NOTES

Antibiotics: It's What's for Dinner

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I. INTRODUCTION

Raising livestock today is a vastly different process than it was just fifty years ago.[1] Hundreds of thousands of independent farms raising a variety of animals have been replaced with just a few thousand "concentrated animal feeding operations" ("CAFOs").[2] These factory farms house hundreds of animals of one

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1. FOOD & WATER WATCH, FACTORY FARM NATION: HOW AMERICA TURNED ITS LIVESTOCK FARMS INTO FACTORIES iv (2010), http://www.factoryfarmmap.org/wp-content/uploads/2010/11/FactoryFarmNation-web.pdf.

2. *Id.* at 2; JAMES M. MACDONALD & WILLIAM D. MCBRIDE, THE TRANSFORMATION OF U.S. AGRICULTURE: SCALE, EFFICIENCY, AND RISKS, U.S. DEP'T OF AGRIC. ECON. INFO. BULL. NO. 43 (Jan. 2009), http://www.ers.usda.gov/media/184977/eib43.pdf. The Environmental Protection Agency ("EPA") defines "CAFO" as an animal feeding operation where animals are "stabled or confined and fed or maintained a total of 45 days or more in a 12-month period." 40 CFR § 122.23(b) (2012). This note uses the terms "CAFO" and "factory farm" interchangeably.

species in warehouse-type buildings or large pens, typically use purchased feed rather than feed grown on-site, and specialize in single stages of livestock production.[3] CAFOs are a farm animal's worst nightmare—they are overcrowded, dirty, poorly ventilated, and house animals bred for rapid and extreme growth.[4] Animal feed is spiked with a cocktail of hormones, additives, and antibiotics to further increase animal size and to reduce the amount of feed necessary to enhance growth.[5] CAFOs do, however, provide a source of low-cost meat due to subsidies, efficiencies, and economies of scale.[6] Today, the United States' four largest livestock industries are beef cattle, broilers (chickens), hogs, and dairy, with most CAFOs concentrated in the center and outer edges of the country.[7] Up to ninety-nine point nine percent of the chicken and seventy-eight percent of the beef Americans consume comes from CAFOs.[8]

Factory farms are able to increase their production rate due in large part to more advanced technologies, including larger and faster equipment, more precise animal breeding techniques, chemical fertilizers that accelerate feed growth, and pharmaceuticals that increase animal size and reduce mortality.[9] Along with new technologies, policies also serve to encourage the growth of large-scale farming.[10] According to a recent report by Food & Water Watch, large agribusinesses pushed three policies that were particularly instrumental in this growth: "farm bills artificially lowered the cost of crops destined for livestock feed; the EPA ignored factory farm pollution; and the Department of Justice ("DOJ") allowed the largest meat packers to merge into a virtual monopoly."[11] Vertical integration of meat production—single farms both producing and processing beef—has further increased output while decreasing cost.[12]

This note discusses a significantly troubling byproduct of the widespread practice of factory farming: antibiotic overuse in livestock production. Moreover, this note highlights the failure to adequately regulate antibiotic overuse in factory farming. Incredibly, there are no mandatory federal prohibitions on the use of

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3. The dairy industry is an exception to this trend; dairy farms generally still grow at least some of their own feed and participate in multiple stages of dairy production. MacDonald & McBride, *supra* note 2, at 1.

4. *See* CTR. FOR FOOD SAFETY, AMERICA'S SECRET ANIMAL DRUG PROBLEM: HOW LACK OF TRANSPARENCY IS ENDANGERING HUMAN HEALTH AND ANIMAL WELFARE (Sept. 2015), http://www.centerforfoodsafety.org/files/animal_drug_final_63173.pdf.

5. *Id.*

6. MacDonald & McBride, *supra* note 2, at 20.

7. *Id.* at 1. In 2012, the top ten livestock producers by state were Iowa, Texas, California, Nebraska, Kansas, North Carolina, Minnesota, Colorado, Idaho, and Wisconsin. FACTORY FARM MAP, FOOD & WATER WATCH, http://www.factoryfarmmap.org (last visited Dec. 18, 2015).

