

Fresh from the Farm: Regulating Concentrated Animal Feeding Operations for Antibiotic Abuse in Tennessee

ELIZABETH B. STAGICH*

I. INTRODUCTION.....	282
II. BACKGROUND	286
A. <i>Evolution of Factory Farming</i>	286
B. <i>Costs to Society</i>	288
1. Air, Water, and Soil Pollution.....	289
2. Spread of Pathogens and Community Health Effects	290
3. Antibiotic Resistance.....	292
4. Animal Welfare Concerns.....	296
III. FEDERAL EFFORTS TO REGULATE ANTIMICROBIAL USE IN LIVESTOCK.....	298
A. <i>FDA Regulations</i>	299
B. <i>FDA Guidance for the Industry</i>	301
C. <i>Executive Order 13,676</i>	306
IV. NEW CONSUMER TRENDS AND LEGISLATION	308
A. <i>U.S. Market for Antimicrobial Drugs</i>	309
B. <i>California Senate Bill No. 27</i>	310
C. <i>Proposed Tennessee Livestock Antimicrobial Law</i>	316
V. CONCLUSION	322

* Juris Doctor Candidate, 2018, The University of Memphis Cecil C. Humphreys School of Law; Notes Editor, *The University of Memphis Law Review*, Vol. 48. I would like to thank Professor Ralph Brashier, George Scoville, Jimmy Peters, and Connor Dugosh for helping me edit this Note.

I. INTRODUCTION

Antibiotics are an essential tool in medical practice. Ever since they first entered the market nearly 70 years ago, antibiotics have drastically improved the treatment of bacterial infections.¹ But imagine living in a world in which antibiotic medicines stopped working. According to Dr. James Johnson, a professor specializing in infectious diseases medicine at the University of Minnesota, “[i]t’s already happening.”² The presence of antibiotic-resistant bacteria, or “superbugs,” is a growing issue in the United States, and modern agricultural practices are causing it in part.

Americans scrutinize agricultural practices more than they did 30 years ago, more actively monitoring the source of their food products.³ Every producer in the food industry, including chefs, restaurant owners, and large food corporations, wants to reassure their customers that foods they purchase are safe.⁴ Today, “factory

1. Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 152 (2d Cir. 2014). For more reading on the history and evolution of antibiotic drugs, see Rustam I. Aminov, *A Brief History of the Antibiotic Era: Lessons Learned and Challenges for the Future*, FRONTIERS IN MICROBIOLOGY, Dec. 2010, at 2–3.

2. Susan Brink, *A Superbug That Resisted 26 Antibiotics*, NAT’L PUB. RADIO (Jan. 17, 2017, 3:01 PM), <http://www.npr.org/sections/goatsandsoda/2017/01/17/510227493/a-superbug-that-resisted-26-antibiotics>. In a news report on the death of a 70-year-old Nevada woman who died from an incurable bacterial infection, Dr. Johnson commented that none of the twenty-six antibiotics available in the United States could treat her. *See id.*

3. *See, e.g.*, AM. VETERINARY MED. ASS’N, RESPONSIBLE USE OF ANTIBIOTICS IN U.S. ANIMAL AGRICULTURE 1 (2015) (“[E]veryone wants to ensure that not only is the food they are buying safe to eat, but that it will not adversely impact their next check-up at the doctor’s office.”).

4. *Id.* In 2014, a survey of grocery shoppers found that “88% [were] aware of antibiotic use in animals and 60% [were] concerned about it.” David Kesmodel, *Meat Companies Go Antibiotics-Free as More Consumers Demand It*, WALL ST. J. (Nov. 3, 2014), <https://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802>. *See also* SASHA STASHWICK ET AL., CHAIN REACTION II: HOW TOP RESTAURANTS RATE ON REDUCING USE OF ANTIBIOTICS IN THEIR MEAT SUPPLY 14 (Sept. 2016) (“Consumer demand for chicken, turkey, pork, and beef raised without the routine use of antibiotics is growing fast. Motivated by personal health, environmental impacts, animal welfare, taste, and quality concerns, today’s consumers are savvy and increasingly seeking alternatives

farms”—also known as animal feeding operations (“AFOs”)⁵ or concentrated animal feeding operations (“CAFOs”)⁶—raise a majority of America’s commercial livestock in under-ventilated, over-crowded, and sordid conditions.⁷ The Environmental Protection Agency (“EPA”) defines an AFO as follows:

[A] lot or facility . . . where . . . [a]nimals (other than aquatic animals) have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period, and [where] [c]rops, vegetation, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility.⁸

The EPA and state environmental agencies further classify AFOs into one of three sizes based on the number of livestock in each facility:

to conventional meat products, which are typically produced with the regular, ongoing use of antibiotics.”).

5. See, e.g., *Animal Feeding Operations*, USDA, <https://www.nrcs.usda.gov/wps/portal/nrcs/main/national/plantsanimals/livestock/af> o/ (last visited Oct. 25, 2017) (describing AFOs).

6. *Id.* (describing CAFOs).

7. *Farm Animals Need Our Help*, AM. SOC’Y FOR THE PREVENTION OF CRUELTY TO ANIMALS, <http://www.aspca.org/animal-cruelty/farm-animal-welfare> (last visited Oct. 25, 2017) (“Over 99% of farm animals in the U.S. are raised in factory farms, which focus on profit and efficiency at the expense of animal welfare.”).

8. 40 C.F.R. § 122.23(b)(1) (2012). See also *Animal Feeding Operation FAQ*, TENN. DEP’T OF AGRIC., <https://www.tn.gov/agriculture/article/ag-farms-cafo-faq> (last visited Oct. 25, 2017) (providing the Tennessee Department of Environment and Conservation’s definition of AFOs).

large,⁹ medium,¹⁰ and small.¹¹ A CAFO is an AFO that meets the size requirements of a medium CAFO or a large CAFO.¹² The EPA and state environmental agencies regulate CAFOs as “point sources”¹³ of water pollution under the Clean Water Act.¹⁴ The CAFO model of livestock production keeps the price of meat, egg, and dairy products relatively cheap¹⁵ and price-conscious consumers happy, but the

9. 40 C.F.R. § 122.23(b)(4) (2017) (“An AFO is defined as a Large CAFO if it stables or confines as many as or more than the numbers of animals specified in any of the following categories: (i) 700 mature dairy cows, whether milked or dry; (ii) 1,000 veal calves; (iii) 1,000 cattle other than mature dairy cows or veal calves . . . ; (iv) 2,500 swine each weighing 55 pounds or more; (v) 10,000 swine each weighing less than 55 pounds; . . . (viii) 55,000 turkeys; (ix) 30,000 laying hens or broilers, if the AFO uses a liquid manure handling system; [or] (x) 125,000 chickens (other than laying hens), if the AFO uses [anything] other than a liquid manure handling system . . .”).

10. 40 C.F.R. § 122.23(b)(6) (2017) (“The term Medium CAFO includes any AFO with the type and number of animals that fall within any of the ranges listed [below] . . . and which has been defined or designated as a CAFO. . . . The type and number of animals that it stables or confines falls within any of the following ranges: (A) 200 to 699 mature dairy cows . . . ; (C) 300 to 999 cattle other than mature dairy cows or veal calves . . . ; (D) 750 to 2,499 swine each weighing 55 pounds or more; (E) 3,000 to 9,999 swine each weighing less than 55 pounds; . . . ; (H) 16,500 to 54,999 turkeys; (I) 9,000 to 29,999 laying hens or broilers, if the AFO uses a liquid manure handling system; [or] (J) 37,500 to 124,999 chickens (other than laying hens), if the AFO uses other than a liquid manure handling system . . .”).

11. A small CAFO is defined as “[a]n AFO that is designated as a CAFO and is not a Medium CAFO.” 40 C.F.R. § 122.23(b)(9) (2017).

12. See 40 C.F.R. § 122.23(b)(2) (2017).

13. A point source is “any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, *concentrated animal feeding operation* . . . from which pollutants are or may be discharged.” 33 U.S.C. § 1362(14) (2012) (emphasis added).

14. See 40 C.F.R. § 122.23(a) (2017). See also TETRA TECH, INC., STATE COMPENDIUM: PROGRAMS AND REGULATORY ACTIVITIES RELATED TO ANIMAL FEEDING OPERATIONS 3–4 (2002) (providing a national overview of state AFO regulatory programs in a report prepared for the EPA).

15. See, e.g., Nathalie Prescott, Note, *Antibiotics: It’s What’s for Dinner*, 28 GEO. ENVTL. L. REV. 307, 308 (2016) (citing JAMES M. MACDONALD & WILLIAM D. MCBRIDE, U.S. DEP’T OF AGRIC., THE TRANSFORMATION OF U.S. LIVESTOCK AGRICULTURE: SCALE, EFFICIENCY, AND RISKS 20 (2009)) (“AFOs . . . provide a source of low-cost meat due to subsidies, efficiencies [in production], and economies of scale.”).

operation of CAFOs creates numerous societal costs, including threats to food safety and human health in addition to environmental pollution that individual states and the EPA regulate.

One need not live in a rural community to experience the harmful health effects of factory farming. For instance, studies show a link between the development of antibiotic-resistant bacteria in humans and egregious nontherapeutic use¹⁶ of antimicrobial medicines in livestock operations.¹⁷ To be clear, “antibiotics” are a class of drugs that narrowly target and kill bacteria, while “antimicrobials” effectively kill bacteria *and* other microorganisms such as fungi, protozoa, viruses, and some fungi and algae.¹⁸ Antibiotic resistance is thus a serious public health threat. Neither Congress nor the Executive Branch, however, has taken sufficient legal action against the livestock industry’s prodigious contribution to the spread of drug-resistant superbugs. On the other hand, the federal government’s failure creates an opportunity for states to implement tougher laws and regulations on livestock producers. California, for example, recently passed a new law that precludes wasteful uses of medically important antimicrobials in livestock production.¹⁹

This Note advocates that the State of Tennessee should act now to confront the issue of antibiotic resistance by adopting a modified

16. “Nontherapeutic uses mean that an entire herd or flock of animals receives small doses [of medication] for an extended period [of time].” FOOD & WATER WATCH, ANTIBIOTIC RESISTANCE 101: HOW ANTIBIOTIC MISUSE ON FACTORY FARMS CAN MAKE YOU SICK 5 (2015) [hereinafter RESISTANCE 101], <https://www.foodandwaterwatch.org/sites/default/files/Antibiotic%20Resistance%20101%20Report%20March%202015.pdf>.

17. See *infra* Section II.B.3.

18. See *Antimicrobial Use and Antimicrobial Resistance FAQ*, AM. VETERINARY MED. ASS’N, <https://www.avma.org/KB/Resources/FAQs/Pages/Antimicrobial-Use-and-Antimicrobial-Resistance-FAQs.aspx> (last visited Oct. 25, 2017). Additionally, antibiotics are subdivided into two categories—broad and narrow spectrum—based on the number and types of bacteria they affect. Broad spectrum antibiotics treat many Gram-positive and Gram-negative bacteria, while narrow spectrum antibiotics are effective against a more limited range of bacteria. Univ. of Minn., *Pharmacology*, ANTI-MICROBIAL RESISTANCE LEARNING SITE, <https://amrls.umn.edu/antimicrobial-resistance-learning-site/pharmacology> (last visited Nov. 6, 2017).

19. See generally CAL. FOOD & AGRIC. CODE §§ 14400–14403 (2017). See also *infra* Section IV.B.

version of California's new livestock antimicrobial law. Part II explains the evolution of factory farming in the United States, outlines environmental and community health hazards associated with CAFOs, and explains the livestock industry's contribution to antibiotic resistance. Part III lays out the federal government's efforts to regulate antimicrobial drug use in the U.S. and concludes that such efforts are inadequate. Finally, Part IV looks at California's recent legislative action to promote judicious use of medically important antimicrobials in livestock husbandry and advocates that Tennessee adopt a similar statute with more stringent language concerning livestock owners' prophylactic use of antimicrobial drugs to compensate for the lack of sanitary housing conditions in AFOs.

