect of the VFD regulations is that certain over-the-counter antimicrobial animal drug products currently approved for use in or on animal feed will be reclassified as VFD drugs so
they can only be administered under a VFD order with veterinary oversight (FDA, 2015).

One of the objectives of the VFD regulations was to slow the potential for the development of drug-resistant bacteria by eliminating production uses of antibiotics in raising food animals. The elimination of production uses of antibiotics comes two decades after several northern European countries took actions to ban selected uses of antibiotics with relatively minor impacts on productivity (Wegener, 2003). Uses of agricultural antibiotics were reduced by approximately 65 percent in Sweden, 47 percent in Denmark, 40 percent in Norway, and 27 percent in Finland (Bengtsson and Wierup, 2006). Although the VFD regulations should help curtail the use of antibiotics in food animal production, a number of limitations suggest that the FDA may need to revise the regulations in the future to ensure the objectives of the VFD are being met. One possible revision to strengthen the VFD is a governmentally-sponsored antibiotic labeling program to help curb the overuse of antibiotics (Animal Legal Defense Fund, 2013). By adopting a recordkeeping and labeling program with information about whether antibiotics were administered, consumers may be more certain about actual antibiotic usage during animal production.

2. Governmental actions

Several important antibiotics are used in animal production that are also used to treat humans (Table 1). These agricultural uses may contribute to the emergence of antibiotic-resistant bacteria that pose a human health threat. The environmental advocacy group Center for Food Safety (2015) estimates that 60-80 percent of antibiotics used in the United States are
administered to food animals for production uses. Given this estimate, considerable attention is focused on adopting regulations that would reduce the amounts used for the production of animal products. Similar efforts are being advanced by Health Canada's Veterinary Drugs Directorate (Health Canada, 2014). The adoption of the VFD regulations instituted five features that will reduce antibiotic usage (CFR, 2015; FDA, 2015), while other ideas for curtailing usage of antibiotics can be identified to encourage producers to reduce antibiotic usage (Table 2).

2.1. The need for the VFD: Human acquired antibiotic resistance from animals raised for food

The use of antibiotics in agriculture has raised concerns about antibiotic resistance for decades (Aarestrup, 2015). In 1969, the Swann Report recommended that antibiotics used in human patients should not be used as growth promoters in livestock (Swann Committee Report, 1969). In the United States, the FDA established a task force of scientists to undertake a comprehensive review of the use of antibiotics in animal feed in 1970, which recommended steps to limit the use of nontherapeutic antibiotics in farm animals for growth promotion (FDA, 2012). Antimicrobial use in animals amplifies the presence of resistant microorganism strains in animals’ intestinal tracts (Sun et al., 2014). Resistance genes can be transferred between bacterial species and resistant zoonotic bacteria may be acquired by humans via the food chain or through contact with infected animals, their feces, or contaminated environments (Chenney et al., 2015).

In 1998, the American Institute of Medicine noted relationships between the use of tetracycline-supplemented feed fed to chickens, the development of tetracycline-resistant
coliforms in the chickens, and the prevalence of tetracycline-resistant coliform organisms in the intestinal tracts of persons caring for the chickens (American Institute of Medicine, 1988). The problem is that the use of antibiotics in animals increases the size of the gene pool to further the emergence of multi-resistant enterococci causing human infections (Bates, 1997). Evidence of potential relationships between the use of animal drugs with resistant bacteria affecting humans have been established by a number of researchers (Alba et al., 2015; Argudín et al., 2015; Feßler et al., 2012; Graveland et al., 2010; Nóbrega and Brocchi, 2014; Schmithausen et al., 2015).

