JUDICIOUS USE OF ANTIBIOTICS: BITING THE HANDS THAT FEED US

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I. INTRODUCTION

The American farmer produces food, fiber, and fuel to feed the world. American agriculture has progressed dramatically, making access to, and quality of, food dependable.[1] Generally, Americans no longer worry about mass food insecurity.[2] However, as consumers recently have become more concerned about the origin of their food and its effects on human health, they have blamed the agriculture industry for environmental degradation, increased allergens, and antibiotic resistance.[3]

For decades, it has been a common practice in high density farm facilities to add small doses of antibiotics into feed rations in order to encourage maximum growth potential and minimize pathogens in livestock, particularly poultry and swine.[4] However, in recent years antibiotic-resistant microbes have become a global public health fear.[5] Across the globe, "antibiotic stewardship campaigns" have been introduced to encourage prudent use of antibiotics in food-producing animals, "with the ultimate goal of preserving their effectiveness for serious and life-threatening infections."[6] Yet, while it is unclear to what extent antibiotic use in food-producing animals contributes

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* J.D. Candidate, May 2020, University of Louisville Louis D. Brandeis School of Law. I would like to thank my mother, Sharla M. Six, a Kentucky educator and my hero. Thank you for demonstrating that knowledge is power, and education is the touchstone to success. I would also like to thank Professor Abramson for believing in me and in this Note. This Note is dedicated to the American farmer and all of those who cultivated a love of agriculture in me.

[1] *See Food Availability and Consumption*, U.S. DEP'T OF AGRIC., https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/food-availability-and-consumption/ (last updated Aug. 28, 2019).

[2] *See Key Statistics & Graphics: Food Security Status of U.S. Households in 2017*, U.S. DEP'T OF AGRIC., https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics/ (last updated Sept. 4, 2019).

[3] *See* INST. OF MED. & NAT'L RESEARCH COUNCIL ET AL., A FRAMEWORK FOR ASSESSING EFFECTS ON THE FOOD SYSTEM 13, 72–73, 127 (Malden C. Nasheim et al. eds., 2015).

[4] NAT'L RESEARCH COUNCIL ET AL., THE EFFECTS ON HUMAN HEALTH OF SUBTHERAPEUTIC USE OF ANTIMICROBIALS IN ANIMAL FEEDS 321 (1980).

[5] Timothy F. Landers et al., *A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential*, PUB. HEALTH REP., Jan.–Feb. 2012, at 4, 4–5.

[6] *Id.* at 5.

to antibiotic resistance in humans,[7] regulations imposed on the agriculture industry—both nationally and internationally—have increased significantly, placing a substantial burden on farmers.[8] Preserving the effectiveness of antibiotics is an important goal. However, any policy should take into account the agricultural realities the farmer faces. The Food and Drug Administration's (FDA) current approach to regulating agricultural uses of antibiotics fails to do this.

This Note begins by discussing the present regulatory state of affairs in the United States, focusing on the FDA's Veterinary Feed Directive (VFD) final rule. Then, the Analysis section offers a comparative analysis of this rule with international regulation of antibiotics in animal agriculture, particularly that of Germany, Canada, and Australia. Finally, the Note's Resolution proposes an amendment to the VFD, combining the best management practices for the judicious use of medically important antibiotics in the animal agriculture industry—one that gives the farmer greater support and flexibility as well as promotes public understanding of agricultural practices.

II. BACKGROUND

Modern medicine has utilized antibiotics "for over 70 years," and has been "widely used in veterinary medicine, starting with penicillin and the sulfa drugs since the 1950's."[9] The appropriate use of antibiotics in animal-agriculture has been a "contentious issue" between veterinarians and producers.[10] Antibiotic resistance in "both human and animal medicine" has become a major concern for public health "due to several instances of specific

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[7] Qiuzhi Chang et al., *Antibiotics in Agriculture and the Risk to Human Health: How Worried Should We Be?*, 8 EVOLUTIONARY APPLICATIONS 244–45 (2015) ("[M]any believe that agricultural antibiotics have become a critical threat to human health. While the concern is not unwarranted, the extent of the problem may be exaggerated. There is no evidence that agriculture is 'largely to blame' for the increase in resistant strains . . . ."); Landers et al., *supra* note 5, at 5 ("While antibiotic use in food animals may represent a risk to human health, the degree and relative impact have not been well characterized.")

[8] American Farm Bureau Federation, *EPA Regulations Suffocating U.S. Agriculture*, FARM PROGRESS (Nov. 23, 2011), https://www.farmprogress.com/government/epa-regulations-suffocating-us-agriculture.

[9] Interview with Robert Stout, DVM, Kentucky State Veterinarian, in Frankfort, Kentucky (Jan. 1, 2017). *See also KFB Candid Conversations: What to Expect with VFD Implementation*, KY. FARM BUREAU (Dec. 14, 2016), https://www.kyfb.com/federation/newsroom/kfb-candid-conversations-what-to-expect-with-vfd-implementation/ (interviewing Robert Stout, DVM, Kentucky State Veterinarian) [hereinafter *Candid Conversations*].

[10] *Candid Conversations*, *supra* note 9.

antibiotics becoming ineffective."[11] The FDA has taken "current action" through VFD regulations which effect producers, feed mills, and veterinarians.[12] Since January 1, 2017, the use of Medically Important Antimicrobial Drugs (MIAD) used in animal feed is under the direct purview of veterinary oversight.[13] Since the enactment of the VFD rule, "off label use" of antibiotics in animal agriculture feed is prohibited.[14] Antibiotics used in animal agriculture are strictly "limited to two specific areas: treatment of disease" and "control of disease."[15] This rule prohibits the use of antibiotics in animal feed for the purposes of "enhancing weight gain and feed efficiency."[16]

Prior to 1996, the FDA regulated the distribution of animal drugs in two classifications, over-the-counter (OTC) and by prescription.[17] Most drugs used in animal feeds were classified and approved as OTC drugs so a producer could go to its local feed mill and purchase medicated feeds for use in production, treating, and preventing the spread of pathogens in their livestock.[18] As technologies and advances in veterinary medicine developed, Congress recognized a need for substantial regulation and greater control of animal drugs than what the OTC status provided.[19] In 1996, Congress enacted the Animal Drug Availability Act (ADAA), which outlined the approval and marketing process of the latest animal drugs.[20]

Additionally, this regulatory scheme created a new category for certain drugs used in animal feed and drinking water known as Veterinary Feed Directive (VFD) drugs.[21] A "veterinary feed directive" is a nonverbal, written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that authorizes the use of a VFD drug or combination of a VFD drug in or on an animal's feed.[22] This written authorization allows

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[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] Veterinary Feed Directive, 80 Fed. Reg. 31,707, 31,709 (Jun. 3, 2015) (codified at 21 C.F.R. § 558). Dr. Stout, Kentucky's State Veterinarian, explained that OTC products include many topical and injectable antibiotics labeled for "veterinary use," and prescription products are products available directly from a veterinarian or by prescription at a pharmacy. *See Candid Conversations*, *supra* note 9. In 1938 Congress delegated to the FDA the control over addressing animal drug issues in the Federal Food, Drug & Cosmetic Act. *See* 21 U.S.C. § 393 (2012).