II. BACKGROUND

The cause and effect relationship between CAFOs and the progression of antibiotic resistance in humans is multifaceted and continues to be hotly debated in the United States. This Section explains the evolution of CAFOs in American agriculture, enumerates the many ways AFOs are bad for the environment, discusses the correlation between human and animal health consequences, and explains how CAFOs exacerbate the proliferation of drug resistant bacteria.

A. Evolution of Factory Farming

Livestock facilities that use traditional pastoral methods of raising animals are environmentally sustainable and healthy.²⁰ Factory farms, on the other hand, focus on "growing animals as units of protein production."²¹ Industrial animal agriculture evolved from the

20. PEW COMM'N ON INDUS. FARM ANIMAL PROD., PUTTING MEAT ON THE TABLE: INDUSTRIAL FARM ANIMAL PRODUCTION IN AMERICA 23 (2008) [hereinafter PEW, PUTTING MEAT ON THE TABLE], http://www.pewtrusts.org/~media/legacy/uploadedfiles/peg/publications/report/PCI_FAPFINAL.pdf.pdf ("[Traditional] agricultural practice and animal husbandry were more or less sustainable, as measured by the balance between agricultural inputs and outputs and ecosystem health, given human population and rate of consumption.").

21. *Id.* at 9.

modernization of farming practices in the early twentieth century²² and grew rapidly after World War II.²³ Over the years, large agribusinesses facilitated the growth of factory farming by successfully lobbying Congress to subsidize production of corn and soybean crops used in animal feed,²⁴ taking advantage of lax federal enforcement of waste disposal regulations,²⁵ and accepting “large infusions of capital to dominate [agricultural] markets.”²⁶

Nowadays, “vertically integrated conglomerates” dominate the food-animal industry and operate on an assembly-line model, with facilities specializing in stages of raising livestock “that are often spread out across different parts of the country: feed production in one factory; breeding in another; ‘finishing,’ or fattening, in a separate facility; and processing or slaughtering in yet another.”²⁷ As of 2015,

22. Daniel Imhoff, *Introduction*, in *THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES* xiii, xiv (Daniel Imhoff ed., 2010) [hereinafter Imhoff, *Introduction*] (“According to the *Oxford English Dictionary*, the first recorded use of the term *factory farming* appeared in an American journal of economics in 1890 . . .”). See also PEW, *PUTTING MEAT ON THE TABLE*, *supra* note 20, at 5 (“Intensive animal production began in the 1930s with America’s highly mechanized swine slaughterhouses.”).

23. See Imhoff, *Introduction*, *supra* note 22.

24. DOUG GURIAN-SHERMAN, *CAFOS UNCOVERED: THE UNTOLD COSTS OF CONFINED ANIMAL FEEDING OPERATIONS* 1, 2 (2008), https://www.organicconsumers.org/sites/default/files/cafos_uncovered.pdf (“Feed accounts for about 60 percent of the costs of producing hogs and chickens and is also an important cost for dairy and beef cows, and federal policies have encouraged the production of inexpensive grain that benefits CAFOs.”).

25. See Daniel Imhoff, *Myth: Industrial Food Is Efficient*, in *THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES* 66, 66 (Daniel Imhoff ed., 2010).

26. *Id.* See also FOOD & WATER WATCH, *FACTORY FARM NATION: HOW AMERICA TURNED ITS LIVESTOCK FARMS INTO FACTORIES* 2 (2010) [hereinafter *FACTORY FARM NATION* 2010] (“Factory farming was facilitated by three policy changes pushed by the largest agribusinesses: A series of farm bills artificially lowered the cost of crops destined for livestock feed; the EPA ignored factory farm pollution; and the Department of Justice . . . allowed the largest meat-packers to merge into a virtual monopoly.”).

27. See Daniel Imhoff, *CAFOs Are Farms, Not Factories*, in *THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES* 72, 73 (Daniel Imhoff ed., 2010).

there are approximately 19,245 CAFOs in the United States.²⁸ According to a 2012 report from the United States Department of Agriculture (“USDA”), “large-scale” farms, defined as farms making more than \$1,000,000 in gross cash farm income per year,²⁹ are responsible for 42% of the value of production, even though they make up only 3% of all farms in the United States.³⁰ The demand for meat products is expected to grow as the human population increases: going forward, experts estimate that the livestock industry will need to produce 455 million metric tons of meat per year by 2050.³¹

B. Costs to Society

There is a great illusion that concentrating livestock animals on small feed lots and in barns increases production efficiency and lowers cost to the consumer.³² CAFO supporters often credit themselves with supplying affordable food to the masses, particularly low-income families.³³ Nevertheless, CAFOs present a significant threat to the

28. See U.S. ENVTL. PROT. AGENCY, NPDES CAFO PERMITTING STATUS REPORT NATIONAL SUMMARY, END YEAR 2015 1 (Dec. 31, 2015), https://www.epa.gov/sites/production/files/2016-06/documents/tracksum_endyear2015.pdf.

29. See U.S. DEP’T. OF AGRIC., *Distribution of Farms and Value of Production Varies by Farm Type*, U.S. DEP’T. OF AGRIC. ECON. RES. SERV., <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58288> (last updated Mar. 8, 2017). “Gross cash farm income . . . includes income from commodity cash receipts, farm-related income, and government payments.” *Id.*

30. See *id.*

31. Greg Rummo, *How Feasible Is Antibiotic-free Meat?*, BEEF MAGAZINE (Feb. 29, 2016), <http://www.beefmagazine.com/beef-quality/how-feasible-antibiotic-free-meat>. See also CTR. FOR DISEASE DYNAMICS, ECON. & POL’Y, THE STATE OF THE WORLD’S ANTIBIOTICS 2015 38 (2015), https://www.cddep.org/publications/state_worlds_antibiotics_2015 (“According to the United Nations Food and Agriculture Organization (FAO), meat consumption will increase by 73 percent and dairy consumption by 58 percent over 2011 levels . . .”).

32. See generally Daniel Imhoff, *Myth: Industrial Food Is Cheap*, in THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES 63, 63–65 (Daniel Imhoff ed., 2010) (discussing the hidden costs of industrial food).

33. Monica Eng, *The Costs of Cheap Meat*, CHI. TRIB. (Sept. 24, 2010, 10:37 AM), <http://www.chicagotribune.com/lifestyles/health/ct-met-cheap-protein--20100923-story.html> (quoting an industry spokesman who said that CAFOs are “the

environment, animals, and human health—external costs that the price of meat or dairy products do not include. This subsection outlines the harms CAFOs cause, including environmental pollution, spread of pathogens and their effects on community health, contributions to antibiotic resistance, and animal welfare concerns.

1. Air, Water, and Soil Pollution

Storage and disposal of animal waste produced by CAFOs places an enormous strain on the environment. In traditional agricultural practices, animal manure provides an eco-benefit by fertilizing pasture land with deposits of nitrogen, phosphorus, and other nutrients. In return, grasses and forbs absorb these nutrients and provide healthy forage-value for livestock. The sheer quantity of livestock on CAFOs, however, leads to excessive concentrations of animal excrement that are difficult to manage.

According to Dr. JoAnn Burkholder, “[a]nimal cultivation in the United States produces 133 million tons of manure per year (on a dry weight basis),” which is thirteen times “more solid waste than human sanitary waste production.”³⁴ In many instances, CAFOs eliminate untreated waste through liquid drainage systems and store it in large, open-pit lagoons for further remediation.³⁵ The most popular mode of remediation is to spray the liquefied waste over crop fields; unfortunately, this causes nutrient saturation of the soils and leads to

most efficient way to meet consumer demand for a high-quality, relatively inexpensive product”). Available data support the spokesman’s claim:

[T]he average American spent just 9.5 percent of his or her disposable income on food last year, a lower percentage than in any country in the world.

And although meat consumption has risen slightly over the past 40 years, its impact on the pocketbook is less than half of what it was in 1970, falling from 4.1 percent to 1.6 percent in 2008.

Id.

34. JoAnn Burkholder et al., *Impacts of Waste from Concentrated Animal Feeding Operations on Water Quality*, 115 ENVTL. HEALTH PERSP. 308, 308 (2007).

35. FOOD & WATER WATCH, FACTORY FARM NATION 2015 EDITION 5 (2015) [hereinafter FACTORY FARM NATION 2015], <https://www.foodandwaterwatch.org/sites/default/files/factory-farm-nation-report-may-2015.pdf>.

groundwater leaching.³⁶ According to a report by Food & Water Watch, states identify AFOs “specifically as the polluters of almost 20,000 miles of rivers and streams and over 250,000 acres of lakes, reservoirs and ponds.”³⁷

Livestock manure and litter used in poultry farming also emits noxious gases such as ammonia, hydrogen sulfide, and methane as it breaks down, impairing the quality of life of anyone living nearby.³⁸ At low concentrations, “[h]ydrogen sulfide . . . can cause eye irritation, a sore throat and cough, and shortness of breath. Exposure to methane can make a person feel tired, dizzy, and have a headache. . . . Ammonia [is a respiratory irritant that] can cause irritation to the skin, eyes, throat, and nose.”³⁹ Additionally, sewage from both livestock and antibiotic-tainted soil can spread antibiotic-resistant bacteria through runoff, spills, and soil leaching.⁴⁰

2. Spread of Pathogens and Community Health Effects

The environment and wildlife are not the only victims of harmful CAFO waste. In some instances, bacteria found in CAFO waste, such as *E. coli* and *Salmonella*,⁴¹ travel to urban landscapes via

36. *Id.* at 21.

37. *Id.*

38. PEW, PUTTING FOOD ON THE TABLE, *supra* note 20, at 16. “CAFO-produced pollution has substantial social impacts. Odor, for instance, can be detected up to 6 miles from CAFOs.” BASS CONNECTIONS ANIMAL WASTE MGMT. & GLOBAL HEALTH, A LOOK AT CONCENTRATED ANIMAL FEEDING OPERATIONS IN NORTH CAROLINA: THE PROBLEMS WITH ANIMAL WASTE & A FRAMEWORK TO SOLVE THEM 7 (2016), https://sustainability.duke.edu/carbon_offsets/loydrayfarms/BC_CAFOPaper.pdf.

39. TENN. DEP’T OF AGRIC., *supra* note 8.

40. J.G. Davis et al., *Antibiotic Transport via Runoff and Soil Loss*, 35 J. ENVTL. QUALITY 2250, 2255–58 (2006).

41. *What Is the Difference Between Salmonella and E. coli?*, U.S. DEP’T OF HEALTH AND HUMAN SERV., <https://www.hhs.gov/answers/public-health-and-safety/what-is-the-difference-between-salmonella-and-e-coli/index.html> (last updated Aug. 11, 2014). *E. coli* and *Salmonella* become part of manure when an animal sheds or excretes them with undigested food from its digestive system in its feces. *See id.* *Salmonella* is the most common cause of foodborne illness in humans; “symptoms usually last 4–7 days” and “include fever, diarrhea, abdominal cramps[,] and headache.” *Id.* *E. coli* “causes bloody diarrhea, and can sometimes cause kidney failure and even death.” *Id.*

water pathways.⁴² Furthermore, transmission of drug-resistant bacteria from animals to humans may occur through a food-borne route.⁴³ It starts when CAFOs spray waste directly on the leaves and stalks of various food crops.⁴⁴ Next, primary consumers (usually herbivores) eat these contaminated plants, and the bacteria flourish inside the gut of that animal. This process is an example of “bioaccumulation,” wherein the concentration of toxins and pathogens accumulate over time in the tissue of animals faster than compared to what would occur naturally.⁴⁵

Effluent from wastewater treatment plants may also play a role in transporting antibiotics into new environments that humans inhabit.⁴⁶ CAFO manure sprayed over fields can leach into groundwater systems, carrying high concentrations of nutrients such as nitrogen and phosphorous into new watersheds.⁴⁷ According to a

42. TENN. DEP’T OF AGRIC., *supra* note 8 (describing land impacts of CAFO farming). Accord PAUL EBNER, CAFOs AND PUBLIC HEALTH: PATHOGENS AND MANURE 2 (2007), <https://www.extension.purdue.edu/extmedia/id/cafo/id-356.pdf> (“[An instance of disease] outbreak occurred in Walkerton, Ontario, when heavy rains washed manure into well water thereby causing high concentrations of *E. coli* and *Campylobacter* to enter public drinking water. Over 2000 people were affected by the outbreak which included seven fatalities.”).