Researchers have concluded that livestock serve as a reservoir for transferable resistance genes directly or through food products (Alba et al., 2015; Monaco et al., 2013; Nóbrega and Brocchi, 2014; Schmithausen et al., 2015). Argudín et al. (2015) observed that methicillin-resistant *Staphylococcus epidermidis* populations in healthy pigs may be transmitted between humans and pigs. Colonized farm personnel and dogs may also contribute to the transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) within different compartments of the farm (Feßler et al., 2012). Cuny et al. (2015) estimated that livestock-associated MSRA was associated with at least 10% of these infections in humans. MRSA may enter the human food chain during slaughtering and may infect humans coming into direct contact with pigs or pork products (Normanno et al., 2015). Other research concluded that the presence of livestock-associated MRSA in foods may disseminate MRSA lineages and contribute to the prevalence and evolution of MRSA clones in the community (Oniciuc et al., 2015). However, no precise estimate exists on the contribution of the animal reservoir of antibiotic resistance for human health (Aarestrup, 2015).
2.2. *The Veterinary Feed Directive regulations*

The FDA prefaced its adoption of the VFD regulations on two Guidance for Industry documents (#209 and #213) released in 2012 and 2013 that offered nonbinding opinions on production uses of antibiotics in agriculture (FDA, 2012, 2013). Guidance for Industry #209 addressed medically important antimicrobial drugs used in food-producing animals, enunciating that medical importance “refers to antimicrobial drugs that are important for therapeutic use in humans” (FDA, 2012, p. 3). The importance of antimicrobial drugs to humans had previously been defined by Guidance for Industry #152 that differentiated critically important, highly important, and important drugs (FDA, 2003). Guidance for Industry #209 evaluated research findings regarding antibiotic resistance and enunciated two significant principles:

Principle 1. The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.

Principle 2. The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation (FDA, 2012).

Drawing upon these principles, Guidance for Industry #213 set forth a recommendation “that affected drug sponsors voluntarily revise the conditions of use of their medically important antimicrobial new animal drugs and combination new animal drug products to reflect the need for the professional oversight of a licensed veterinarian” (FDA, 2013).

These Guidance for Industry documents provided notice to producers and the industry of anticipated regulatory provisions, which subsequently were included in the VFD regulations.
Several requirements of the VFD regulations should help reduce antibiotic usage. First, some over-the-counter drugs will transition to VFD marketing status, meaning that use of these drugs require a written order by a licensed veterinarian (FDA, 2015). Second, medicated feeds containing a VFD drug cannot be fed for production uses of weight gain or feed efficiency. Third, veterinarians can only issue a VFD order if they have a valid veterinarian-client-patient relationship with the animal and the client (owner of the animals) (CFR, 2015). Due to this requirement, veterinarians will be limited in prescribing VFD drugs without knowledge about the animals and communicating with the client on the selected course of treatment (California Code of Regulations, 2015, § 2032.1). In some US states, a veterinarian-client-patient relationship may further require that the veterinarian be readily available for follow-up in case of adverse reactions or failure of the treatment regimen (Illinois Compiled Statutes Annotated, 2015). Fourth, distributors of medicated feeds must keep records of the receipt and distribution of all medicated animal feeds containing a VFD drug for two years (CFR, 2015). Finally, a veterinarian who issues a VFD order without complying with applicable regulations may be charged with adulterating or misbranding the VFD drug in violation of federal law (United States Code, 2012, tit. 21, §§ 351, 352). This might result in a warning letter but could lead to a charge of a misdemeanor in appropriate cases.

2.3. **Features for additional regulation**

Producers of food animals who eliminate uses of antibiotics have a risk of a disease outbreak with corresponding financial losses. To counter this risk, producers may claim they
need to use VFD drugs to prevent disease, and this usage is permitted under the VFD regulations. However, because many of the drugs used to prevent disease also promote growth (Table 3), some producers may claim their usage is to prevent disease. This could mean that there will not be any marked reduction in the use of production antibiotics unless further restrictions are adopted. In 2015, California legislators enacted a bill with provisions that go beyond the VFD regulations to curtail the use of antimicrobial drugs in agriculture in the state (California Senate Bill #27, 2015). The California legislature noted that the bill would foster a better understanding of the links between antimicrobial use patterns in livestock and the development of antimicrobial-resistant bacterial infections.

While conforming to the VFD regulations, the California provisions adopt a further restriction to preclude some uses of antibiotics for preventing disease. The bill enunciates four situations when producers may use medically important antimicrobial drugs.