[18] *See* Veterinary Feed Directive, 80 Fed. Reg. at 31,709.

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *Id.*

the veterinarian's clients—owners or caretakers of the animal(s)—to obtain and administer animal feed bearing or containing a VFD drug or combination VFD drug to treat their animals, but only in accordance with the approved use conditions set by the FDA.[23] Pursuant to C.F.R. § 558.6(a)(1), an animal feed which contains a VFD drug "may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian."[24] The VFD statement includes information about the number and specific species of animals to receive feed containing one or more VFD drugs and any other information required pursuant to C.F.R. § 558.6.[25] VFD drugs include most antibiotics that are fed to livestock with some exceptions.[26]

Based on public feedback about how burdensome the initial VFD was, in 2012 the FDA implemented its revised final policy framework in regard to VFD drugs, which fundamentally changed the methods used by animal agriculture producers in managing their herds.[27] While the FDA acknowledges that antimicrobials mixed into feed rations play an integral part in controlling, treating, and preventing disease in food producing animals, the FDA issued stricter regulations for the authorization and use of antibiotics as recently as January 1, 2017.[28] This final rule provides that the veterinarian must issue the VFD in the context of a valid veterinarian-client-patient relationship (VCPR) as defined by the state requirements applicable to where the veterinarian practices.[29] In states that lack appropriate VCPR requirements applicable to VFDs, the veterinarian must issue the VFD consistent with the federally defined VCPR standard.[30]

Antibiotics scheduled as VFD drugs now require the strict supervision of a licensed veterinarian, and the classification altogether prohibits their use in animal feed and drinking water for production purposes, such as promoting growth and increasing feed efficiency.[31] The overall objective of the FDA is

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[23] 21 C.F.R. § 558.3(b)(7) (2019).

[24] *Id.* § 558.6(a)(1).

[25] *See id.* § 558.6(b)(ii)(3).

[26] *Veterinary Feed Directive*, CORNELL UNI. COLL. OF VETERINARY MED., https://ahdc.vet.cornell.edu/programs/NYSCHAP/nysvfrp/vfd.cfm (last visited Sept. 10, 2019). Exceptions to the rule include the use of Ionophores such as Rumensin and Bovatec. These medications are not deemed "medically important" to human health. *See id. See also Candid Conversations*, *supra* note 9.

[27] Veterinary Feed Directive, 80 Fed. Reg. 31,707, 31,709 (Jun. 3, 2015).

[28] *Fact Sheet: Veterinary Feed Directive Final Rule and Next Steps*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm449019.htm (last visited Sept. 10, 2019). Food producing animals include swine, cattle, small ruminants, and bees. *See Candid Conversations*, *supra* note 9.

[29] Veterinary Feed Directive, 80 Fed. Reg. 31,707, 31,709 (Jun. 3, 2015).

[30] *Id.*

[31] *Fact Sheet*, *supra* note 28.

to combat antimicrobial resistance and assure the judicious use of medically important antimicrobials considered essential to human health.[32] The FDA classifies "medically important antibiotics" as those that are of therapeutic importance in human medicine and possess a risk of microbial resistance development if they are not used judiciously.[33] One major change to VFD regulation in the final rule of C.F.R. § 558.6 includes changing the classification of VFD drugs.[34] Now, the categorization of VFD drugs will be determined on a case-by-case basis, based on the likelihood that the particular drug at issue will produce an unsafe residue in edible products derived from treated animals, as is currently the case for non-VFD feed-use drugs, giving the FDA discretion to re-categorize drugs at any given moment.[35]

The current VFD involves three important groups and their inter-relationships: veterinarians, the client, and the distributor.[36] In order for a veterinarian to issue a VFD drug to a producer, she must be both licensed to practice veterinary medicine and establish a VCPR under the terms of both federal and state regulations.[37] While the FDA claims to defer to state legislatures in outlining the requirements for establishing a VCPR, states must comply with federal guidelines in order to ensure veterinarians conduct themselves in accordance with nationally consistent standards.[38] This arrangement "has the advantage of being able to leverage the accountability that comes with State licensing board oversight to ensure compliance with the VCPR requirement, while providing States the flexibility to adapt their VCPR requirements appropriately to local conditions."[39]

The federal components of establishing a VCPR require the veterinarian to "(1) [e]ngage with the client to assume responsibility for making clinical judgments about patient health, (2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where patient is managed, and (3) provide for any necessary followup evaluation or care."[40] Due to the VFD's regulatory scheme, veterinarians may be subject to greater liability for ensuring that the farmer adheres to the duration and use

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[32] *Id.*

[33] *Veterinary Feed Directive*, *supra* note 26.

[34] Veterinary Feed Directive, 80 Fed. Reg. at 31,709.

[35] *See id.*

[36] *Fact Sheet*, *supra* note 28. A distributor is "any person who distributes a medicated feed containing a VFD drug to another person," narrowing the scope of who is defined as a distributor. 21 C.F.R. § 558(b)(9) (2019).

[37] Veterinary Feed Directive, 80 Fed. Reg. at 31,708–09.

[38] *Id.*

[39] *Id.* at 31,715.

[40] *Id.*

restrictions indicated with the prescription.[41] Veterinarians then issue three copies of the VFD—one for their own records, one for their client, and one to the client's VFD feed distributor.[42] Pursuant to C.F.R. § 558.6(a)(4) and (b)(8), the veterinarian is required to keep the original hardcopy or electronic copy of the VFD and the client and distributor must also retain a hardcopy or electronic copy of the VFD.[43]

The impact of the VFD's final rule, in addition to continuing increased oversight and regulation, is heavily burdensome to animal agriculture producers. The effects of the decision to change the status of many OTC drugs to the VFD category of drugs, as well as requiring duplicative compliance with both state and federal VCPR standards, has been disadvantageous in regard to livestock producers' preventative use of antibiotics administered through antibiotic feeds.[44] Along with establishing a consistent VCPR, producers must maintain a copy of the VFD order for at least two years and provide VFD orders at will for inspection and copying upon FDA request.[45] Furthermore, livestock producers can only use medicated feeds for therapeutic purposes.[46] This means that farmers can no longer go to a feed store and purchase antibiotic feed and or additive to supplement animal feed or drinking water for strictly preventative purposes in managing their herds.[47] In order for a veterinarian to prescribe antimicrobial medicated feeds, the farmer must establish a VCPR; whereas before the VFD, a farmer could treat according to their own knowledge and experience, the time elapsed in order to establish a VCPR results in the possibility of the animal affected by a pathogen posing a risk of an outbreak to the entire herd before it can be treated.[48] This makes production inefficient and expensive. It is concerning to consider that some producers may choose to altogether exit the cattle business—finding the economic concerns and

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[41] Interview with Ryan F. Quarles, Ky. Comm'r of Agric., in Frankfort, Kentucky (Sept. 16, 2018).