43. See Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718, 725 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3194830/pdf/zcm718.pdf> (discussing food-borne transmission of antibiotic resistant bacteria to humans).

44. For instance, researchers have found *E. coli* contamination on leafy greens growing 180 meters (590 feet) away from a cattle feed lot. Elaine D. Berry et al., *Effect of Proximity to a Cattle Feedlot on Escherichia Coli O157:H7 Contamination of Leafy Greens and Evaluation of the Potential for Airborne Transmission*, 81 APPLIED & ENVTL. MICROBIOLOGY 1101 (2015), <http://aem.asm.org/content/81/3/1101.long>.

45. See Or. State Univ., *Bioaccumulation*, EXTENSION TECH. NETWORK, <http://extoxnet.orst.edu/tibs/bioaccum.htm>.

46. See Rama Pulicharla et al., *A Persistent Antibiotic Partitioning and Correlation with Metals in Wastewater Treatment Plant—Chlortetracycline*, 2 J. ENVTL. CHEMICAL ENGINEERING 1596, 1596–97 (2014).

47. See Sara Kangas, *Water Pollution Concerns Surround CAFOs*, NAT’L FARMER’S UNION BLOG (Oct. 30, 2015), <https://nfu.org/2015/10/30/water-pollution-concerns-surround-cafos/>. See generally Bernard T. Nolan & Kerie J. Hitt, *Vulnerability of Shallow Groundwater and Drinking-Water Wells to Nitrate in the*

report published by Food & Water Watch, “[s]everal studies . . . have linked nitrates in the drinking water to birth defects, disruption of thyroid function, and various types of cancers.”⁴⁸

Transmission of drug-resistant microbes from animals to humans can also occur through direct contact between animals and humans. Farmers, veterinarians, and slaughterhouse workers who work closely with CAFO livestock are at the highest risk of coming into contact with drug-resistant bacteria via direct contact with infected animals.⁴⁹ Professor Levy first reported this phenomenon when he found the same tetracycline-resistant *E. coli* strains in the gut flora of both chicken-farm workers and chickens consuming tetracycline-laced feed.⁵⁰

3. Antibiotic Resistance

Man’s misuse of antibiotics is the number one driving factor behind global antibiotic resistance.⁵¹ Researchers estimate that “[a]bout one-third of the antibiotics used in the United States each year is routinely added to animal feed to increase growth.”⁵² Many livestock producers use low doses of antibiotics to optimize production

United States, 40 ENVTL. SCI. & TECH. 7834 (2006) (“Groundwater is an important national resource that provides drinking water for nearly half the people in the United States.”).

48. FOOD & WATER WATCH, TURNING FARMS INTO FACTORIES: HOW THE CONCENTRATION OF ANIMAL AGRICULTURE THREATENS HUMAN HEALTH, THE ENVIRONMENT, AND RURAL COMMUNITIES 7 (2007) [hereinafter TURNING FARMS INTO FACTORIES]. For more information about the carcinogenic effects of nitrates, see generally Peter J. Weyer et al., *Municipal Drinking Water Nitrate Level and Cancer Risk in Older Women: The Iowa Women’s Health Study*, 12 EPIDEMIOLOGY 327 (2001).

49. Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718, 723 (2011), <http://cmr.asm.org/content/24/4/718.full.pdf+html>.

50. *Id.* at 723, 725.

51. CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 11 (2013) [hereinafter ANTIBIOTIC RESISTANCE THREATS], <https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>.

52. Burkholder et al., *supra* note 34, at 309.

output and prevent infections in densely packed, sordid AFOs.⁵³ This practice started in the 1950s when scientists discovered that residues of the antibiotic chlortetracycline increased weight gain in chickens.⁵⁴ Long-term nontherapeutic use of antibiotics fuels the development of deadly multi-drug resistant bacteria; furthermore, mixing medicine into animal feed makes dosing imprecise and not as effective for disease treatment.⁵⁵

Under-dosing antibiotics is a serious problem because it creates an opportunity for bacteria to survive and become resistant.⁵⁶ Biologically speaking, bacteria become drug-resistant in two ways: (1) by spontaneous genetic mutation; or (2) by acquiring DNA from a neighboring drug-resistant bacterium in a process called “horizontal gene transfer.”⁵⁷ Bacteria can also gobble up “naked, ‘free’ DNA” from the surrounding environment of cells that have burst.⁵⁸ Therefore, drug-resistant genes have multiple pathways of entering new microbial environments, creating large “reservoirs of resistance.”⁵⁹ Reservoirs can exist in humans, animals, and the environment. For instance,

53. See CTR. FOR DISEASE DYNAMICS, ECON. & POL’Y, *supra* note 31, at 39 (“In the United States, about three-quarters of feedlots administered at least one antibiotic for growth promotion or disease prevention in 2011.”).

54. See R.H. Gustafson & R.E. Bowen, *Antibiotic Use in Animal Agriculture*, 83 J. APPLIED MICROBIOLOGY 531, 531–32 (1997).

55. See D.C. Love et al., *Feather Meal: A Previously Unrecognized Route for Reentry into the Food Supply of Multiple Pharmaceuticals and Personal Care Products*, 46 ENVTL. SCI. & TECH. 3795, 3796 (2012).

56. “Frequent, low doses of antibiotics that are not strong enough to kill all bacteria encourage some bacteria to develop means of survival, or to become ‘resistant.’” PEW CHARITABLE TRS., HOW ANTIBIOTIC RESISTANCE HAPPENS 1 (2010), http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/antibioticresistancepdf.pdf (explaining how bacteria become resistant to drugs).

57. See RESISTANCE 101, *supra* note 16, at 6. See also generally *General Background: About Antibiotic Resistance*, ALLIANCE FOR PRUDENT USE OF ANTIBIOTICS (last visited Nov. 1, 2017) [hereinafter APUA], http://emerald.tufts.edu/med/apua/about_issue/about_antibioticres.shtml.

58. APUA, *supra* note 57.

59. RESISTANCE 101, *supra* note 16, at 6. A reservoir is “[a] person, animal, insect, plant, or other host that is carrying a pathogen (for example, bacteria or fungi) that causes infectious diseases.” ANTIBIOTIC RESISTANCE THREATS, *supra* note 51, at 111.

researchers at the CDC have found that bacteria that cause *Salmonella* and *Campylobacter* infections in humans have animal reservoirs.⁶⁰

Researchers have established the link between antibiotic use in livestock production and antibiotic resistance in humans. In the 1990s, scientists confirmed antibiotic use in livestock production and antibiotic resistance in humans for the antibiotic drug avoparcin, which was indicated for use in poultry, but not in human medicine.⁶¹ According to Paul Ebner, professor of animal sciences at Purdue University, “[b]acteria that [were] resistant to avoparcin, however, [were] also resistant to vancomycin, one of only a few remaining drugs available to treat methicillin resistant *Staphylococcus aureus* (MRSA) in humans.”⁶²

The livestock industry also relies on several other classes of antibiotics essential to human medicine, including tetracyclines, streptomycin, penicillins, and sulfonamides.⁶³ In 2013, the CDC published a report outlining the top eighteen drug-resistant bacteria threats to the United States.⁶⁴ The CDC categorized these threats based on three levels of concern: urgent, serious, and concerning.⁶⁵ Two of the bacteria on the list, drug-resistant *Campylobacter* and drug-resistant non-typhoidal *Salmonella*, come from animal reservoirs, and the CDC considers them serious threats.⁶⁶ Scientific researchers have been studying the link between nontherapeutic use of antimicrobials in

60. See ANTIBIOTIC RESISTANCE THREATS, *supra* note 51, at 36.

61. PAUL EBNER, CAFOS AND PUBLIC HEALTH: THE ISSUE OF ANTIBIOTIC RESISTANCE 2 (2007), <https://www.extension.purdue.edu/extmedia/ID/cafo/ID-349.pdf> (“In Europe, avoparcin was widely used in the early 1990s in the poultry industry.”).

62. *Id.* “Europeans acquired vancomycin-resistant bacteria from the community at-large with the only community source able to drive increases in resistance being the use of avoparcin in birds.” *Id.*

63. See NAT’L RESEARCH COUNCIL, THE EFFECTS ON HUMAN HEALTH OF SUBTHERAPEUTIC USE OF ANTIMICROBIALS IN ANIMAL FEEDS 7, 70 (1980), https://www.ncbi.nlm.nih.gov/books/NBK216513/pdf/Bookshelf_NBK216513.pdf.

64. See generally ANTIBIOTIC RESISTANCE THREATS, *supra* note 51, at 49–92.

65. *Id.* at 6–7. “In general, threats assigned to the urgent and serious categories require more monitoring and prevention activities, whereas the threats in the concerning category require less.” *Id.* at 21.

66. *Id.* at 7, 36.

livestock and antibiotic resistance since the late 1960s.⁶⁷ More recently, in 2016, researchers from Ohio State University found drug-resistant *E. coli* bacteria in samples from a Midwestern pig farm.⁶⁸ According to the Center for Food Safety, researchers found these *E. coli* to be “resistant to carbapenems, one of the last classes of antibiotics that doctors rely on to treat multi-drug resistant infections in humans.”⁶⁹

The U.S. Food and Drug Administration (“FDA”) attributes the rise in antimicrobial resistance to “human exposure to food containing antimicrobial-resistant bacteria resulting from the exposure of food-producing animals to antimicrobials.”⁷⁰ In the United States, antibiotic resistance places an extraordinary toll on human life. In fact, the CDC estimates that around 2 million Americans experience antibiotic resistant infections each year, leading to 23,000 deaths.⁷¹ Antibiotic

67. See generally 791 Parl Deb HC (1969) col. 360 (UK) (reporting an increase in the numbers of strains of enteric bacteria of animal origin showing resistance to one or more antibiotics); Antonio Roberto Vieira, *Association Between Tetracycline Consumption and Tetracycline Resistance in Escherichia Coli from Healthy Danish Slaughter Pigs*, in 1 *FOODBORNE PATHOGENS AND DISEASE* 99, 99 (2009) (“[T]etracycline usage, the time span between last treatment and sampling date, together with herd size and the proportion of animals being treated in a herd, increase the probability of obtaining an [antibiotic] resistant isolate.”); Lance B. Price, Professor, Department of Environmental and Occupational Health, Milken Institute of Public Health, The George Washington University, Written Testimony to the President’s Council of Advisors on Science and Technology (Apr. 4, 2014) (citing, *inter alia*, U.S. BUREAU OF VETERINARY MED. & SEATTLE-KING CITY. DEP’T OF PUB. HEALTH, SURVEILLANCE OF THE FLOW OF SALMONELLA AND CAMPYLOBACTER IN A COMMUNITY 3 (1984), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/price_lance.pdf (reporting that “isolates from human cases and those from retail poultry had similar antibiotic susceptibility patterns, including prevalence of 29.7% and 32.8%, respectively, for tetracycline resistance”)).

68. Press Release, Ctr. for Food Safety, Another Superbug Found on Pig Farm in the U.S. (Dec. 6, 2016), <http://www.centerforfoodsafety.org/issues/310/ge-trees/press-releases/4592/another-superbug-found-on-pig-farm-in-the-us#>.

69. *Id.*

70. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition, 77 Fed. Reg. 735, 738 (Jan. 6, 2012) (to be codified at 7 C.F.R. pt. 530).