A. Necessary to treat a disease or infection.
B. Necessary to control the spread of a disease or infection.
C. Necessary in relation to surgery or a medical procedure.
D. For prophylaxis to address an elevated risk of contraction of a particular disease or infection (California Food and Agriculture Code, 2015).

Unless the administration of the drug is consistent with one of these situations, a person shall not administer a medically-important antimicrobial drug in a regular pattern.

A major issue is whether the approval of drugs for preventing disease prescribed by the VFD regulations is too broad. The differentiation between a production use and preventing disease can be difficult because many animal drugs do both (Table 3).
for Industry #213, the WashPIRG Foundation (2014) noted that if producers and their veterinarians claim medicated animal feed is necessary to prevent disease rather than promote growth, new regulations may not lead to marked reductions in the use of antibiotics. The California provisions limit preventive use to prophylactic drugs addressing an elevated risk of contracting a particular disease or infection. The differentiation between these situations will need to be established, but it should help further reduce the use of antibiotics in food animal production.

The California legislation also imposes requirements for the state Department of Food and Agriculture to more proactively regulate the usage of antibiotics. The Department needs to develop antimicrobial stewardship guidelines and best management practices to serve as guidance for phasing out some uses of antibiotics. This might include the administration of antibiotics to fewer animals or for shorter lengths of time.

For the development of good hygiene and management practices, information on medically important antimicrobial drug sales, usage, and management practices are needed. The California legislation grants the state Department of Food and Agriculture authority to gather this information. It is hoped that this information will help illuminate usage and husbandry practices that can lead to reduced antibiotic usage. Although the federal VFD regulations require distributors of veterinary drugs to tabulate amounts of VFD drugs used in animal production, data at the farm level could provide helpful information on what practices are important in enabling animals to be raised without antibiotics. Additional information could be used for developing educational programs for producers about husbandry practices that support animal production without medicated feeds containing VFD drugs.
Finally, the California legislation includes civil penalties so that persons violating the law can incur fines. Any person convicted of a civil penalty must attend an educational program on the judicious use of medically important antimicrobial drugs.

3. Responding to antibiotic resistance

Given empirical studies have documented that food animals serve as reservoirs of antibiotic-resistant genes (Nóbrega and Brocchi, 2014; Schmithausen et al., 2015), the proliferation of veterinary drug use in agriculture may be contributing to a public health threat. Reducing the use of veterinary drugs could reduce numbers of antibiotic-resistant pathogens contributing to antibiotic resistance (Kaszanyitzky et al., 2006). Research suggests that the need for antibiotics is reduced when veterinarians provide more information to producers on husbandry practices that reduce animal illness (Cattaneo et al., 2009). Producers can alter management and feeding practices to reduce animal health problems requiring antibiotics (Jensen and Hayes, 2014; Kil and Stein, 2010). Another option is to find the minimal concentration of an antibiotic that exerts selection of antibiotic-resistant bacteria (Bengtsson-Palme and Larsson, 2016; Jutkina et al., 2016).

Congress has charged the FDA with the promotion of public health by ensuring that human and veterinary drugs are safe and effective (United States Code, 2012, tit. 21, § 393). Because drug effectiveness includes the minimization of antibiotic resistance (FDA, 2015, p. 31709), the FDA needs to take appropriate action to reduce the rate of development of resistant bacteria. Three categories of options may be identified through which the FDA might address antibiotic
resistance in order to maintain effective veterinary drugs. First, the FDA might develop prohibitions on the use of enumerated antibiotics in agriculture due to their need in human medicine. This could involve a ban on farm use of certain antibiotics beyond the extra-label uses already prohibited by the FDA (CFR, 2015, tit. 21, § 530.41). Denmark adopted this strategy in its actions to lessen the development of antibiotic resistant bacteria (Jensen and Hayes, 2014).

Second, the FDA might ensure that the veterinary drugs are effective without a prohibition or regulation. If the FDA concludes that there is no action that can markedly slacken the development of antibiotic-resistant bacteria, the agency would be able to decline to act further. Alternatively, the FDA could conclude that additional voluntary efforts to reduce an antibiotic usage effectively address the health problem.