[42] 21 C.F.R. § 558.6(b)(8)–(9) (2019).

[43] 21 C.F.R. § 558.6(a)(4) (2019). "All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy." *Id.* "The veterinarian must send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client." *Id.* § 558.6(b)(8).

[44] Telephone Interview with Fred DeGraves, DVM, Ph.D., Assoc. Professor of Animal Sci. at W. Ky. Univ. (Sept. 14, 2018) [hereinafter DeGraves Interview]

[45] 21 C.F.R. § 558.6(b)(4)–(5).

[46] *Fact Sheet*, *supra* note 28.

[47] *See id.*

[48] DeGraves Interview, *supra* note 44.

overly burdensome regulations intolerable, such as establishing a VCPR and keeping up with the excessive amount of paperwork.[49]

It is a physiological reality that when we use more antibiotics, the more resistant we become—and we know this to be true in humans and animals.[50] The debate is still ongoing as to whether science and data can/will *definitively prove* a direct causal link between antibiotics used in animal-agriculture and resistance in human medicine.[51] The FDA recognizes that the VFD final rule and strategies are potentially burdensome and adjusting to the new policy poses challenges for livestock production.[52]

The FDA is "applying a risk-based approach" in order to "combat antimicrobial resistance and preserve the effectiveness of antimicrobial drugs."[53] These efforts include evaluating "new and currently approved antimicrobial products for animals, collaborating with key stakeholders to support stewardship of these products by end users, and collecting data on resistance and antimicrobial use to monitor the effectiveness of our actions to slow the development of resistance."[54]

As farmers are charged with feeding the world, the FDA continues to walk the tight rope and engage in a balancing act between adequate authorization of administering medically important antimicrobials in animal feed and drinking water while safeguarding both human and animal health.

The American agriculture industry has experienced an evolution in which science, education, and infrastructure developments have enabled American farmers to innovate as they raise their livestock for human consumption. Historically, and in general, barns used to be dilapidated with poor air quality and farmers had to use more antibiotics in order to maintain animal health.[55]

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[49] Telephone Interview with Warren Beeler, Ky. Exec. Dir. of the Governor's Office of Agric. Policy (Sept. 13, 2018) (discussing the regulation of agriculture) [hereinafter Beeler Interview].

[50] DeGraves Interview, *supra* note 44. *See also* Anthony E. van den Bogaard, *Epidemiology of Resistance to Antibiotics: Links Between Animals and Humans*, INT'L J. OF ANTIMICROBIAL AGENTS, May 2000, at 327, 327–28 (2000).

[51] DeGraves Interview, *supra* note 44. *See also* George G. Khachatourians, *Agricultural use of antibiotics and the evolution and transfer of antibiotic resistant bacteria,* CANANDIAN MEDICAL ASSOCIATION (Nov. 3, 1998), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1229782/pdf/cmaj_159_9_1129.pdf.

[52] *FDA Announces Implementation of GFI #213, Outlines Continuing Efforts to Address Antimicrobial Resistance*, U.S. FOOD AND DRUG ADMIN. (Jan. 3, 2017), https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-implementation-gfi-213-outlines-continuing-efforts-address-antimicrobial-resistance.

[53] *Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019–2023*, FDA Ctr. For Veterinary Med. 2 (Sept. 2018), https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf.

[54] *Id.*

[55] *See generally* Pipestone Veterinary Service, *Early Investment in Filtration Pays Dividends for Animal Health*, FARM J. PORK (May 9, 2019), https://www.porkbusiness.com/article/early-investment-

Today, barns are good quality, with secure, efficient, and sustainable structures that reduce animal stress and promote maximum genetic growth.[56] Farmers use fewer antibiotics because they are able to focus on pathogen elimination and herd health, instead of using medicinal alternatives.[57]

III. ANALYSIS

The United States is only one country seizing the opportunity to identify ways to combat antibiotic resistance through regulation of the animal agriculture industry. Gross Domestic Product (GDP) provides a useful basis for comparing other countries with regard to the importance of agriculture economics and agriculture-related standards.[58]

In the United States, agriculture, food, and related industries contributed $992 billion to its GDP in 2015.[59] America's farms contributed $136.7 billion of this sum—about one percent of the country's GDP.[60] By 2017, 21.6 million full and part-time jobs were related to the agricultural and food sectors.[61] In a typical American household, 12.9 percent of expenditures are spent on food, ranking third behind housing and transportation.[62]

In Germany, agriculture contributed 6.24 billion euros to the GDP in the third quarter of 2018.[63] In Canada, agriculture and agri-food systems generated $111.9 billion of the GDP and accounted for 6.7 percent of Canada's total GDP in 2016.[64] That year, the Canadian agriculture industry employed approximately 2.3 million people, representing 12.5 percent of Canadian employment.[65] In Australia, the agriculture industry

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filtration-pays-dividends-animal-health ("If we can prevent one new virus introduction, the installation and maintenance of filtration pays for itself and provides health and economic benefits at the sow farm and for farmers raising those pigs across the system").

[56] *See* Tracey Erickson, *Understanding and Mitigating Heat Stress in Young Dairy Animals*, S.D. ST. U. EXTENSION, https://extension.sdstate.edu/understanding-and-mitigating-heat-stress-young-dairy-animals (last updated July 3, 2019).

[57] Beeler Interview, *supra* note 49.

[58] *Ag and Food Sectors and the Economy*, U.S. DEP'T OF AGRIC. ECON. RES. SERV., https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy.aspx (last updated Aug. 20, 2019).

[59] *Id.*

[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] *Germany GDP From Agriculture*, TRADING ECON., https://tradingeconomics.com/germany/gdp-from-agriculture (last visited July 14, 2019).

[64] *An Overview of the Canadian Agriculture and Agri-Food System of 2017*, GOV'T OF CAN., http://www.agr.gc.ca/eng/about-us/publications/economic-publications/an-overview-of-the-canadian-agriculture-and-agri-food-system-2017/?id=1510326669269 (last modified Nov. 10, 2017).

[65] *Id.*

contributes three percent to Australia's total GDP.[66] A 2016–2017 study indicates that 304,200 people are directly employed in Australian agriculture.[67]

Prior to a comparative analysis of the regulations for the United States, Germany, Canada, and Australia, this Note will describe the nature of each country's current regulatory structure.

A. Policy, Procedure, and Regulatory Action

1. United States

As previously discussed,[68] in an effort to combat antibiotic resistance and ensure the wise use of antibiotics in food-producing animals, the FDA has approved a new class of drugs, known as "VFD" drugs, which must be prescribed by a licensed veterinarian.[69] Any animal feed containing a VFD drug "may be fed to livestock only by or upon a lawful VFD issued by a licensed veterinarian."[70] The producer must adhere to a specific sequence of dates allotted on the prescription for feeding a VFD drug to livestock, and must not feed past the expiration date of the prescription.[71] The use and labeling of a VFD drug in feed is limited to the "approved, conditionally approved, or indexed conditions of use."[72] Thus, any use not directed on its label is prohibited.[73] A copy of the VFD must be retained for two (2) years by the veterinarian, the distributor, and the client, which must be available for inspection upon request by any representative of the FDA.[74]

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[66] *Farm Facts*, NAT'L FARMERS' FED., https://www.nff.org.au/farm-facts.html (last visited Aug. 25, 2019).