71. *Antibiotic/Antimicrobial Resistance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/> (last updated Aug. 18, 2017).

resistance makes treatment of bacterial infections nearly impossible, increases how long people are sick, limits therapeutic options (in both humans and animals), and increases mortality rate.⁷² The resulting financial costs to the U.S. healthcare system is alarming.⁷³ In the United States, antibiotic resistance adds an estimated \$20 billion in excess direct health care costs,⁷⁴ “with additional costs to society for lost productivity as high as \$35 billion a year”⁷⁵ Most importantly, the potential for loss of human life increases. In 2016, the United Kingdom’s Review on Antimicrobial Resistance “estimated that without appropriate action, antibiotic-resistant infections will kill 10 million people globally per year by 2050”⁷⁶

4. Animal Welfare Concerns

Crowded conditions in CAFOs increase stress on the livestock and promote animals’ susceptibility to infection and disease. The Animal Welfare Act of 1966 (“AWA”) is the only federal law that regulates the treatment of animals.⁷⁷ The AWA excludes farm animals,⁷⁸ however, leaving the creation and enforcement of laws

72. See FDA, GUIDANCE FOR INDUSTRY #152 EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN 7 (Oct. 23, 2003) [hereinafter GFI #152], <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>.

73. ANTIBIOTIC RESISTANCE THREATS, *supra* note 51, at 11.

74. *Id.* “In most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional doctor visits and healthcare use, and result in greater disability and death compared with infections that are easily treatable with antibiotics.” *Id.*

75. *Id.*

76. Ctr. for Food Safety, *supra* note 68.

77. USDA, *Animal Welfare Act*, NAT’L AGRIC. LIBR., <https://www.nal.usda.gov/awic/animal-welfare-act> (last visited Nov. 1, 2017). The AWA promulgates minimum standards of care and treatment for animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. See 7 U.S.C. § 2131 (2012).

78. Under section 2132(g),

[t]he term “animal” means any live or dead dog, cat, monkey . . . guinea pig, hamster, rabbit, or such other warm-blooded animal [that] is being used, or is intended for use, for research, testing,

protecting farm animals to the states. Unfortunately, most states' anticruelty statutes, including Tennessee's, are failing to protect livestock from abuse due to exemptions for "customary" farming practices.⁷⁹ In fact, twenty-eight states exempt farm animals from anticruelty laws so long as the act against the animal is deemed to be an "accepted," "common," "customary," or "normal" farming practice.⁸⁰

Livestock on CAFOs also suffer because they have to eat unnatural diets. Cows and other ruminants are obligate grass eaters, adapted to eating entirely fibrous plants, while "[p]igs and chickens in the wild eat mainly grass, worms, and insects."⁸¹ Nevertheless, most factory farms choose to feed their livestock unnatural, grain-rich feed that contributes to illness and disease.⁸² CAFOs give livestock corn-

experimentation . . . or as a pet; but such term *excludes* . . . farm animals, such as, but not limited to livestock or poultry, used or intended for use as food . . . or intended for . . . improving animal nutrition, breeding, management, or production efficiency

7 U.S.C. § 2132(g) (2012).

79. See TENN. CODE ANN. § 39-14-202(f)(1) (2014) ("Nothing in this section [titled "Cruelty to animals"] shall be construed as prohibiting the owner of a farm animal or someone acting with the consent of the owner of that animal from engaging in *usual and customary* practices which are accepted by colleges of agriculture or veterinary medicine with respect to that animal." (emphasis added)). Expanding the definition of "animal cruelty" to cover farm animals under Tennessee law warrants further discussion following the passage of the Tennessee Animal Abuser Registration Act. See generally TENN. CODE ANN. §§ 40-39-101 to -104 (2014 & Supp. 2017).

80. David J. Wolfson, *Beyond the Law: Agribusiness and the Systemic Abuse of Animals Raised for Food or Food Production*, 2 ANIMAL L. 123, 123 (1996). "Normal agricultural practices are defined as normal activities, practices and procedures that farmers adopt, use or engage in year after year in the production and preparation for market of poultry and livestock." *Id.* at 153 (citing, *inter alia*, 18 PA. STAT. AND CONS. STAT. ANN. § 5511(c) (Supp. 1994)).

81. Anastasia S. Stathopoulos, Note, *You Are What Your Food Eats: How Regulation of Factory Farm Conditions Could Improve Human Health and Animal Welfare Alike*, 13 N.Y.U. J. LEGIS. & PUB. POL'Y 407, 416 (2010).

82. Amanda Belanger, *A Holistic Solution for Antibiotic Resistance: Phasing out Factory Farms in Order to Protect Human Health*, 11 J. HEALTH & BIOMEDICAL L. 145, 154 (2015).

and soy-based feeds because those feeds are cheap.⁸³ They also promote rapid growth and weight gain in beef cattle and increase milk production in dairy cattle.⁸⁴

The problem with this system is that cows have not evolved to digest corn and soybeans; these feeds create all sorts of problems.⁸⁵ Specifically, grain-rich cattle diets “increase the concentration and the length of time that *E. coli*, including dangerous strains like O157:H7, survives in manure.”⁸⁶ At the other end of the spectrum, some CAFO operations mix scraps of animal carcasses into a base of corn or grain to create a protein-rich meal that decreases feed costs.⁸⁷ All of these issues lead to conditions that produce unhealthy animals that are imminently vulnerable to communicable diseases, which in turn fuels CAFO farmers and ranchers’ reliance on medically important antibiotics as a means of maintaining production efficiencies.

III. FEDERAL EFFORTS TO REGULATE ANTIMICROBIAL USE IN LIVESTOCK

Congress and agencies with jurisdiction over CAFOs have taken little action despite rising costs to society. The federal government’s public recognition of antibiotic resistance backdates to the 1970s.⁸⁸ Even though almost fifty years have passed, federal

83. See Michael Pollan, *Power Steer*, in *THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES* 97 (Daniel Imhoff ed. 2010) (“[T]here is no other feed quite as cheap or plentiful [as corn] . . .”).

84. See Stathopoulos, *supra* note 81, at 416–17.

85. See generally Robin Graber, *A Difficult Reality to Digest: The Effects of a Corn-Based Diet on the Digestive System of Cattle*, 8 *EUKARYON* 51, 51–53 (2012) (explaining the anatomy and physiology of bovine digestion and the medical issues that coincide with feeding cattle a corn-based diet).

86. *FACTORY FARM NATION 2015*, *supra* note 35, at 28.

87. Belanger, *supra* note 82, at 155 (“Factories may grind up animal corpses to mix with animal feed, which produces a meal consisting of feathers, skin, hair, hooves, blood, and intestines.”).

88. In 1970, the FDA instituted a task force to study the use of antibiotics in animal husbandry. Two years later, the task force published its report concluding:

(1) the use of antibiotics in “subtherapeutic amounts” favors the selection of antibiotic-resistant bacteria; (2) animals treated with such doses of antibiotics can serve as hosts for resistant bacteria, which can then be transferred to humans; (3) the prevalence of

regulatory efforts to oversee antibiotic use in livestock remain fragmented among federal regulations, guidance documents, and executive orders. This Part analyzes each of these pieces in turn and concludes that there are numerous loopholes and industry exemptions that undermine the federal government's ability to adequately regulate antibiotic use in livestock production.

A. FDA Regulations

The FDA regulates the sale and distribution of all antibiotics under the Federal Food, Drug, and Cosmetic Act (“the FD&C Act”).⁸⁹ Within the FDA, the Center for Veterinary Medicine (“CVM”) regulates the manufacture and distribution of veterinary medicines,⁹⁰ including antibiotics, and regulates medicated feed. The CVM ensures that animal pharmaceuticals are safe and effective by monitoring for health risks in animals and humans who might consume products from the treated animal, and it also conducts drug-safety research.⁹¹

The FD&C Act defines a “new animal drug” to include any drug intended for use in animals, including animal feed.⁹² The CVM's standards and processes for reviewing pharmaceuticals intended for animals are in many ways similar to the FDA's process for reviewing

resistant bacteria had increased; and (4) resistant bacteria had been found in meat and meat products intended for human consumption.

Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 154 (2d Cir. 2014).

89. See generally Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended in 21 U.S.C.).

90. FDA, *About the Center for Veterinary Medicine (CVM)*, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm> (last updated Apr. 4, 2017). The FD&C Act defines the term “drug” to include, among other things, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man *or other animals*” and “articles (other than food) intended to affect the structure or any function of the body of man *or other animals*.” 21 U.S.C. § 321(g)(1)(B)–(C) (2012) (emphasis added).

91. Christine Donovan, Note, *If the FDA Does Not Regulate Food, Who Will? A Study of Hormones and Antibiotics in Meat Production*, 41 AM. J.L. & MED. 459, 468 (2015).

92. 21 U.S.C. § 321(v) (2012). See also 21 C.F.R. § 510.110(f) (2017) (“Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations, including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives.”).

pharmaceuticals intended for humans. First, drug sponsors who wish to make and sell drug products in the United States must go through the New Animal Drug Application (“NADA”) process,⁹³ which the CVM administers. The NADA process reveals the drug’s historical development and contains information about the drug’s pharmacology and proposed label, including target animal safety,⁹⁴ effectiveness, human food safety, chemistry and manufacturing, and environmental impact.⁹⁵ After receiving the NADA, “a team of CVM personnel, including veterinarians, animal scientists, biostatisticians, chemists, microbiologists, pharmacologists, and toxicologists” reviews its content.⁹⁶ The CVM checks each new animal drug for effectiveness, consistency, and safety with respect to each target species.⁹⁷ After the CVM deems the new animal drug to be safe, the drug sponsor may start legally selling the drug.⁹⁸

The problem with the NADA process is that, once the CVM approves a new animal drug for use in animals, the FDA does little monitoring regarding how consumers use the drug. For instance, “drug sponsors are required to send the FDA annual reports on the quantities distributed and the target animals but not on the buyers’ identities or

93. See FDA, GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT (GADPTRA) [hereinafter GADPTRA], <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRuleRegulations/ucm049100.htm> (last visited Sept. 10, 2017).

94. Differences in species pharmacology mean that some drugs are safe to use in one species but not in another. “The goals of target animal safety study/studies [sic] are to identify the toxic effects of the drug and establish a margin of safety for the labeled dosage regimen (dose, route, frequency, duration).” Cindy L. Burnsteel, Director, FDA Division of Therapeutic Drugs for Food Animals, Target Animal Safety Overview Presentation to the American Academy of Veterinary Pharmacology and Therapeutics “Veterinary Drug Regulatory Life Cycle (A to Z)” Conference (Mar. 1, 2011), <http://c.ymcdn.com/sites/www.aavpt.org/resource/resmgr/imported/11Burnsteel.pdf>.

95. *From an Idea to the Marketplace: The Journey of an Animal Drug Through the Approval Process*, FDA, <https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm> (last updated Oct. 19, 2017).

96. *Id.*

97. *Id.*

98. *Id.*

which animals actually receive the drugs.”⁹⁹ Without this information, the FDA has no way of distinguishing which livestock producers are using medically important antibiotics judiciously and which are not.

B. FDA Guidance for the Industry

In December 2013, the FDA published two guidance documents in an attempt to address misuse of medically important antibiotics in AFOs. The first document, Guidance for Industry #209 (“GFI #209”), outlines the “Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals,”¹⁰⁰ recommends limiting uses of medically important antimicrobials to those necessary to protect animal health, and attempts to limit antibiotic use for growth promotion and feed efficiency purposes.¹⁰¹ The FDA considers “judicious use” of antimicrobials in the livestock setting to include uses that are necessary for assuring the health of food-producing animals; this includes using antimicrobials in association “with the treatment, control, or prevention of specific diseases, including administration through feed or water”¹⁰² The second document, Guidance for Industry #213 (“GFI #213”), asks animal drug companies to *voluntarily* remove growth-promotion and feed-efficiency indicators from approved uses of antibiotic products, and it requires veterinarians to oversee the addition of antibiotics to livestock feed and

99. Prescott, *supra* note 15, at 317. Accord 21 C.F.R. § 514.87(b) (2017) (“[Annual reports] must include the following information for each new animal drug product . . . : (1) A listing of each antimicrobial active ingredient contained in the product; (2) A description of each product sold or distributed by unit, including the container size, strength, and dosage form of such product units; (3) For each such product, a listing of the *target animal species*, indications, and production classes that are specified on the approved label; (4) For each such product, the *number of units sold* or distributed in the United States . . . for each month of the reporting year; and (5) For each such product, the *number of units sold* or distributed outside the United States . . . for each month of the reporting year (emphasis added)).