A third category of regulatory options is for the government to devise additional strategies that would further reduce antibiotic usage in agriculture. Since the US uses more antibiotics per kg of produced meat than countries in Europe, some of the European approaches might assist in reducing usage (Aarestrup, 2015). One option is to determine whether minimal levels of antibiotics may be used without significant development of resistant bacteria (Bengtsson-Palme and Larsson, 2016). Encouraging product differentiation so consumers can purchase products from animals that never received antibiotics can also reduce usage. Currently, the USDA has a voluntary "Never Ever 3" verification program which defines meat products from cattle that never received antibiotics, growth promotants, or animal by-products from birth to slaughter (USDA, 2015). However, since antibiotic usage in the United States remains high, it is not clear that existing actions are sufficient in ensuring veterinary drugs are effective. Moreover, the listed features in Table 2 and the provisions of the California legislation highlight inadequacies of the
federal VFD regulations in reducing antibiotic usage.

3.1. US federal statutory provisions and labeling

The documented health threat posed by antibiotic resistance allows governments to take actions for reducing antibiotic usage to achieve corresponding reductions in the development of antibiotic-resistant bacteria. Labeling is one potential approach. Labels identifying antibiotic usage could reveal information that would affect the willingness-to-pay of consumers desiring food products from animals raised without antibiotics (Costanigro and Lusk, 2014).

The provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act preclude misbranding (Table 4). For the labeling of meat products, the provisions grant the Secretary of Agriculture discretion in prescribing standards of identity “not inconsistent with any standards established under the Federal Food, Drug, and Cosmetic Act” (United States Code, 2012, tit. 21, §§ 458, 678). The Secretary has delegated this authority to the United States Department of Agriculture’s Food Safety and Inspection Service (Sneeringer et al, 2015).

With respect to antibiotics used in animal production, the congressional order says that the FDA shall protect public health by ensuring that “veterinary drugs are safe and effective” (United States Code, 2012, tit. 21, § 393). The FDA’s authority in regulating food labels is mandatory rather than discretionary: it uses the word “shall” (Table 4). In regulating veterinary drugs, the FDA is statutorily obligated to take action to protect public health by ensuring veterinary drugs are effective. Because human health risks may flow from the unnecessary use of antibiotics in animal production and the consumption of meat products, it may be contended that the FDA
should require product labeling with respect to the use of antibiotics in the production of animals to maintain the effectiveness of antibiotics.

The FDA's VFD regulations encompassing more animal drug administration should help reduce usage of agricultural antibiotics. However, the continued use of antibiotics for preventive purposes, as highlighted by Table 3, suggests the VFD regulations may not meaningfully address antibiotic usage that contributes to resistance. Given the potential health risks posed by antibiotic resistance that is related to animal antibiotic usage, a governmentally-sponsored labeling program may be appropriate.

The division of authority over meat labeling and misbranding between the USDA and the FDA suggests the agencies need to work together to implement labels denoting the use of antibiotics in animal agriculture. The USDA has primary authority in labeling meat products, but no clear obligation concerning labels denoting antibiotic usage. The FDA, an agency under the Department of Health and Human Services, has an obligation to ensure effective veterinary drugs that encompass consideration of the development of antibiotic-resistant bacteria, but no clear authority on labeling meat products. To provide this protection, the FDA considers evidence of the dangers posed by antibiotic resistance.

Congress anticipated the need for these agencies to coordinate efforts by providing that the meat and poultry acts do not fully replace the provisions of the Federal Food, Drug, and Cosmetic Act (United States Code, 2012, tit. 21, §§ 457, 607). Rather, the meat and poultry acts contain provisions under which the Secretary of Agriculture "shall be in consultation" with the Secretary of Health and Human Services to avoid inconsistencies and possible impairment of the coordinated effective administration of labeling provisions. Under the statutory directives, the
FDA can consult with the USDA to devise a meat labeling program that would address the health problem of antibiotic resistance. Although labeling is an indirect method that may or may not increase the demand for products from animals not administered antibiotics, it might lead to reductions in antibiotic usage that would also reduce the development of antibiotic-resistant genes. Given the associations among veterinary drug usages, antibiotic resistance, and the maintenance of effective antibiotics, the FDA may be amiss in not taking further action to curtail antibiotic resistance by instituting an antibiotics used in animal production labeling program.