[67] *Id.*

[68] *See supra* Part II.

[69] *See* 21 C.F.R. § 558.6(a) (2019) (listing the general requirements for Veterinary Feed Directive drugs).

[70] "Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian." § 558.6(a)(1).

[71] "A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD." § 558.6(a)(2).

[72] "Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use." § 558.6(a)(3).

[73] "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra label use) is not permitted." *Id.*

[74] "All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy." § 558.6(a)(4).

2. Germany

Germany seems to have efficient and effective reporting, policing, and accountability measures in place. Germany's central data reporting office provides detailed reports of the number of antibiotics used and the number of species treated.[75] The Federal Gazette reports this information to consumers, thereby creating transparency among producers and consumers and further reducing the effects of advertising and food campaigns attacking the agriculture industry.[76] Consumer information about particular species enables citizens to make educated decisions about eating choices.

Germany requires that if an individual farm exceeds the benchmark of frequency of use of antimicrobials, that farm must contact their veterinarians to discuss how to lower antibiotic usage, creating a plan to reduce the use of antibiotics.[77] The help of a licensed medical professional increases awareness about how a farmer can improve the overall health of their livestock, while remaining aware of antibiotic use during production.[78] Failure to comply with the plan or an executed order results in the loss of production privileges for a specified period.[79] Such sanctions encourage farmers to make a good faith effort to reduce the use of antibiotics and work to promote animal husbandry.[80]

"All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request." § 558.6(a)(5).

[75] *Antibiotics in Agriculture*, FED. MINISTRY OF FOOD AND AGRIC., https://www.bmel.de/EN/Animals/AnimalHealth/_Texte/Antibiotics-In-Agriculture.html.

[76] The Federal Gazette is a public news source issued by the Federal Ministry of Justice and Consumer Protection. BUNDESANZEIGER, https://www.bundesanzeiger.de/ebanzwww/wexsservlet?global_data.language=en (last visited Aug. 25, 2019).

[77] *See* Fed. Ministry of Health et al., *DART: German Antimicrobial Resistance Strategy* (Nov. 2008), https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Berichte/DART_-_German_Antimicrobial_Resistance_Strategy.pdf.

[78] *See id.*

[79] Gesetz über den Verkehr mit Arzneimitteln [Medicinal Products Act], Dec. 12, 2005, BGBL I at § 58d(4), *translation at* http://www.gesetze-im-internet.de/englisch_amg/ (Ger.) [hereinafter Medicinal Products Act].

[80] The Federal Ministry of Food and Agriculture is responsible for regulating, promoting, and developing policy for the agriculture and food industries in Germany. *See* FED. MINISTRY OF FOOD AND AGRIC., https://www.bmel.de/EN/Homepage/homepage_node.html (last visited Jan. 25, 2020). The Federal Ministry of Food and Agriculture translates to "Bundesministerium für Ernährung und Landwirtschaft" in German and is commonly abbreviated "BMEL." *See* Bundesministerium für Ernährung und Landwirtschaft, https://www.bmel.de/DE/Startseite/startseite_node.html (last visited Jan. 25, 2020). "The BMEL's approach to the [prudent] use of antibiotics is based on the following factors: [1)] An improvement of animal husbandry conditions, [2)] the tightening of rules in veterinary medicines legislation[,] and [3)] the promotion of alternatives to the use of antibiotics, e.g. within the scope of research. The Federal Ministry of Food and Agriculture (BMEL) will, by means of a package of targeted measures, better record the use of antibiotics in livestock husbandry and establish new rules for the use of

The German Medicinal Products Act (GMPA) regulates the use of antibiotics for both humans and food-producing animals.[81] The GMPA mandates the use of antibiotics in the treatment of diseased animals, but not as a growth promoter (the violation of which would result in a punishable offense).[82] Sections 58, 58a, and 58b of the GMPA contain the relevant legal provisions for antibiotics used in food producing animals.[83] In those relevant sections, the GMPA dictates that "animal keepers," or those who raise livestock (but are not licensed veterinarians), "may administer prescription-only medicinal products or other medicinal products prescribed by or purchased from a veterinarian to livestock."[84]

Medicinal products not subject to a prescription do not have to be administered on the basis of treatment instructions from a veterinarian and may be administered if they are authorized for marketing to the specific animal species and for the specified use on the label in a quantity corresponding to the label.[85] The Federal Ministry of Food and Agriculture has full authority to prohibit medicinal products intended for food-producing animals from being marketed for particular therapeutic purposes, as long as the drug is deemed necessary to prevent an indirect hazard to human health.[86]

Additionally, pursuant to section 58a, the GMPA requires the reporting of "animal keeping" in electronic or written form.[87] The statute provides that those who professionally or commercially raise or keep cattle, pigs, chickens, or turkeys must notify the "competent authority of the keeping of these animals no later than 14 days after commencement of keeping the animals, stating the name of the animal keeper, address of the livestock enterprise, and the particular species kept."[88] Realistically, this particular requirement is burdensome on the producer. Most farmers lack the time to complete copious amounts of paperwork while running a commercial livestock or poultry operation, which most days can be a sunup to sundown job.

Section 58b of the GMPA discusses the notification process for using "medicinal products containing antibacterially active substances."[89] The

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data. This is an important step towards more animal welfare and better animal health." *Antibiotics in Agriculture*, *supra* note 75.

[81] *See* Medicinal Products Act, *supra* note 79, §§ 58–58b.

[82] *Id.*

[83] *See Infra* notes 84–90 and accompanying text.

[84] Medicinal Products Act, *supra* note 79, § 58(1).

[85] *Id.*

[86] *Id.*

[87] *Id.* § 58b(1).

[88] *Id.* § 58a(1).

[89] *Id.* § 58b(1).

notification must contain 1) the name of the medicinal product used; 2) the number and species of the animals treated; 3) the number of days of treatment; and 4) the total amount of medicinal products containing antibacterially active substances that was used.[90]

Section 58c of the Medicinal Products Act deals with computing the frequency of treatment.[91] Using information provided in the notification and reporting requirement, the particular authority will multiply "the number of treated animals with the number of treatment days for each substance used and then adding together the resulting figures for all of the substances administered during the half-yearly period ..."[92] The authority then divides the figure resulting by "the average number of animals of the affected species that were kept during the half-yearly period (half-yearly treatment frequency in enterprises)."[93]

Section 58d describes the circumstances by which a reduction of treatment in use of antibacterially active substances may be ordered.[94] If the frequency of antibiotic use for a specific species is particularly high, or above the first parameter of the nationwide half yearly treatment frequency, the animal keeper must consult a veterinarian to determine why the first parameter was exceeded, and how the antibiotic treatment could be reduced.[95] If the frequency is above the second parameter of the nationwide half-yearly treatment frequency, the animal keeper must execute a written plan to reduce treatment with use of antibiotics based on veterinary advice.[96]

If the animal keeper does not comply with orders issued, the competent authority may order the suspension of animal husbandry in the animal keeper's operation for a specified period, up to a maximum of three years.[97]

3. Canada

Canada is developing legislation for antibiotic use in food-producing animals consistent with international standards and its trading partners.[98] Canada is focusing on adopting a balance between regulatory and non-

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[90] *Id.*

[91] *Id.* § 58c.