100. FDA, GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD PRODUCING ANIMALS (Apr. 13, 2012) [hereinafter GFI #209], <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>.

101. *Id.* at 3–4.

102. *Id.* at 21 (citation omitted).

water for any reason.¹⁰³ In other words, after drug manufacturers voluntarily make these changes, CAFOs can no longer use antimicrobial drug products for growth promotion purposes. Additionally, antimicrobials will lose over-the-counter marketing status and require veterinary oversight.¹⁰⁴ In preparation for implementing the changes it made in GFI #213, the FDA published three documents in the Federal Register: the first noticed the FDA's withdrawal of eleven NADAs that were deemed to be "antimicrobial drugs of importance to human medicine";¹⁰⁵ the second modified the marketing status of forty-three antimicrobial NADAs from over-the-counter to prescription-only status;¹⁰⁶ and the third rejected and approved NADAs to be used in animal feed according to the CVM's judicious use principles.¹⁰⁷

103. See FDA, GUIDANCE FOR INDUSTRY #213: NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS; RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209, 4–5 (Dec. 12, 2013) [hereinafter GFI #213], <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>. The purpose of GFI #213 is to

provide[] two recommended principles regarding the appropriate or judicious use of medically important antimicrobial drugs:

- (1) Limit medically important antimicrobial drugs to uses in animals that are considered necessary for assuring animal health, and
- (2) Limit medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation.

GFI #213, *supra*, at 4.

104. FDA's Strategy on Antimicrobial Resistance—Questions and Answers, FDA (last updated Feb. 2, 2017), <https://www.fda.gov/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216939.htm>. See also *infra* note 121 and accompanying text.

105. New Animal Drugs; Withdrawal of Approval of New Animal Drugs, 81 Fed. Reg. 95025 (Dec. 27, 2016).

106. Oral Dosage Form New Animal Drugs; Approval of New Animal Drug Applications, 81 Fed. Reg. 94987 (Dec. 27, 2016) (to be codified at 21 C.F.R. pts. 520, 529).

107. New Animal Drugs for Use in Animal Feed; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications, 81 Fed. Reg. 94991 (Dec. 27, 2016) (to be codified at 21 C.F.R. pts. 556, 558).

One problem with GFI #209 and GFI #213 is that they do not establish “legally enforceable responsibilities.”¹⁰⁸ For example, the phrase “Contains Nonbinding Recommendations” appears at the top of each page of the guidance documents.¹⁰⁹ Additionally, the guidance documents do not force animal drug companies to commit to judicious use principles; instead, the FDA depends on drug companies’ cooperation to voluntarily remove indicators for growth promotion.¹¹⁰ There is good news on this front, however. Since January 2017, most animal drug companies have voluntarily cooperated with the guidance set out in GFI #213; as a result, 283 affected NADAs “have either aligned with the recommendations outlined in GFI #213, or their approvals have been voluntarily withdrawn.”¹¹¹ As a result, producers of animal feed and veterinarians should cease administering medically important antibiotics for growth-promotion and feed-efficiency purposes.¹¹²

Unfortunately, the FDA’s guidelines and publications in the Federal Register fail to address a glaring problem: virtually all CAFOs, by their nature of being filthy, over-crowded, and under

108. See FDA, GUIDANCE FOR INDUSTRY #233: VETERINARY FEED DIRECTIVE COMMON FORMAT QUESTIONS AND ANSWERS 4 (Sept. 2016) [hereinafter GFI #233], <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM474640.pdf> (“In general, FDA guidance documents do not establish legally enforceable responsibilities. Instead, guidelines describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.”).

109. See GFI #209, *supra* note 100, at 2–26; GFI #213 *supra* note 103, at 1–18; GFI #233, *supra* note 108, at 2–16.

110. “[The] FDA believes a voluntary approach, conducted in a cooperative and timely manner, is the most effective approach to achieve the common goal of more judicious use of medically important antimicrobials in animal agriculture.” GFI #213, *supra* note 103, at 5.

111. Press Release, FDA, FDA Announces Implementation of GFI #213, Outlines Continuing Efforts to Address Antimicrobial Resistance (Jan. 3, 2017), <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm535154.htm> (last updated Oct. 17, 2017).

112. See THE PEW CHARITABLE TR., JUDICIOUS ANIMAL ANTIBIOTIC USE REQUIRES DRUG LABEL REFINEMENTS 1 (Oct. 2016), http://www.pewtrusts.org/~/media/assets/2016/10/judicious_animal_antibiotic_use_requires_drug_label_refinements.pdf.

market pressure to meet a growing demand for meat, will continue to require vast quantities of antibiotics for disease-prevention purposes to keep their livestock healthy and fertile. In the end, CAFO owners' primary concerns are their production output and bottom line. The total quantity of antibiotics that CAFO livestock consume will not likely decrease under current FDA guidelines because the disease-prevention exception creates a back door for CAFO owners to ignore environmental conditions that exacerbate the spread of diseases among livestock in the first place: high density and poor sanitation. Moreover, CAFO owners may continue to subversively use antibiotics for growth promotion under the disguise of "disease prevention."¹¹³ In 2016, the Pew Charitable Trust reported that "[o]f the 389 labels for medically important antibiotics . . . more than 140 labels do not fully meet FDA's judicious use standards, and around three-quarters of these potentially problematic labels are for [brand-name] drugs."¹¹⁴ The FDA's guidance documents also failed to adequately curtail the duration of treatment and dosage levels for many of the labels that the Pew Foundation studied.¹¹⁵

Furthermore, the FDA's guidance fails to address gaps in antibiotic reporting data. Importantly, the FDA does not require antibiotic usage reports from individual livestock farms; thus, it is impossible to know which livestock producers are complying with judicious use standards.¹¹⁶ To wit, the FDA has not announced any proposals to collect such data.¹¹⁷ Instead, the FDA is currently focused on improving reporting of antibiotic sales from animal drug companies. In July 2016, the FDA implemented a final rule requiring drug sponsors to report annual antibiotics sales on a species by species

113. According to the Pew Charitable Trust, some "injurious uses" of antibiotics may persist, even after the implementation of GFI #213. *Id.* at 2.

114. *Id.*

115. One hundred of the 389 labels "lack adequate restrictions on the duration of use, several labels do not identify a narrowly defined dosage, and eighty labels raise concerns about whether the specified indication is judicious." *Id.* "[S]ome problematic labels have duration limits that are tied to poorly defined external factors, such as during 'times of stress.'" THE PEW CHARITABLE TR., *supra* note 112, at 4.

116. See STASHWICK ET AL., *supra* note 4, at 13.

117. *Id.*

basis.¹¹⁸ This new rule is a modest improvement of antibiotic reporting requirements, but more data is needed from the individual livestock producers.

The most recent Veterinary Feed Directive (“VFD”) regulation mandates veterinary oversight for use of medically important antimicrobials in water and animal feed.¹¹⁹ A livestock producer will need a VFD to purchase feed products containing antibiotics, which come in three varieties.¹²⁰ A VFD Order is a written form, certified by a licensed veterinarian, authorizing a client “to obtain and use [animal feeds that contain medically important antibiotics] in accordance with [FDA] label directions.”¹²¹ Any veterinarian seeking to authorize a VFD must do so under the proviso of a veterinarian-client-patient relationship.¹²² According to the FDA, “[t]he VFD final rule also

118. Antimicrobial Animal Drug Sales and Distribution Reporting, 81 Fed. Reg. 29129 (May 11, 2016) (to be codified at 21 C.F.R. 514).

119. See generally 21 C.F.R. § 558.6 (2017).

120. Medicated feeds fall into Type A, Type B, and Type C classifications:

Type A feeds are the most concentrated forms of the drug and are designed to be incorporated in a premix before inclusion in a final ration. Type B feeds are premixes, which include the drug in a form ready to be incorporated into the final ration. Type C feeds are the final ration ready for feeding.

Mike Apley, *Changes to Antibiotics Regulations Coming December 2016*, BEEF CATTLE INST., <https://www.beefcattleinstitute.org/changes-antibiotics-regulations> (last visited Nov. 2, 2017).

121. *Veterinary Feed Directive (VFD)*, FOOD ANIMAL RESIDUE AVOIDANCE DATABANK, <http://www.farad.org/regulatory/vfd.asp> (last visited Mar. 16, 2017). Current VFD drugs include avilamycin, florfenicol, tilmicosin, and tylvalosin. *Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status*, FDA, <https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm> (last updated Aug. 8, 2016). The following drugs are transitioning from over-the-counter status to VFD status: chlortetracycline, chlortetracycline/sulfamethazine, chlortetracycline/sulfamethazine/penicillin, hygromycin B, lincomycin, oxytetracycline, oxytetracycline/neomycin, sulfadimethoxine/ormetoprim, tylosin, tylosin/sulfamethazine, virginiamycin. *Id.*

122. 21 C.F.R. § 558.6(b)(1)(ii) (2017). A veterinarian-client-patient relationship (“VCPR”) is

the basis for interaction among veterinarians, their clients, and their patients A VCPR means that all of the following are required.

updates recordkeeping requirements and takes advantage of electronic tools to make the process of issuing VFD drugs more efficient and flexible.”¹²³

C. Executive Order 13,676

In September 2014, former President Barack Obama issued Executive Order (“E.O.”) 13,676, establishing the U.S. Government Task Force for Combating Antibiotic Resistance (“Task Force”) and directing it to create a five-year plan for the federal government to study antibiotic resistance and create a plan for fighting it.¹²⁴ Representatives from several federal agencies, including the EPA, the U.S. Department for Health and Human Services, the Office of Science and Technology Policy, the National Science Foundation, and the

(1) The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the patient and the client has agreed to follow the veterinarians’ instructions. (2) The veterinarian has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition of the patient. This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of a timely examination of the patient by the veterinarian, or medically appropriate and timely visits by the veterinarian to the operation where the patient is managed. (3) The veterinarian is readily available for follow-up evaluation or has arranged for the following: veterinary emergency coverage, and continuing care and treatment. (4) The veterinarian provides oversight of treatment, compliance, and outcome. (5) Patient records are maintained.

Stanley Smith, *What Is a Veterinarian-Client-Patient-Relationship?*, THE OHIO ST. UNIV., (May 18, 2016, 8:12 AM), <https://u.osu.edu/beef/2016/05/18/what-is-a-veterinarian-client-patient-relationship/>.

123. Press Release, FDA, FDA Releases Biannual Progress Report, Announces Public Meeting on Use of Antimicrobials in Food-producing Animals (Aug. 21, 2015), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm459365.htm>; accord 21 C.F.R. § 558.6(b)(8) (2017).

124. Exec. Order No. 13,676, 184 Fed. Reg. 56931 (Sept. 18, 2014), <https://obamawhitehouse.archives.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria>.

USDA, comprise the Task Force.¹²⁵ Interestingly, the FDA has no representative.¹²⁶ Pursuant to E.O. 13,676, the Task Force created the National Action Plan for Combating Antibiotic-Resistant Bacteria (“National Action Plan”) in 2015.¹²⁷ Broadly speaking, the National Action Plan set five distinct goals to be achieved by 2020:

1. Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections.
2. Strengthen National One-Health¹²⁸ Surveillance Efforts to Combat Resistance.
3. Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria.
4. Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines.
5. Improve International Collaboration and Capacities for Antibiotic-resistance Prevention, Surveillance, Control, and Antibiotic Research and Development.¹²⁹

The National Action Plan does a good job of establishing an interdisciplinary policy plan addressing antibiotic resistance—but it fails to set specific benchmarks for limiting antibiotic use in livestock, and it does not mandate individual livestock farms to report antibiotic usage data.¹³⁰ More generally, the National Action Plan sets numeric

125. THE WHITE HOUSE, NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 8 (Mar. 2015), https://obamawhitehouse.archives.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf.