While the USDA might not be anxious to participate in a labeling program, the absence of labeling involves a risk of alternative actions by the FDA. Advocacy groups are working to eliminate the routine use of antibiotics in animals raised for food (Friends of the Earth et al., 2015; Gelband et al., 2015), and may advance legal challenges requesting further action by the FDA to ensure that veterinary antibiotics do not unreasonably contribute to a public health risk (Animal Legal Defense Fund, 2013). The FDA may decide to revise its rules on veterinary drug usage by adopting specific prohibitions on the usage of selected drugs in agriculture that are needed to protect human health. The compromise of a labeling program may be superior to the outright ban of named veterinary drugs.

3.2. Interpreting the FDA directive

To discern the meaning of the FDA’s obligations in safeguarding the effectiveness of antibiotic drugs, the statutory directive on food labeling can be examined and compared to a statutory directive on air pollution. The air pollution directive has been selected due to a US
Supreme Court finding that the directive required the government to regulate the emission of carbon dioxide gases from new motor vehicles. The judicial analysis of the air pollution directive posits the contention that the FDA needs to address the health threat of antibiotic resistance through a meat labeling requirement.

In the lawsuit *Massachusetts vs. Environmental Protection Agency* (2007), it was alleged that the US Environmental Protection Agency (EPA) needed to regulate four greenhouse gases from new motor vehicles due to the statutory command of the Clean Air Act. The act said that the EPA administrator “shall by regulation prescribe” standards for air pollutants. At issue was whether the EPA's refusal to regulate these gases was consistent with the statute. The Supreme Court found that if the emissions endangered public health, the EPA was required to regulate the emissions, or in the alternative, establish a justification for not taking action. Absent any provisions or justification, the EPA's refusal to regulate these gases was arbitrary and capricious, contrary to federal law.

To examine the meaning of the *Massachusetts* lawsuit to labeling products produced with antibiotics, three groups of congressional provisions are analyzed in Table 4: meat and poultry products labeling, other food labeling, and air pollutants. The analysis looks at the statutory command, subject, when or how the statute applies, and the accorded protection. As noted, the command for meat labeling is discretionary: the Secretary of Agriculture may prescribe labeling. The commands for air pollution and food labeling are mandatory. The Supreme Court's interpretation of the mandatory air pollution command in the *Massachusetts* lawsuit leads to a conclusion that the FDA needs to take appropriate action to promote public health by addressing usages of veterinary drugs in animal husbandry that contribute to antibiotic resistance.
3.3. Consumer demand for meat products

Some American consumers want to be able to eat meat products from animals that were not given antibiotics and are asking firms and restaurants for such products (Strom, 2014). In many cases, these consumers are willing to pay more for meat products with guarantees that no antibiotics were used (Brewer and Rojas, 2008; McKendree et al., 2013; Li and Hooker, 2009; Sneeringer et al., 2015). This requires the labeling of meat products that were produced without using antibiotics so consumers can make purchasing decisions based on this additional information. The expected higher prices for meat products produced without antibiotics provide encouragement for producers to alter husbandry practices to eliminate the use of antibiotics in the production of their animals (Strom, 2015b). Further labeling guidance might help allay confusion reported by the media and advocacy groups about current voluntary labels identifying attributes for meat products (Bohne and Halloran, 2012; Strom, 2015a).

Firms and restaurants are reported to already source meat products from producers who have voluntarily refrained from administering antibiotics (Brown, 2015; Reichl, 2014, Strom, 2014, 2015b, 2015c, 2015d). Sellers of meat products relate this information through product labels and advertising. Alternatively, it has been reported in the media that buyers solicit food vendors of meat products produced without antibiotics (Himes, 2014). However, current production practices at farms, feedlots, and slaughterhouses make it difficult to ascertain whether antibiotics were administered to animals supplying the meat products. While governmental residue testing results show less than one percent of samples in violation of federal law (USDA, 2014), the lack of residues in meat products does not mean antibiotics were not administered.
Many antibiotics clear the animal's system leaving no trace. In the absence of mandatory records of antibiotic usage on a farm, guaranteeing antibiotic non-usage is difficult to verify.