[92] *Id.* § 58c(1).

[93] *Id.* By the end of the second month of the semi-annual period following the notification, the competent authority must report to the Federal Office of Consumer Protection and Food Safety, which takes the information and conducts a risk assessment in the area of resistance to antibiotics. *Id.* at § 58c(2).

[94] *Id.* § 58d.

[95] *Id.* § 58d(2).

[96] *Id.*

[97] *Id.* § 58d(4).

[98] Food and Drug Regulations (Veterinary Drugs—Antimicrobial Resistance), SOR/2017–76 (Can.).

regulatory practices to provide risk management while reducing the degree of burden imposed upon farmers, veterinarians, and manufacturers.[99]

Statutorily, in its effort to promote the responsible use of medically important antimicrobials, Canada amended its Food and Drug Regulations Act effective December 1, 2018.[100] The amendments re-categorize certain drugs from over-the-counter status to requiring a prescription from a licensed veterinarian, mandate increased veterinary oversight, and prohibit the use of antibiotics for growth promotion — limiting the use of antibiotics to treating and preventing disease.[101]

These amendments also reduce the availability of inexpensive antimicrobials available to Canadian farmers.[102] Due to this regulation, the Canadian government is concerned that farmers will rely heavily on unauthorized drugs.[103] The legislative intent is that instead, farmers will replace certain antimicrobials having limited access with authorized drugs that their veterinarian deems safe and appropriate.[104] While the legislation does not restrict the use of unauthorized antimicrobials, one statutory amendment allows if upon "reasonable grounds" the Minister believes that a veterinary health product "may no longer be safe, the Minister may request that the manufacturer or importer of the veterinary health product provide the Minister, within 15 days after the day on which the request is received, with information and documents demonstrating that the veterinary health product is safe."[105]

Distributors of veterinary health products and antibiotic feeds considered as medically important antimicrobials must "submit . . . an annual report identifying for each drug, the total quantity sold or compounded and an estimate of the quantity sold or compounded for each intended animal species."[106] The data reported must be electronically submitted within thirty days.[107] Any changes to the notification must also be reported "at least 30

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[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] Food and Drug Regulations, C.R.C., c. 870 at C.01.616 (Can.).

[106] *Id.* at C.01.612(1).

[107] *Id.* at C.01.615(1). The notification must contain: 1) "the name, mailing address, telephone number and email address of the manufacturer or importer;" 2) "the brand name under which the veterinary health product is sold;" 3) "the pharmaceutical form in which the veterinary health product is sold;" 4) "the strength per dosage unit;" 5) "the route of administration;" 6) "a quantitative list of the medicinal ingredients and a qualitative list of the non-medicinal ingredients;" 7) "the species of animal for which the veterinary health product is recommended;" and 8) "the use or purpose for which the veterinary health product is recommended." *Id.* at C.01.615(2).

days before the day on which the veterinary health product to which the changes relate is sold."[108]

4. Australia

In 2015, Australia's government created its first National Antimicrobial Resistance Strategy, which continues through 2019.[109] This strategy calls to action the collective views of involved stakeholders in animal and human health as well as the food and agriculture sectors.[110] Focused on implementing appropriate usage of antibiotics in both veterinary and human medicine, the strategy supports global efforts to reduce antimicrobial resistance.[111] Australia is still developing the most efficient approach to improve data collection of antibiotic use and sales.[112]

The Australian Government Department of Agriculture and Water Resources has also emphasized the importance of education by funding and collaborating with Veterinary Schools of Australia and New Zealand to develop further curriculum focused on stewardship of antimicrobials in veterinary medicine.[113] In 2017, Australia released a progress report to discuss how the strategy's implementation plan is working — noting achievements as well as areas for growth.[114] According to the progress report released,

> [s]ignificant progress has been made over the last few years. However, there is still a long way to go. We must continue to identify and fill gaps, test and refine existing systems, and frequently review what works to ensure that optimal arrangements are in place to ensure antimicrobials are preserved for future treatments.[115]

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[108] *Id.* at C.01.615(3).

[109] DEP'T OF HEALTH ET AL., RESPONDING TO THE THREAT OF ANTIMICROBIAL RESISTANCE: AUSTRALIA'S FIRST NATIONAL ANTIMICROBIAL RESISTANCE STRATEGY 2015-2019 (2015), http://www.agriculture.gov.au/SiteCollectionDocuments/animal-plant/animal-health/amr/responding-threat-antimicrobial-resistance.pdf.

[110] Hon. Sussan Ley MP & Hon. Barnaby Joyce MP, *foreword* to DEP'T OF HEALTH ET AL., *supra* note 109, at iii-iv.

[111] *Id.*

[112] DEP'T OF HEALTH ET AL., *supra* note 109, at 16–19.

[113] DEP'T OF HEALTH ET AL., AUSTRALIA'S FIRST NATIONAL ANTIMICROBIAL RESISTANCE STRATEGY 2015–2019: PROGRESS REPORT 5 (2017), https://www.amr.gov.au/resources/australias-first-national-antimicrobial-resistance-strategy-2015-2019-progress-report [hereinafter PROGRESS REPORT].

[114] *Id.* at 3.

[115] Brendan Murphy & Mark Schipp, *foreword* to PROGRESS REPORT, *supra* note 113, at 2

In addition, the Australian government has outlined three levels of control for the introduction of new veterinary chemical products that contain antibiotics and are used in livestock: customs control at the point of entry, required registration with the Australian Pesticides and Veterinary Medicines Authority, and control-of-use legislation in each of the Australian states and territories.[116] First, because no antibiotics are manufactured in Australia, national governmental customs officials control antibiotic import at the point of entry.[117] Second, all antimicrobials for use in food producing animals must be registered with and approved by the Australian Pesticides and Veterinary Medicines Authority.[118] In registering, an application must be submitted along with a "qualitative risk assessment" addressing "possible contribution of the proposed use pattern to antibiotic resistance."[119] Furthermore, a risk profile is used to determine hazard characterization, exposure characterization, impact characterization, and risk characterization. The profile also assesses the uncertainty of the data used in the risk assessment, along with the benefits of use of the antibiotic in Australian animal health.[120] Third, pursuant to the control-of-use legislation is the implementation of removing the use of antibiotics that are medically important in human medicine in food producing animals as growth promoting aids.[121] This legislation is regulated by the states.[122]

By placing several roadblocks in the way of introducing a new veterinary drug to be used in food-producing animals, these three levels seem to work together in order to reduce the unnecessary additional antimicrobial residue contributed by the Australian agriculture industry.