126. See Exec. Order No. 13,676 § 3(a), 184 Fed. Reg. 56931, 56931–32 (Sept. 18, 2014) (listing members of the Task Force).

127. THE WHITE HOUSE, *supra* note 125.

128. The One Health paradigm embraces a multidisciplinary approach to monitoring and controlling public health threats, in which physicians, ecologists, and veterinarians study how diseases spread among people, animals, and the environment. See *One Health Basics*, CDC, <https://www.cdc.gov/onehealth/basics/index.html> (last visited Sept. 30, 2017).

129. THE WHITE HOUSE, *supra* note 125, at 2.

130. Michael J. Martin et al., *Antibiotics Overuse in Animal Agriculture: A Call to Action for Health Care Providers*, 105 AM. J. PUB. HEALTH 2409, 2409 (2015).

goals to reduce the incidence of various resistant infections and improve data collection in human medicine settings.¹³¹

IV. NEW CONSUMER TRENDS AND LEGISLATION

Antibiotics are not production tools; they are drugs that doctors and veterinarians should only use to treat sick people and animals. This author is not alone in holding this belief: recent consumer trends indicate a growing demand for chicken, turkey, pork, and beef raised without the routine use of antibiotics.¹³² The federal government has failed to take meaningful action to prevent nontherapeutic use of antibiotics in food-producing animals. According to a report published by the Food & Water Watch, “63% [of the 217 medically important antibiotics listed in GFI #213] also have disease-prevention indications, meaning that [these] drugs can continue to be used nontherapeutically, which will continue to promote the development of antibiotic resistance.”¹³³ Consequently, the federal government’s failure to stop the livestock industry’s nontherapeutic use of medically important antibiotics means that states have the opportunity to address the issue of antibiotic resistance with their own laws, regulations, or both.¹³⁴

Several states, including New York, Minnesota, New Jersey, North Carolina, West Virginia, and Pennsylvania, have considered proposed legislation to limit nontherapeutic use of antimicrobials in food-producing animals, all to no avail.¹³⁵ California, on the other hand, became the first state to successfully supplant the federal government’s weak regulatory scheme with its own law when it passed Senate Bill 27 (“S.B. 27”) in response to public outcry over prolonged

131. See THE WHITE HOUSE, *supra* note 125 at 6, 10.

132. See STASHWICK ET AL., *supra* note 4, at 14–15 (showing how consumers are affecting where fast-food companies source their poultry products).

133. RESISTANCE 101, *supra* note 16, at 15.

134. See *Gonzales v. Raich*, 545 U.S. 1, 42 (2005) (O’Connor, J., dissenting) (describing states as “laboratories” of democracy).

135. Rudolf H. Beese & Phillip Bradley, *States Are Taking Charge of Antibiotic Use in Animals*, LAW360 (Nov. 5, 2015, 4:41 PM), <https://www.law360.com/articles/723687>.

use of antimicrobial drugs in livestock.¹³⁶ This Part highlights changing consumer demands for animal products raised without antibiotics, analyzes the efficacy of S.B. 27, advocates for Tennessee to enact similar legislation, and concludes with a proposed statute.

A. U.S. Market for Antimicrobial Drugs

Food safety advocates have faced an uphill battle in the last seven years, trying to enact policy change in how the livestock industry uses antibiotics. In 2010, the national meat industry successfully lobbied Washington lawmakers against vigorously regulating antibiotic use in livestock by casting doubt on the science connecting antibiotic use on farms to global antibiotic resistance and emphasizing the negative impact an antibiotics ban would have on meat prices.¹³⁷ Now, however, consumer demand for organic foods and meat raised without antibiotics is driving several major meat suppliers to kick the antibiotic habit.¹³⁸ Moreover, some food industry and state lawmaker actions already show a willingness to move away from antibiotic use.¹³⁹

Despite increased consumer and restaurant industry demands for non-antibiotic animal products, the FDA found in 2015 that “[U.S.] sales and distribution of antimicrobials approved for use in food-producing animals *increased* by 24% from 2009 through 2015”¹⁴⁰ The FDA also reported that U.S. sales of “medically important antimicrobials accounted for 62% of the domestic sales of all

136. See generally *Livestock: Use of Antimicrobial Drugs*, 2015 Cal. Stat. ch. 675 (2015) (codified at CAL. FOOD & AGRIC. CODE §§ 14400–14408 (2017)).

137. See Helena Bottemiller, *Meat Industry Defends Antibiotic Use*, FOOD SAFETY NEWS (Feb. 25, 2010), <http://www.foodsafetynews.com/2010/02/meat-industry-defends-antibiotic-use-on-the-hill/>.

138. See STASHWICK ET AL., *supra* note 4, at 14 (reporting that Perdue Farms, Tyson Foods, Foster Farms, and Pilgrim’s Pride—the four largest chicken producers in the United States—are moving away from using antibiotics).

139. See *infra* Section IV.B. See also Andrew Amelinckx, *Big Chicken Goes Antibiotic-Free*, MODERN FARMER (Mar. 9, 2017), <http://modernfarmer.com/2017/03/big-chicken-goes-antibiotic-free/> (stating that Tyson, the largest chicken processor in the United States, plans to stop using antibiotics in the company’s U.S. poultry products by June 2017).

140. See FDA, 2015 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 6 (2016) (emphasis added).

antimicrobials approved for use in food-producing animals.”¹⁴¹ Despite drug sponsors’ voluntary compliance with GFI #213, livestock producers are clearly continuing to purchase large quantities of products containing medically important antibiotics (including animal feed and water additives), which raises the question: are the FDA’s guidelines and reports on the threat of antibiotic resistance providing adequate deterrence to completely prevent livestock owners from administering medically important antibiotic drugs to food-animals? The answer appears to be “no.”

B. California Senate Bill No. 27

In 2015, California enacted S.B. 27 in response to public concern over prolonged use of antimicrobial drugs in livestock.¹⁴² It is the first state law in the United States to substantively limit the livestock industry’s access to and use of medically important antimicrobial drugs.¹⁴³ S.B. 27 takes effect January 1, 2018, giving

141. *Id.* The FDA’s report also compares annual sales totals from different classes of medically important antimicrobials: “Tetracyclines accounted for 71% of these sales, penicillins for 10%, macrolides for 6%, sulfas for 4%, aminoglycosides for 4%, lincosamides for 2%, and amphenicols, cephalosporins, and fluoroquinolones each for less than 1%.” *Id.*

142. The overuse and misuse of antibiotics . . . contributes to antibiotic resistance as a growing public health threat. . . . Antibiotic stewardship programs have been effective in reducing inappropriate antibiotic use in humans, as well in reducing antibiotic resistance[. . . .] However, there is no similar requirement that veterinarians and livestock . . . producers follow antibiotic stewardship guidelines.

Livestock: Use of Antimicrobials Drugs: Third Reading of S.B. 27 Before the S. Comm. on Agric., 2015–16 Reg. Sess. 3 (Cal. 2015) (quoting California Senator Jerry Hill, author of S.B. 27). Later, in 2016, Senator Hill commented: “We have a crisis on our hands The growth of antibiotic resistance threatens our very way of life. Anything we can do to slow down its development, we should do. We [the citizens of California] have an imperative to act.” Press Release, Senator Jerry Hill, Senator Hill to Introduce Bill Requiring Reporting of Superbug Infections (Oct. 10, 2016), <http://sd13.senate.ca.gov/news/2016-10-10-senator-hill-introduce-bill-requiring-reporting-superbug-infections>.

143. STASHWICK ET AL., *supra* note 4, at 13 (“California is the first state in the nation to take on the critical issue of antibiotic misuse in livestock and set clear requirements beyond the FDA’s weak program.”).

livestock owners three years to adjust to the new law administered by the California Department of Food and Agriculture (“CDFA”).¹⁴⁴

The first section of S.B. 27 defines three terms: (1) “medically important antimicrobial drug” means any drug listed in Appendix A of GFI #152;¹⁴⁵ (2) “livestock” means “all animals and poultry, including aquatic and amphibian species, that are raised, kept, or used for profit”;¹⁴⁶ and (3) “veterinary feed directive” is a written statement issued by a licensed veterinarian that orders the use of a VFD drug or combination VFD drug in or on animal feed.¹⁴⁷ Through S.B. 27, California’s legislature adopted two key recommendations set forth in GFI #209 and #213. First, S.B. 27 eliminates over-the-counter availability of “medically important antimicrobial drugs”¹⁴⁸ by requiring livestock owners to obtain a veterinarian’s prescription or feed directive before use.¹⁴⁹ Second, S.B. 27 outlaws administration of medically important antimicrobials to livestock for the sole purpose of increasing weight-gain or improving feed efficiency.¹⁵⁰ The heart of S.B. 27 is section 14402, which provides:

[A] medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is . . . :

(1) Necessary to treat a disease or infection.

144. See generally *Livestock: Use of Antimicrobial Drugs*, 2015 Cal. Stat. ch. 675 (2015) (codified at CAL. FOOD & AGRIC. CODE §§ 14400–14408 (2017)).

145. See CAL. FOOD & AGRIC. CODE § 14400(a) (2017). Appendix A to GFI #152 is an extensive list of antimicrobial drugs that ranks antimicrobial drugs into three tiers, “critically important,” “highly important,” or “important,” in regard to their human medical importance. See GFI #152, *supra* note 72, at 6. Notably, the FDA can amend Appendix A at any time to keep up with changes in drug guidelines. *Id.* at 28–33.

146. CAL. FOOD & AGRIC. CODE § 14400(b) (2017). “Livestock does not include bees or those species that are usually kept as pets, such as dogs, cats, and pet birds.” *Id.*

147. This provision of the law defines “veterinary feed directive” in the same manner as the FDA defined it. CAL. FOOD & AGRIC. CODE § 14400(c) (2017); 21 C.F.R. § 558.3 (2017).

148. CAL. FOOD & AGRIC. CODE § 14400(a) (2017).

149. See CAL. FOOD & AGRIC. CODE § 14401 (2017).

150. CAL. FOOD & AGRIC. CODE § 14402(c) (2017).

- (2) Necessary to control the spread of a disease or infection.
- (3) Necessary in relation to surgery or a medical procedure.
- (4) . . . [or] needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.¹⁵¹

S.B. 27 then provides a plan for implementing and monitoring livestock owners' compliance with these standards. Under Section 14404, the CDFA must work with public health agencies and cooperative extensions to establish best practice guidelines for antimicrobial stewardship, to be used by veterinarians and food-producers, that dictate "the proper use of medically important antimicrobial drugs for disease treatment, control, and prevention."¹⁵² Notably, these guidelines "must include scientifically validated *practical alternatives* to antimicrobial use such as introducing effective vaccines and developing good hygiene practices."¹⁵³ Any person, other than a licensed veterinarian,¹⁵⁴ caught violating any provision of S.B. 27 faces a civil penalty of \$250 for each day a violation occurs and must complete an educational course on the judicious use of medically important antimicrobial drugs within 90 days from the occurrence of the violation; the penalty for subsequent violations increases to \$500 for each day a violation occurs.¹⁵⁵

S.B. 27 is a step in the right direction toward phasing out the use of antibiotics in livestock production; however, there remain a few key weaknesses in the law. The biggest concern relates to livestock owners' use of antimicrobial drugs when disease symptoms *are not*

151. CAL. FOOD & AGRIC. CODE § 14402(a) (2017).

152. See CAL. FOOD & AGRIC. CODE § 14404(a) (2017).

153. *Id.* (emphasis added).

154. Instead of facing civil penalties, veterinarians who fail to comply with the provisions of S.B. 27 may face disciplinary sanctions pursuant to the Veterinary Medicine Practice Act. See CAL. FOOD & AGRIC. CODE § 14408(c) (2017).