4. Concluding comments

The most prevalent use of antibiotics in the United States is in animal production. Considerable scientific evidence suggests that agricultural usages create reservoirs of antibiotic-resistant genes (Alba et al., 2015; EFSA, 2014; Monaco et al., 2013; Nóbrega and Brocchi, 2014; Schmithausen et al., 2015). In 2015, the FDA adopted VFD regulations with provisions directed at reducing antibiotic usage in animal production. However, more could be done to reduce antibiotic usage. The continued usage of veterinary drugs is contributing additional strains of resistant bacteria that may induce a need for new veterinary drugs and possibly new antibiotics for human use.

Under the Federal Food, Drug, and Cosmetic Act, the FDA is obligated to take action to ensure veterinary drugs are effective. Congress has not provided further direction on the action required, but it can be concluded that drug effectiveness embodies reductions of the development of antibiotic-resistant bacteria. Reductions in antibiotic usage in agriculture would help reduce the development of antibiotic-resistant bacteria. Given the quantities of antibiotics used in animal production and the associated problem of antibiotic resistance, it may be contended that the FDA has not met its statutory obligation of promoting public health by ensuring veterinary drugs are effective (Animal Legal Defense Fund, 2013).

Due to the health threat posed by antibiotic-resistant bacterial infections that cause 23,000
deaths each year in the United States (CDC, 2013), some nongovernmental organizations and consumers feel that the government should have a more organized and forceful response. Some advocacy groups would ban antibiotics used in animal production outright ( Friends of the Earth et al., 2015) while others seek greater state oversight (California Senate Bill #27, 2015).
Consumers might also decide to petition for state antibiotic labeling laws similar to recent citizen and legislative actions responding to genetically modified organisms (Amaru, 2014; Kling, 2014).

Under federal statutory directives to promote public health and avoid false labeling, the FDA and USDA are charged with assuring consumers that meat products are correctly labeled. The self-selected voluntary labeling claims of meat producers concerning the nonuse of antibiotics that currently exist raise questions about whether the agencies are meeting their charges. Labeling of other food products has raised questions about the accuracy in labeling claims (Animal Welfare Institute, 2014; Heinzerling, 2015). More information is needed on whether the VFD regulations adequately address antibiotic resistance and whether animals receiving antibiotics are being sold as never having received antibiotics. A governmentally-sponsored labeling program offers an idea to encourage the reduction of antibiotic usage in agriculture, reduce the development of antibiotic-resistant bacteria, and lessen deaths from antibiotic-resistant bacterial infections.

Acknowledgment

The research presented here is based on work supported by the Cooperative State Research
Education and Extension Service, the US Department of Agriculture Project No. GEO00684.

References


http://www.fsis.usda.gov/wps/wcm/connect/12aeca93-4d3e-4ac7-b624-d5fc0b0dbae0/Petition_Animal_Legal_Defense_Fund_060313.pdf?MOD=AJPERES [accessed 18 February 2016].

Packages Deceive Consumers. Animal Welfare Institute, Washington, DC; May 2014.


Brown L. Panera ridding food menu of more than 150 artificial ingredients. St. Louis Post-Dispatch (Missouri); 6 May 2015, Section News, p. 1.


California Code of Regulations. Section 2032.1; 2015.

California Food and Agriculture Code. Section 14402; 2015.
California Senate Bill #27. An act to add Chapter 4.5 (commencing with Section 14400) to Division 7 of the Food and Agricultural Code, relating to livestock; 2015.


Health Canada. Notice to stakeholders: Collaborative efforts to promote the judicious use of medically-important antimicrobial drugs in food animal production. 2014.


Himes T. LAUSD schools among first to adopt antibiotic-free chicken standards. San Gabriel Valley Tribune (California); 10 December 2014, section News.


methicillin-resistant *Staphylococcus aureus* responsible for human colonization and infection in an area of Italy with high density of pig farming. BMC Infect Dis 2013;13:258.