B. Comparative Analysis of the Countries' Practices

Each of the above referenced countries seeks to reduce the use of antibiotics that are medically important to human medicine in animal agriculture production. The primary motivation for the increased regulation is the notion that antibiotic resistance in humans is caused by antibiotic use

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[116] *Antibiotic Resistance*, AUSTL. GOV'T PESTICIDES AND VETERINARY MEDS. AUTHORITY, https://apvma.gov.au/node/1013 (last updated July 1, 2014).

[117] RAMON Z. SHABAN ET AL., SURVEILLANCE AND REPORTING OF ANTIMICROBIAL RESISTANCE AND ANTIBIOTIC USAGE IN ANIMALS AND AGRICULTURE IN AUSTRALIA 43 (2017).

[118] *Antibiotic Resistance*, *supra* note 116.

[119] *Id.*

[120] *Id.*

[121] *Id.* The only growth-promoting antibiotics still registered in Australia are ionophores, kitasamycin, flavophospholipol, avilamycin and roxarsone. *See* Interview with Robert Stout, *supra* note 9.

[122] *Antibiotic Resistance*, *supra* note 116.

in animals that we eat.[123] However, there is little scientific data to validate this theory.[124] Additionally, each country has prohibited the use of antibiotics as a growth promoter because speeding up the growth of the herd is achievable through best management practices and animal husbandry on the farm.[125] Finally, each country seems to support increased veterinary oversight as an important part of antimicrobial stewardship.[126] Veterinarians have the medical knowledge and training to assess and diagnose animal disease, and are in the best position to determine whether antimicrobial drugs are necessary to prescribe according to the appropriate use and duration.

Germany's Medicinal Products Act puts forth the most detailed plan to promote the goal of animal husbandry and the judicious use of antibiotics. While its regulations and sanctions may seem overly excessive and burdensome, the governing statute makes clear how they oversee the issue, provide information to consumers, and work to create a positive relationship between producers and veterinarians. Unlike the other countries, Germany has found ways to use effective measures to hold producers accountable for their livestock's antibiotic use, i.e., if a producer exceeds the frequency of use, that producer must create a plan implementing best management practices, in conjunction with a veterinarian's expertise, to reduce the amount of antimicrobial active substances or forfeit the privilege of raising livestock.[127]

By contrast, the United States lacks clearly defined police powers and accountability measures. The FDA could show up at a livestock farmer's door to request a records inspection.[128] United States regulations also fail to provide constructive interactions among producers and veterinarians to prepare a contingency plan if antibiotic use becomes excessive.

Germany educates consumers by publishing information in the Federal Gazette about species-specific antibiotic use.[129] By contrast, the United States allows food-marketing schemes that take advantage of ill-informed consumers instead of educating them about the origins of its food as well as the transportation processes delivering it to market.[130] For instance, popular

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[123] Chang et al., *supra* note 7.

[124] *Id.*

[125] Ben Stockton, *Antibiotic Use Plummets on U.S. Farms After Ban on Using Drugs to Make Livestock Grow Faster*, BUREAU OF INVESTIGATIVE JOURNALISM (Dec. 19, 2018), https://www.thebureauinvestigates.com/stories/2018-12-19/antibiotic-use-falls-on-us-farms-after-ban-on-using-drugs-to-make-livestock-grow-faster.

[126] *See supra* Part III(A).

[127] *See Antibiotics in Agriculture*, *supra* note 75.

[128] 21 C.F.R. § 558.6(a)(5) (2019).

[129] *See* Bundesanzeiger, *supra* note 76.

[130] *See* Council for Agric. Sci. and Tech., *Impact of Free-Range Poultry Production Systems on*

Mexican restaurant, Chipotle, frequently capitalizes on incendiary propaganda aimed at attacking the commercial agriculture industry.[131] Chipotle endorses that their food has "integrity" with "pork from pigs allowed to freely root and roam outdoors or in deeply bedded barns."[132] Consumers assume that "free range" livestock is somehow better for the animal,[133] but what they don't realize is that, in pigs, being on a concrete floor is better for increasing hygiene and mobility.[134] Being exposed to the outdoor elements at all times leaves the animal vulnerable to diseases that could lead to foot rot and lameness in their structure—inhibiting their immune system and their muscle production.[135]

While the U.S. system blames the animal agriculture industry for human health degradation, German regulations are fact-based, mostly agriculture friendly, veterinarian friendly, and consumer friendly.

United States and Canadian regulations are similar with both countries re-categorizing specific drugs in order to differentiate farmers' access through over the counter or prescription from a licensed veterinarian due to the antibiotics' medical significance or importance in humans.[136] These regulations appear to be pro-consumer. However, if the Canadian government is concerned with farmers' use of unauthorized drugs due to antimicrobial restrictions, then it should eliminate all unauthorized farm uses of unauthorized drugs.[137] Canada has foreseen, from a practical standpoint,

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Animal Health, Human Health, Productivity, Environment, Food Safety, and Animal Welfare Issues, CAST Issue Paper 61 (July 2018), *available at* https://www.cast-science.org/wp-content/uploads/2018/12/CAST_IP61_Freerange_Poultry_7ED476A8DE169.pdf.

[131] *Our Values*, CHIPOTLE MEXICAN GRILL, https://www.chipotle.com/values (last visited Aug. 25, 2019).

[132] *Id.*

[133] *See generally* Rebecca Nicholson, *What Does 'Free-Range' Actually Mean? It's Complicated*, GUARDIAN: FOOD (Feb. 28, 2017), https://www.theguardian.com/lifeandstyle/shortcuts/2017/feb/28/what-does-free-range-actually-mean-its-complicated.

[134] *See* Cheryl Day, *Footing Starts on the Floor*, NAT'L HOG FARMER (Mar. 23, 2016), https://www.nationalhogfarmer.com/facilities/footing-starts-floor. Slats, the flooring mentioned in the Day article, are built from a concrete and metal combination. *Flooring*, HOG SLAT, https://www.hogslat.com/hog-slats-trideck-poly-swine-flooring (last visited Aug. 25, 2019).

[135] *See* John Campbell, *Foot Rot Only One Cause of Lameness in Cattle*, WESTERN PRODUCER (Jun. 4, 2015), https://www.producer.com/2015/06/foot-rot-only-one-cause-of-lameness-in-cattle/ (while this article specifically discusses cattle, lameness and foot rot are conditions that affect other livestock, such as pigs); *see also Lameness*, PIG PROGRESS, https://www.pigprogress.net/Health/Health-Tool/diseases/Lameness/ (last visited Aug. 25, 2019).

[136] *Compare supra* Parts III(A)(1) and III(A)(3) *with* Parts III(A)(2) and III(A)(4).