155. CAL. FOOD & AGRIC. CODE § 14408(a)–(b) (2017). The penalties section is significantly watered-down from what drafters of the bill initially proposed. An earlier draft of S.B. 27 called for violations to be a misdemeanor "punishable by up to six months in county jail and/or a fine not exceeding \$1,000." *Livestock: Use of Antibiotics: Hearing on S.B. 27 Before the S. Comm. on Agric.*, 2015–16 Reg. Sess. 5 (Cal. 2015).

clinically present in animal herds. Specifically, the language of subsections 14402(d) and 14402(b) create ambiguity. Section 14402(d) prohibits a person from administering a medically important antimicrobial drug in a “regular pattern” *unless* it is for the purpose of treating a disease or infection, controlling the spread of a disease or infection, or in relation to surgery or a medical procedure.¹⁵⁶ Conversely, section 14402(b) provides: “A medically important antimicrobial drug may . . . be used when . . . it is needed for *prophylaxis* to address an *elevated risk* of contraction of a particular disease or infection.”¹⁵⁷ Legislative reports show that lawmakers intended others to interpret “prophylaxis” according to its plain ordinary meaning as “steps taken to *prevent* a particular disease or condition”¹⁵⁸ On the contrary, S.B. 27 does not define the term “regular pattern,” nor did any subsequent language in section 14402(d) modify the bill.¹⁵⁹

So far, S.B. 27 has not faced any challenges in court; food safety advocates, however, argue that the term “regular pattern” in section 14402(d) controverts section 14402(b)’s express permission for prophylactic use, thereby creating a loophole for livestock producers to continue administering sub-therapeutic doses of medically important antimicrobials to livestock and fostering a perpetual cycle of breeding antibiotic-resistant bacteria.¹⁶⁰ “[A] drug ostensibly will

156. See CAL. FOOD & AGRIC. CODE § 14402(d) (2015).

157. See CAL. FOOD & AGRIC. CODE § 14402(b) (2015) (emphasis added).

158. S. 27-2319, Bill Analysis: Senate Third Reading, at 5 (Calif. 2015), http://www.leginfo.ca.gov/pub/15-16/bill/sen/sb_0001-0050/sb_27_cfa_20150911_200348_asm_floor.html (“[T]his bill explicitly authorizes the routine use of antibiotics on animals that are not sick through the exception for prophylactic use to *prevent disease transmission or infection.*” (emphasis added)). See also Harvard Medical School, *Medical Dictionary of Health Terms: J-P*, HARV. HEALTH PUBL’G (Dec. 2011), <http://www.health.harvard.edu/medical-dictionary-of-health-terms/j-through-p#P-terms> (defining “prophylaxis” as “[s]teps taken to prevent a particular disease or condition”).

159. See generally CAL. FOOD & AGRIC. CODE §§ 14400–14408 (2017); see also Prescott, *supra* note 15, at 327.

160. See *Livestock: Use of Antibiotics: Hearing on S.B. 27 Before the S. Comm. on Agric.*, 2015–16 Reg. Sess. 6 (Cal. 2015) (“All of the organizations listed on this analysis with the position of ‘oppose unless amended’ have the same concern:

always be administered in a regular pattern, unless one pill [or injection] is sufficient for treatment.”¹⁶¹ Even if one dose of a drug is sufficient for the treatment of an acute medical condition, prophylactic use of a single-dose medicine consistently over time may arguably constitute a “regular pattern” use that section 14402(d) purports to outlaw.¹⁶² Additionally, legal prophylactic use of medically important antimicrobials hinges on a veterinarian’s definition of an “elevated risk.”¹⁶³ It is unclear whether veterinarians must find the presence or absence of an elevated risk based on a subjective or objective standard. Factory farms constantly expose animals to sordid, cramped conditions that create an elevated risk for contracting communicable diseases.¹⁶⁴ Thus, prophylaxis in the context of factory farming reasonably suggests that CAFOs will always routinely administer antimicrobial medicines to their livestock. Section 14402(b) does not completely close the prophylactic loophole, potentially allowing livestock owners to secretly feed their animals antibiotics for the purpose of promoting growth and increasing feed efficiency under the veil of medical necessity.¹⁶⁵

S.B. 27’s feeble data reporting requirements only require the CDFA to work only with “willing participants” to gather information about antibiotic sales and usage.¹⁶⁶ California’s reliance on individual livestock producers to volunteer information about their antibiotic consumption is woefully optimistic and diminishes S.B. 27’s overall impact. The data-reporting requirements do not obligate livestock owners to report the total quantity of antibiotics they use on each farm, which also contributes to the dearth of available data in monitoring and

namely, that this bill does not go far enough to restrict the use of antimicrobial drugs for preventative or routine uses in livestock.”).

161. Prescott, *supra* note 15, at 327. Cf. THE PEW CHARITABLE TR., *supra* note 112, at 6 (describing the lack of dosage instructions on drug labels).

162. See CAL. FOOD & AGRIC. CODE § 14402(d) (2017).

163. CAL. FOOD & AGRIC. CODE § 14402(b) (2017). The term “elevated risk” lacks its own statutory definition. See CAL. FOOD & AGRIC. CODE § 14400 (2017).

164. Roberto A. Saenz et al., *Confined Animal Feeding Operations as Amplifiers of Influenza*, 6 VECTOR BORNE ZOONOTIC DISEASES 338, 338 (2006) (“The crowding of swine and poultry in CAFOs increases the transmission of influenza viruses.”).

165. Prescott, *supra* note 15, at 327–28.

166. CAL. FOOD & AGRIC. CODE § 14405(c) (2017) (emphasis added).

enforcement efforts.¹⁶⁷ California should require this information because it is necessary to ensure effective enforcement of civil penalties against violators.

Overall, S.B. 27 faced weak opposition from veterinarians, livestock owners, and health advocacy groups. In early drafting stages of S.B. 27, the California Veterinary Medical Association (“CVMA”) argued that restricting antimicrobial use impedes veterinarians’ ability to make the “best medical decisions for the health and welfare of their patients.”¹⁶⁸ According to the CVMA, “[t]here are many instances where it is important to administer antibiotics prophylactically, such as to prevent the active spread of ‘silent killer’ diseases such as *Chlamydophila abortus*¹⁶⁹ in sheep, particularly when there is no test available to determine which sheep are the carriers of the disease.”¹⁷⁰ Additionally, Justin Oldfield, a representative of the California Cattlemen’s Association, argued that small cattle ranchers in rural areas may have a harder time getting medicine approved by a veterinarian.¹⁷¹ S.B. 27 also faced opposition from Physicians for Social Responsibility-Los Angeles, the Southern California Public Health Association, and the Urban Environmental Policy Institute.¹⁷²

167. See CAL. FOOD & AGRIC. CODE § 14405 (2017); *Livestock: Use of Antimicrobials Drugs: Third Reading of S.B. 27 Before the S. Agric. Comm. & the S. Appropriations Comm.*, 2015–16 Reg. Sess. 10 (Cal. 2015) (“The Consumers Union [is] . . . concern[ed] that ‘the data reporting part of the bill does not require reporting of total quantity of antibiotics used.’”).

168. *Livestock: Use of Antimicrobials Drugs: Third Reading of S.B. 27 Before the S. Agric. Comm. & the S. Appropriations Comm.*, 2015–16 Reg. Sess. 7 (Cal. 2015).

169. Frequently observed among sheep flocks, *Chlamydophila abortus* is a bacterium that causes “spontaneous abortion, stillbirth, or delivery of weak lambs.” See Gernot Walder et al., *Chlamydophila Abortus Pelvic Inflammatory Disease*, 9 EMERGING INFECTIOUS DISEASES 1642, 1642 (2003), <https://wwwnc.cdc.gov/eid/article/9/12/pdfs/02-0566.pdf>.

170. *Livestock: Use of Antimicrobials Drugs: Third Reading of S.B. 27 Before the S. Agric. Comm. & the S. Appropriations Comm.*, 2015–16 Reg. Sess. 7 (Cal. 2015).

171. See Patrick McGreevy, *California to Restrict Antibiotics Use in Farm Animals*, L.A. TIMES (Oct. 10, 2015, 3:28 P.M.), <http://www.latimes.com/local/political/la-me-pc-california-antibiotics-farm-animals-20151005-story.html>.

172. *Id.*

The absence of fervent opposition from these stakeholders suggests that a majority of interested Californians agreed with the spirit of the law and what it was designed to accomplish. Moreover, the thin opposition that lawmakers faced in California, a state with a large CAFO industry, suggests that other states like Tennessee may readily adopt a law similar to S.B. 27.

C. Proposed Tennessee Livestock Antimicrobial Law

“Antibiotic resistance rates in Tennessee are among the highest in the nation.”¹⁷³ The Tennessee Department of Food and Agriculture (“T DFA”) should work with Tennessee legislators to develop new and effective laws that reduce the nontherapeutic use of antibiotics in the livestock industry. Government leaders in Tennessee’s legislative and administrative branches already recognize the threat of antibiotic resistance.¹⁷⁴ In 2007, the state legislature enacted legislation that directs a committee created by the Tennessee Department of Health (“TDH”), known as the Infections Taskforce, to meet twice a year to create “strategies and recommendations for the prevention and control of antibiotic resistant infections.”¹⁷⁵ This task force, however, mainly reported on the presence of invasive MRSA in hospitals—not on farms—and the statute’s mandate for biannual reports expired in 2011.¹⁷⁶

173. *Appropriate Antibiotic Use*, TENN. DEP’T OF HEALTH, <https://www.tn.gov/health/cedep/appropriate-antibiotic-use.html> (last visited Dec. 10, 2017). “In 2000, Tennessee’s utilization rates for [the antibiotics] penicillin, cephalosporins, and trimethoprim-sulfamethoxazole were over 20% higher than the national average.” TENN. DEP’T OF HEALTH, TENNESSEE’S APPROPRIATE ANTIBIOTIC USE CAMPAIGN 1 (Oct. 2002), https://tn.gov/assets/entities/health/attachments/Newsletter_Oct_2002.pdf.

174. In 2016, for example, Governor Bill Haslam declared November 14–20, 2016, as “Get Smart for Antibiotics Week in Tennessee” as a part of the CDC’s Campaign to Promote Appropriate Antibiotic Use. *Appropriate Antibiotic Use*, TENN. DEP’T OF HEALTH, <https://www.tn.gov/health/cedep/appropriate-antibiotic-use.html> (last visited Dec. 10, 2017).

175. 2007 Tenn. Pub. Acts 157 (codified at TENN. CODE ANN. § 68-11-267(a) (2013)).

176. See TENN. CODE ANN. § 68-11-267(b) (2013). “Tennessee is a leader in collecting and reporting on antibiotic resistant infections by having made invasive [MRSA] cases reportable to the Department of Health’s Communicable and

Additionally, in 2008, the TDH received funding from the CDC to develop a campaign called “Keep Antimicrobials Working”¹⁷⁷ to address antimicrobial resistance in agricultural and veterinary settings in Tennessee.¹⁷⁸ In the spirit of this campaign, the TDH established the Tennessee Team on Antimicrobial Resistance (“TTAR”), a coalition comprised of members from the TDH, TFDA, the University of Tennessee College of Veterinary Medicine, Tennessee Veterinary Medical Association, UT Extension Service, Tennessee Agricultural Experiment Station, and Tennessee Cattlemen’s Association.¹⁷⁹ TTAR’s initial objective was to conduct a survey among beef cattle producers—purveyors of the leading agricultural commodity in Tennessee—“[to] address knowledge, attitudes, practices, and needs related to biosecurity and the use of antimicrobials.”¹⁸⁰ Based on the survey results and other current resources, TTAR developed and distributed educational brochures “to provide the most current information possible for beef cattle producers and veterinarians about antimicrobial resistance and guidelines for appropriate [antimicrobial] use.”¹⁸¹ The establishment of TTAR and the Infections Taskforce shows that Tennessee policymakers are aware of the link between

Environmental Disease Services section in June 2004.” TENN. DEP’T OF HEALTH, METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS* (MRSA) INFECTIONS: PROGRESS REPORT AND RECOMMENDATIONS OF THE TENNESSEE DEPARTMENT OF HEALTH AND THE INFECTIONS TASKFORCE 1 (2011), https://www.tn.gov/content/dam/tn/health/documents/MRSA_Annual_Report_2010.pdf.