Swann Committee Report, 1969. Report of the Joint Committee on the use of antibiotics in animal husbandry and veterinary medicine. HMSO.


Table 1. Critically and highly important antibiotics.*

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Animal Use</th>
<th>Concerns about the continued use for humans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracyclines</td>
<td>Cattle, swine, poultry</td>
<td><em>Brucella, Chlamydia</em> spp. and <em>Rickettsia</em> spp. infections</td>
</tr>
<tr>
<td>Macrolides</td>
<td>Cattle, swine, poultry</td>
<td>Limited therapy for <em>Legionella, Campylobacter</em> and MDR <em>Salmonella</em> and <em>Shigella</em> infections; May result from transmission of <em>Campylobacter</em> spp. and <em>Salmonella</em> from non-human sources</td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>Swine, poultry</td>
<td>Transmission of <em>Enterococcus</em>, <em>Enterobacteriaceae</em> (including <em>Escherichia coli</em>) and <em>Mycobacterium</em> spp. from non-human sources</td>
</tr>
<tr>
<td>Sulfonamides</td>
<td>Cattle, swine, poultry</td>
<td>One of the limited therapies for acute bacterial meningitis, systemic non-typhoidal salmonella infections and other infections; may result from transmission of <em>Enterobacteriaceae</em> including <em>E. coli</em> from non-human sources</td>
</tr>
<tr>
<td>Lincosamides</td>
<td>Swine, poultry</td>
<td>Human infection may result from transmission of <em>Enterococcus</em> spp. and <em>Staphylococcus</em> aureus including MRSA from non-human sources</td>
</tr>
</tbody>
</table>

* WHO, 2011.
Table 2. Features to encourage the reduction in uses of antibiotics in animal production.

<table>
<thead>
<tr>
<th>Feature</th>
<th>VDF Rule</th>
<th>Possible New Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulate additional over-the-counter drugs</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Prohibited use for weight gain or feed efficiency</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Veterinary-client relationship</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Distributor records</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Veterinarian misconduct and misbranding</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Site visit prior to prescribing a VFD</td>
<td></td>
<td>California Code of Regulations § 2032.1</td>
</tr>
<tr>
<td>Proscribe disease prevention</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Producer records</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Stewardship guidelines</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Best management practices</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Penalties for violations</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Educational rehabilitation for violators</td>
<td></td>
<td>California Senate Bill No. 27, 2015</td>
</tr>
<tr>
<td>Ban specific antibiotics</td>
<td></td>
<td>EU Council Regulation (EC) No. 2821/98</td>
</tr>
<tr>
<td>Minimal selective concentrations</td>
<td></td>
<td>Bengtsson-Palme and Larsson, 2015</td>
</tr>
<tr>
<td>Require labeling on antibiotic usage</td>
<td></td>
<td>Animal Legal Defense Fund, 2013</td>
</tr>
</tbody>
</table>
Table 3. Classes of antibiotics for production uses and disease prevention.*

<table>
<thead>
<tr>
<th>Antibiotic class</th>
<th>Production uses</th>
<th>Prevention uses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chickens</td>
<td>Cattle</td>
</tr>
<tr>
<td>Lincosamides</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Macrolides</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Penicillin</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Streptogramins</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

*Davis et al., 2014.
Table 4. Comparisons of the statutory directives for air pollution, food labeling, and meat and poultry labeling.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>standards of identity</td>
<td>public health</td>
<td>standards for air pollutants</td>
</tr>
<tr>
<td>When or how</td>
<td>in labeling</td>
<td>by ensuring</td>
<td>cause or contribute to air pollution</td>
</tr>
<tr>
<td>Protection accorded</td>
<td>to avoid false or misleading labeling</td>
<td>veterinary drugs are safe and effective</td>
<td>no endangerment of public health or welfare</td>
</tr>
<tr>
<td>Qualification</td>
<td>not inconsistent with standards established under the Federal Food, Drug, and Cosmetic Act</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>