[137] *See generally* PUB. HEALTH AGENCY OF CAN., FEDERAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE AND USE IN CANADA: BUILDING ON THE FEDERAL FRAMEWORK FOR ACTION (2015), http://healthycanadians.gc.ca/alt/pdf/publications/drugs-products-medicaments-produits/antibiotic-resistance-antibiotique/action-plan-daction-eng.pdf.

that it would be difficult to convince livestock producers to avoid veterinary products that have historically worked well on their operation and are readily accessible on the market in other jurisdictions. Producers may fail to recognize the harm in the continued use of these products in Canada and accept the associated risks of using the unauthorized products. The United States could adopt the Canadian balance of regulatory and non-regulatory techniques to reduce antibiotic use in food-producing animals. Like Canada, U.S. animal husbandry and the judicious use of antibiotics can be realized by involving the necessary stakeholders through less burdensome, non-regulatory means.

Australia's focus seems to be on the individual producer — determining the risk she poses and her contribution to the overall antibiotic usage in the country. Australia's government will eventually mandate statutory policy with regard to judicious antibiotic use, although "trial and error" data collected from the 2015–2019 Strategy and Implementation Plan focusing on reducing antimicrobial use will facilitate specific policy to serve all involved stakeholders.[138] The Strategy itself is in a transition period, which typically signals that the nature of the statutory changes will be dramatic. Australia seems to be working through the logistical and practical changes through this implementation plan period.

Further, with regard to the introduction of new animal drugs, an area in which Australia has enacted policy, the level of specificity in the risk assessment data is needed in the United States. The data would enable federal agencies and local legislatures to address antibiotic usage where it is needed—specially targeting veterinary school programs and emphasizing the need for decreasing antimicrobial usage in food-producing animals. Of utmost importance, Australia's focus on both human and animal health combats the inappropriate use of prescribing, dispensing, and administering antibiotics as a whole and not just in livestock.

1. Benefits and Burdens

Increased veterinary oversight of the amount, type, and use of antibiotics is a positive outcome of all legislation involving antibiotics used in food-producing animals.[139] Like other professional programs, veterinarians complete a 4-year degree—learning and studying how to care for large and

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[138] DEP'T OF HEALTH ET AL., *supra* note 109, at 7.

[139] Karin Hoelzer, *Veterinarians Should Oversee All Antibiotic Use in Food Animals*, PEW CHARITABLE TRS. (Aug. 21, 2019), https://www.pewtrusts.org/en/research-and-analysis/articles/2019/08/21/veterinarians-should-oversee-all-antibiotic-use-in-food-animals.

small animals. Just as a lawyer is in the best position, with requisite skill and knowledge, to litigate a client's position in the courtroom, veterinarians are in the best position, possessing the requisite skill and knowledge to care for an ill animal.

However, requiring establishment of a VCPR creates both a time and financial concern for American farmers. Farmers have to take time away from production to have a veterinarian visit the farm as well as pay for the veterinarian's visit.[140] Additionally, the costs associated with the manufacturer in changing labels of drugs get passed down the line to the producer.[141] In other words, the producer ends up paying an inflated cost for a medicated feed due to the cost of newly regulated and changed labels. Further, veterinarians will have to charge for their time in establishing a VCPR and to issue the VFD. In sum, as costs increase for veterinarians and manufacturers of antibiotics, that cost gets shifted to the producer.

Another problem with the U.S. policy is the restricted use description as stated on the antibiotic label by the manufacturer. The use stated by the manufacturer, and regulated by the FDA, is the only authorized reason producers can administer the drug. As an example, historically, a very common practice was the usage of Chlortetracycline (CTC) in combination with a mineral mix, especially in the summer months, as a preventative for pink eye in livestock.[142] While this has always been a sensible use of CTC, fitting the parameters for disease treatment and control, this use is prohibited by the FDA because CTC's label does not expressly enumerate its use for preventing pink eye.[143] This is only one example of the potentially harmful ramifications of the FDA's VFD regulations.

The expiration date for usage also needs to be addressed in the U.S. There is no feasible or efficient way for the FDA to monitor the exact duration of use of a VFD drug because VFD prescriptions are proper for use for approximately 6 months and the producer can use the VFD at any time within those 6 months for a maximum of 21 days at a time.[144] Because bees are considered food-producing animals, they too are subject to regulation in the

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[140] Virginia A. Ishler, *Don't Skimp on Health Costs*, PENN ST. EXTENSION, https://extension.psu.edu/dont-skimp-on-health-costs (last updated Apr. 15, 2016) ("[T]he average cost per cow for vet and medicine is $108 with a range from $88 to $126/cow.").

[141] *See generally* Avik Roy, *Drug Companies, Not "Middlemen," Are Responsible For High Drug Prices*, FORBES (Oct. 22, 2018), https://www.forbes.com/sites/theapothecary/2018/10/22/drug-companies-are-responsible-for-high-drug-prices-not-middlemen/#1e11d6814947.

[142] *See Candid Conversations*, *supra* note 9.

[143] *See* Dee Griffin, *How the FDA May Differentiate Antibiotic Uses (of CTC) for Pinkeye and Foot Rot*, PROGRESSIVE CATTLE (July 25, 2016), https://www.progressivecattle.com/topics/herd-health/how-the-fda-may-differentiate-antibiotic-uses-of-ctc-for-pinkeye-and-foot-rot.

[144] *See Candid Conversations*, *supra* note 9.

United States. However, generally, veterinarians have limited knowledge regarding bees, yet they are listed as the person who would have to sign off on the use of a VFD in beekeeping production.[145] The FDA should defer to the state apiarist.

Taken as a whole, it is in a farmer's best interest to care for their animals and practice animal welfare. After all, a farmer's livelihood is based on the quality of the animals they produce. Antibiotic feeds are expensive. Farmers only want to use the minimum amount of antibiotics necessary. Furthermore, many common misconceptions about farmers in the industry could easily be eliminated through increased agriculture education.

IV. RESOLUTION

This portion of the Note is a proposed amendment to the Veterinary Feed Directive for the United States Code of Federal Regulations. The amendment will reduce the number of antibiotics used in animal feed, while still considering the important role the American farmer plays — putting the food on our tables.

A. Proposed Amendment to The Federal Veterinary Feed Directive

PURPOSE: To hold accountable and defer to agriculture producers of food-producing animals and to reduce the use of antibiotics in food-producing animals through continued increased veterinary and state department of agriculture oversight and continued limitation of non-therapeutic uses of antibiotics, along with increased consumer agriculture education.