177. TENN. DEP’T OF HEALTH, KEEP ANTIMICROBIALS WORKING!, <https://www.tn.gov/health/cedep/appropriate-antibiotic-use/keep-antimicrobials-working.html> (last visited Mar. 14, 2017) [hereinafter KEEP ANTIMICROBIALS WORKING!].

178. Tennessee Team on Antimicrobial Resistance received funding from the CDC’s “Get Smart on the Farm initiative.” ASS’N OF STATE & TERRITORIAL HEALTH OFFICIALS, MEETING SUMMARY: MULTISECTOR COLLABORATION—“ONE HEALTH” APPROACH TO ADDRESSING ANTIBIOTIC RESISTANCE 2 (2015), <http://www.astho.org/Programs/Infectious-Disease/Antimicrobial-Resistance/Multisector-Collaboration---One-Health-Approach-to-Addressing-Antibiotic-Resistance/>.

179. TENN. DEP’T OF HEALTH, ANTIBIOTIC USE IN ANIMALS, <https://www.tn.gov/health/cedep/appropriate-antibiotic-use/antibiotic-use-in-animals.html> (last visited Dec. 10, 2017).

180. KEEP ANTIMICROBIALS WORKING!, *supra* note 177.

181. *Id.*

antibiotic resistance and nontherapeutic use of antimicrobials in livestock animals. But the General Assembly should take further legislative action to establish uniform animal husbandry practices that do not rely on antibiotics.

Furthermore, the materialization of TTAR and growing consumer demand for animal-products raised without antibiotics means now is the perfect time for Tennessee to adopt new legislation to limit antimicrobial use in the livestock industry. Tennessee has the authority to regulate livestock antibiotics under the Tennessee Food, Drug and Cosmetic Act.¹⁸² This author recommends that Tennessee use S.B. 27 as a template to create its own livestock-antibiotics law and retain the overall organization of S.B. 27 with its nine sections: section one defines key terms;¹⁸³ section two restricts access to medically important antimicrobial drugs via a veterinary prescription or VFD;¹⁸⁴ section three explains acceptable uses of medically important antimicrobial drugs;¹⁸⁵ section four indicates retailers' ability to sell medically important antimicrobial drugs in feed or water;¹⁸⁶ section five lays the foundation for the departments' establishing "antimicrobial stewardship guidelines and best management practices" on proper use of medically important antimicrobial drugs;¹⁸⁷ section six establishes data reporting standards on use of medically important antimicrobial drugs in livestock;¹⁸⁸ section seven relays the department's authority to collect VFDs;¹⁸⁹ section eight asserts confidentiality of data reported under section six;¹⁹⁰ and section nine establishes civil penalties for violators.¹⁹¹

182. See TENN. CODE ANN. § 53-1-207(a)(2) (2008) ("The commissioner is authorized to make regulations promulgated under this chapter conform, insofar as practicable, with those promulgated under the federal [Food, Drug, and Cosmetic] act.").

183. See generally CAL. FOOD & AGRIC. CODE § 14400 (2017).

184. See generally CAL. FOOD & AGRIC. CODE § 14401 (2017).

185. See generally CAL. FOOD & AGRIC. CODE § 14402 (2017).

186. See generally CAL. FOOD & AGRIC. CODE § 14403 (2017).

187. See generally CAL. FOOD & AGRIC. CODE § 14404 (2017).

188. See generally CAL. FOOD & AGRIC. CODE § 14405 (2017).

189. See generally CAL. FOOD & AGRIC. CODE § 14406 (2017).

190. See generally CAL. FOOD & AGRIC. CODE § 14407 (2017).

191. See generally CAL. FOOD & AGRIC. CODE § 14408 (2017).

S.B. 27 needs a few major changes, however. First, Tennessee should improve S.B. 27 by defining “nontherapeutic use” as “the use of a medically important antimicrobial drug for the purposes of: (1) promoting weight gain or growth; (2) improving feed efficiency; or (3) routine disease prevention.”¹⁹² Expressly defining nontherapeutic use to include “routine disease prevention” serves an important purpose: eliminating the possibility of prophylactic use. Second, Tennessee should completely eliminate subsection 14402(b) to eliminate the possibility of prophylactic use as a pretext for promoting growth.¹⁹³ Third, the General Assembly should replace the phrase “for purposes of promoting weight gain or improving feed efficiency” from subsection 14402(c) with the phrase “for any nontherapeutic purpose.”¹⁹⁴ This change will eliminate all prophylactic use, which

192. The new statute would read:

TENN. CODE ANN. § 43-41-101. Definitions.

For purposes of this chapter, the following definitions apply:

(a) ‘Medically important antimicrobial drug’ means an antimicrobial drug listed in Appendix A of the federal FDA’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

(b) ‘Livestock’ means all animals and poultry, including aquatic and amphibian species, that are raised, kept, or used for profit. Livestock does not include bees or those species that are usually kept as pets, such as dogs, cats, and pet birds.

(c) ‘Veterinary feed directive’ has the same definition as in Section 558.3 of Title 21 of the CFR.

(d) ‘Nontherapeutic Use’ means the use of a medically important antimicrobial drug, as defined in this section, for the following purposes: (1) promoting weight gain or growth, (2) improving feed efficiency, or (3) routine disease prevention.

(emphasis added).

193. See *supra* notes 156–165 and accompanying text.

194. The new statute would read:

TENN. CODE ANN. § 43-41-103. Use of medically important antimicrobial drug; conditions

(a) A medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:

- (1) Necessary to treat a disease or infection.
- (2) Necessary to control the spread of a disease or infection.

will consequently force CAFO owners to cleanup environmental conditions of factory farms by providing animals with more space and cleaner paddocks or cages, among other remedial measures. Fourth, Tennessee lawmakers should rewrite section 14405's data reporting requirements to force veterinarians and livestock producers to provide statistically relevant data. Tennessee law already authorizes the TDH to mandate the reporting of certain communicable diseases and conditions.¹⁹⁵ This author recommends replacing the phrase "on medically important antimicrobial drug sales and usage, as well as antimicrobial resistant bacteria and livestock management practice data" in subsection 14405(b)(1) with the phrase "on the administration of each medically important antimicrobial drug, including the number and species of livestock, the type of drug and disease, and the duration of use."¹⁹⁶ Finally, lawmakers should replace subsection 14405(c)'s

(3) Necessary in relation to surgery or a medical procedure.

(b) A person shall not administer a medically important antimicrobial drug to livestock *for any nontherapeutic purpose*.

(c) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.

(emphasis added).

195. "The commissioner [of TDH] is authorized and directed to promulgate and publish such rules and regulations as may be necessary to prevent the spread of contagious or communicable diseases in order to protect the public health and welfare." TENN. CODE ANN. § 68-5-104(a)(2) (2013).

196. Incorporating the proposed changes would result in a provision that states: TENN. CODE ANN. § 43-41-106. Data and sample gathering; report to Legislature

(a) It is the intent of the Legislature that the department coordinate with the United States Department of Agriculture, the federal Food and Drug Administration, and the federal Centers for Disease Control and Prevention to implement the expanded antimicrobial resistance surveillance efforts included in the National Action Plan for Combating Antibiotic-Resistant Bacteria, and that the information gathered through this effort will help lead to a better understanding of the links between antimicrobial use patterns in livestock and the development of antimicrobial resistant bacterial infections.

(b)(1) *Tennessee Department of Agriculture* shall gather information *on the administration of each medically important antimicrobial drug, including the number and species of*

mandate to work with “willing participants” to collect data on farms’ usage of medically important antimicrobials with mandates on livestock producers to report lists of the antimicrobial agents they use and the approximate volume they administer to their livestock.¹⁹⁷ By making these changes, Tennessee can best limit the use of

livestock, the type of drug and disease, and the duration of use.

Monitoring efforts shall not be duplicative of the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System, and, to the extent feasible, the department shall coordinate with the United States Department of Agriculture, the federal Centers for Disease Control and Prevention, and the federal Food and Drug Administration in the development of these efforts.

(2) In coordinating with the National Animal Health Monitoring System and the National Antimicrobial Resistant Monitoring System, the department shall gather representative samples from all of the following:

- (A) *Tennessee’s* major livestock segments.
- (B) Regions with considerable livestock production.
- (C) Representative segments of the food production chain.

(c) The department shall promulgate regulations requiring animal reporting by food-animal operations—on the use of antimicrobial agents in livestock, including a list of the antimicrobial agents used and the approximate volume administered. The department shall also consult with, and conduct outreach to, livestock producers, licensed veterinarians, and any other relevant stakeholders on the implementation of the monitoring efforts. Participation in this effort shall be done in a manner that does not breach veterinary-client-patient confidentiality laws.

(d) The *Tennessee Department of Agriculture* shall report to the Legislature the results of its outreach activities and monitoring efforts. The department shall advise the Legislature as to whether or not participation is sufficient to provide statistically relevant data. The report shall be submitted in compliance with *Tenn. Code Ann. 3-1-114*.

(e) The department shall seek funds from federal, state, and other sources to implement this section.

(f) The department may promulgate regulations to implement this section.

(emphasis added).

197. See TENN. CODE. ANN. § 68-11-267(b) (2013); see also *supra* text accompanying note 176.

antimicrobial drugs in the state's livestock industry and consequently mitigate the threat of livestock-based antibiotic resistance in all Tennessee communities.

V. CONCLUSION

The correlation between the livestock industry's prodigious consumption of medically important antimicrobial drugs and the spread of antibiotic-resistant infections is cause for alarm. Part of the problem lies in America's love affair with cheap animal products and the industrialization of livestock-raising practices, particularly the rise of CAFOs. Factory farms' reliance on cheap animal feed and deleterious waste-disposal mechanisms cause enormous harm to humans, animals, and the environment. Antibiotic resistance will continue to threaten public health in America so long as state and federal governments allow CAFOs to continue relying on antimicrobials as a production tool to avoid inevitable illness and disease associated with raising livestock in sordid, crowded conditions.

Neither Congress nor the Executive Branch have taken sufficient legal action to prevent CAFO owners from using medically important antimicrobials for non-judicious purposes.¹⁹⁸ First, the FDA does not adequately monitor how manufacturers sell or the livestock industry consumes new animal drugs. Second, the FDA's guidance documents do not create legally enforceable responsibilities for livestock owners and animal drug companies to adhere to judicious-use principles. Third, President Obama's Task Force for Combating Antibiotic Resistance failed to set national targets to reduce antibiotic use in animal agriculture and did not mandate the collection of antibiotic usage data for livestock.

The federal government's failures create an opportunity for states to implement tougher laws and regulations on livestock producers. California's S.B. 27 is a step in the right direction because it restricts livestock producers' ability to obtain and use medically

198. Beese & Bradley, *supra* note 135 (“[D]espite . . . activity on . . . the federal regulatory front, efforts to pass more robust federal legislation have thus far failed. An important example of this [legacy] is the Preservation of Antibiotics for Medical Treatment Act, which Rep. Louise Slaughter, D-NY, has either sponsored or cosponsored since 1999. This legislation would ban nontherapeutic uses of medically important antibiotics in food animal production.”).

important antimicrobials for growth and feed efficiency purposes. The public, however, needs more stringent legislative reforms. Specifically, states like Tennessee, which boasts 323 CAFOs¹⁹⁹ and high rates of antibiotic resistance, need to adopt legislation that eliminates livestock producers' prophylactic use of antibiotics in livestock and compels participation in antimicrobial reporting programs that track the amount of medically important antimicrobials being sold to each livestock farm. By incorporating these two missing pieces into legislation, states will indirectly force CAFO owners to improve the cleanliness of their facilities, address animal welfare issues that they have long ignored, and most importantly, stem the tide of antibiotic resistance to promote the safety and health of both humans and animals.

199. As of September 30, 2017, there are 323 CAFOs in Tennessee with active NPDES permits. To obtain this number using the database, I filtered the permit type to "CAFO" then I set the status to "active." Tenn. Dep't of Env't and Conservation, *Heritage WPC Permits in Tennessee*, TENN. DIV. OF WATER RES., http://environment-online.tn.gov:8080/pls/enf_reports/f?p=9034:34001 (last visited Nov. 13, 2017).