(a) Each state must create VCPR requirements that comply with the national VCPR standards as determined by United States Department of Agriculture personnel. This will ensure that each state is working to tailor VCPR regulations to the particular geographic area. Once an approved VCPR has been established between the veterinarian and the producer, the veterinarian no longer needs to be on site at the farm when prescribing or

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[145] *See* Veterinary Feed Directive, 80 Fed. Reg. 31,707, 31,709 (Jun. 3, 2015). *See also Honey Bees 101 for Veterinarians*, AM. VETERINARY MED. ASS'N., https://www.avma.org/KB/Resources/Pages/Honey-Bees-101-Veterinarians.aspx (last visited Aug. 25, 2016) ("Until the federal government's Veterinary Feed Directive (VFD) final rule was issued, most veterinarians in the United States had little to no reason to be concerned about apiculture (beekeeping) and honey bee medicine. Honeybees now fall into veterinarians' purview, though, because of the VFD rule and changes in FDA policy on medically important antimicrobials.").

administering an antibiotic. This will help cut farm visit costs for the producer;

(b) The FDA must set a yearly benchmark for VFD drug use according to the number of head on a particular farm production operation. This will hold all parties accountable to reducing the use of antibiotics on the farm;

(c) Every year on December 1, large, food producing animal veterinarians must report to the state Agriculture Department the itemized frequency of the number and species of VFD drugs prescribed. The state Agriculture Department must then release the numbers to the public by species so that there will be transparency among producers and consumers by February 1. The state agriculture department must be the competent authority working with producers. The state departments of agriculture are the advocates for agriculture. The state agriculture departments will then report data findings to the FDA;

(d) If a producer exceeds the stated number of permitted antibiotic use on their farm, the producer must work with its veterinarian in developing a plan to reduce the use of antibiotics on the farm through efficient management practices promoting herd health;

(e) Antibiotic use in bees will be under the purview of the State Apiarist;

(f) Small animal veterinarians must report the number of antibiotics prescribed yearly to dogs and cats; and

(g) All publicly funded and charter high schools must have an agriculture education program in which each student must, at minimum, take and pass an introductory agriculture course incorporating state-approved curriculum covering animal science, horticulture, and crop production.

B. Commentary in Support of Proposed Amendment's Statutory Language

As with most statutory proposals, a commentary follows to accompany the foregoing proposed Amendments to the Federal Veterinary Feed Directive. It is important that VCPR regulations are state appropriate for the

type of agriculture production occurring there. No two states are the same.[146] Farming practices should be tailored to the diversified and individualized production schemes of the geographic region. For example, in Kentucky, there may be three available large animal veterinarians in a thirty-mile radius, whereas in Texas or Iowa, a farmer has multiple large animal veterinarian specialists to choose from.[147] The VCPR guidelines should reflect this difference.

The only way to determine whether a particular threshold of antibiotic use has been met is accurate record keeping and data collection from both the veterinarian and the producer. That information enables the state department of agriculture to evaluate which species, geographic areas, and veterinarians need to improve medicinal product usage in the field. Practically speaking, record-keeping on a small scale and large-scale farm differ, but all veterinarians should be held to the same standard and accountability for prescribing only what is necessary on the particular farm. The mutuality of both veterinarians and producers working together should result in optimal implementation of fewer antibiotic usage on farms.

Small animal veterinarians should be regulated even though consumers do not eat the domesticated animals they treat. If large animals that we eat are "contributing" to antibiotic resistance, perhaps so are the domesticated animals in which we pet, sleep with, and that are in our homes each day.

Today, systematic marketing, such as "Non-GMO," "Antibiotic-Free," and "Free-Range," have created fear and distrust of the American farmer by the American consumer.[148] People believe what they see on summary labels without knowing the facts. For example, a package of meat might say "antibiotic-free" but the reality is that no producer injects antibiotics into the part of the animal in which consumers eat. In cattle, the antibiotic is injected into the neck; U.S. consumers rarely eat the neck.[149] Further, producers wait to slaughter the animal until a period after the antibiotic has been injected in order to ensure that the antibiotic is no longer active in the bloodstream of

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[146] *See Veterinary Services Shortage Situations*, U.S. DEP'T OF AGRIC., https://nifa.usda.gov/vmlrp-map (last visited Aug. 25, 2019).

[147] *Compare Veterinary Services Shortage Situations: Kentucky*, U.S. DEP'T OF AGRIC., https://nifa.usda.gov/vmlrp-map?state=530 (last visited Aug. 25, 2019), *with Veterinary Services Shortage Situations: Texas*, U.S. DEP'T OF AGRIC., https://nifa.usda.gov/vmlrp-map?state=222 (last visited Aug. 25, 2019) *and Veterinary Services Shortage Situations: Iowa*, U.S. DEP'T OF AGRIC., https://nifa.usda.gov/vmlrp-map?state=287 (last visited Aug. 25, 2019).

[148] *See* Cary Funk & Brian Kennedy, *The New Food Fights: U.S. Public Divides Over Food Science*, PEW RES. CTR. 9 (Dec. 1, 2016), https://www.pewinternet.org/wp-content/uploads/sites/9/2016/11/PS_2016.12.01_Food-Science_FINAL.pdf.

[149] NATIONAL DAIRY HERD INFORMATION ASSOCIATION, DAIRY ANIMAL CARE QUALITY ASSURANCE 30, https://www.bqa.org/Media/BQA/Docs/dairybqamanual.pdf.

the animal.[150] Agriculture education is key. It is also important that the FDA hold human-treating physicians and pediatricians accountable for their contribution to antibiotic resistance – keeping better records of the antibiotic usage by frequency of prescription, age groups, and specific types of illnesses treated.

V. CONCLUSION

Our Founders knew that agriculture was an industry critical to the growth and survival of the young nation.[151] An important means to realizing long-term goals was not only to support food producers but also to hold them accountable. To remain a nation with high quality food at reasonably affordable prices, American farmers need broad national support. In a global market structure, the agricultural community does not need a regulatory structure that burdens rather than encourages innovation, or that penalizes efficiency instead of rewarding it. The proposed amendment to the Federal Veterinary Feed Directive works to report, police, and encourage the reduction of antibiotic use on farms by promoting herd health, as well as increased education and awareness so that consumer confidence in the animal food production industry remains high.

The practice of herd health management on the farm is a valuable and realistic technique that lessens and even eliminates the need to use antibiotics as a preventative aid. Farmers' consistent observation of the environmental conditions of the herd allows them to make timely and informed decisions regarding the optimal welfare of the livestock.

Educated consumers must take a more active role by participating in the food production process, providing constructive fact-based feedback about the quality of domestic food production. Doctors, pediatricians, and nurse practitioners also must actively join the antibiotic resistance discussion. Finally, attorneys and legislators can contribute to a regulatory process that ensures the wise use of antibiotics on the farm—one that does not serve as a

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[150] *The Facts About Antibiotics in Livestock & Poultry Production*, N. AM. MEAT INST. 8, https://www.meatinstitute.org/index.php?ht=a/GetDocumentAction/i/99943 (last visited Aug. 25, 2019) ("Whenever an antibiotic is given to a food animal, a strict waiting or 'withdrawal' period is required before that animal can be processed into meat or poultry. USDA's Food Safety and Inspection Service (FSIS) conducts a monitoring program to ensure that antibiotics are effectively eliminated from animals' systems and that no unsafe residues are detected in meat and poultry.").

[151] "Agriculture . . . is our wisest pursuit, because it will in the end contribute most to real wealth, good morals, and happiness." Letter from Thomas Jefferson to George Washington (Aug. 14, 1787), *available at* https://founders.archives.gov/documents/Jefferson/01-12-02-0040.

regulatory weapon against the American farmer, but instead enhances a flourishing animal production industry.

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