8. FOOD & WATER WATCH, *supra* note 1, at 2.

9. MacDonald & McBride, *supra* note 2, at 2.

10. THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES 222–23 (Daniel Imhoff ed. 2010).

11. FOOD & WATER WATCH, *supra* note 1, at 2.

12. UNION OF CONCERNED SCIENTISTS, CAFOS UNCOVERED: THE UNTOLD COSTS OF CONFINED ANIMAL FEEDING OPERATIONS, 10 (2008), http://www.ucsusa.org/sites/default/files/legacy/assets/documents/food_and_agriculture/cafos-uncovered.pdf.

animal antibiotics, despite deep-rooted concerns about the practice, multiple laws and regulations touching on the subject, and consistent criticism by the medical community about overuse.[13] This note discusses the effects of antibiotic use in livestock, the failure of the federal regulatory framework surrounding the practice, and two recent missed opportunities to effectively address the health and environmental consequences of antibiotic overuse.

Part II reviews the science of antibiotic overuse on CAFOs, including effects on human health and the environment, as well as the possible effects of a required reduction in their use. Part III reviews and evaluates the current federal regulatory regime for antibiotic use in livestock. Part IV analyzes two recent missed opportunities for regulating antibiotic use in livestock, including California Senate Bill No. 27[14] and the Food and Drug Administration's ("FDA") new rule on standards for growing produce.[15] Part V concludes by suggesting improvements to the antibiotic regulatory regime.

II. SCIENCE OF ANTIBIOTIC OVERUSE IN CAFOS AND POSSIBLE EFFECTS OF A BAN

Antibiotic use in livestock has increased significantly over the past one hundred years. This section will first discuss the effects of antibiotic overuse in livestock on human health and the environment. It will then describe Denmark's efforts to reduce the use of antibiotics in livestock and the strategies leading to its success.

A. ANTIBIOTIC USE IN CAFOS

CAFOs are defined as facilities where animals are "stabled or confined and fed or maintained for a total of forty-five days or more in a twelve-month period."[16] Hundreds of animals are typically crammed into warehouses or pens where they eat, live, and defecate all in the same place.[17] CAFOs produce hundreds of millions of tons of manure per year, far exceeding the amount produced by human sewage, which animals stand and lie in for most of their lives.[18] The unhygienic and cramped conditions greatly increase stresses on the animal

13. Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 760 F.3d 151, 154 (2d Cir. 2014). The FDA itself even limited the use of cephalosporins in food-producing animals in 2012. *See 35 Years of Resistance*, NATURE REVIEWS MICROBIOLOGY 10, 373 (June 2012), http://www.nature.com/nrmicro/journal/v10/n6/full/nrmicro2813.html.

14. CAL. FOOD & AGRIC. CODE § 14400 (2015).

15. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74,353 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, and 112) [hereinafter FSMA Final Rule on Produce Safety].

16. 40 C.F.R. § 122.23 (2012). Regulations define CAFOs by the number of animals they house. For instance, large CAFOs house more than 1,000 cattle, 10,000 swine, or 125,000 chickens. 40 C.F.R. § 122.23(b)(4). Medium-sized CAFOs house more than 300 cattle, 3,000 swine, or 37,500 chickens. 40 C.F.R. § 122.23(b)(6).

17. FOOD & WATER WATCH, *supra* note 1, at 30.

18. *Id.* at 1.

populations and heightens their susceptibility to infections and disease.[19]

Sustained medication of livestock has become the most popular "Band-Aid" response to this problem.[20] According to the Center for Food Safety ("CFS"), "[t]he animal agriculture industry uses over 450 animal drugs, drug combinations, and other feed additives to promote animal growth and to suppress the negative effects that heavily-concentrated confinement has on farm animals."[21] Livestock antibiotic use is not consigned to CAFOs, but because the vast majority of American livestock for slaughter is raised in these facilities, they are responsible for the largest share of animal antibiotic use.[22]

American livestock producers use antibiotics in their animals for treatment, prophylaxis, and growth promotion.[23] Animals consume antibiotics at much higher levels than humans.[24] Prophylactic use involves administering subtherapeutic doses of antibiotics to non-diseased animals for disease prevention, as opposed to treating acute illness or other pathological conditions.[25] Subtherapeutic administration is also used to promote animal growth and improve feed efficiency.[26] This reduces the amount of feed necessary for production by reducing the microbes in an animal's gut and allowing the energy otherwise used for an immune response to instead be invested in growth.[27]

Subtherapeutic use, both for prophylaxis and growth promotion, acts to select for particularly resistant genes in microbes.[28] Inundating animal feed with a constant source of antibiotics has been shown to increase the development of antibiotic-resistant pathogens ("ARPs," colloquially known as "superbugs") such as Salmonella and E. coli on farms and in the surrounding environment.[29] Antibiotic overuse can increase the longevity of weak or sick animals, thereby passing their weaker traits onto their offspring, and eventually making entire animal populations more susceptible to disease.[30] Roughly eighty percent of the

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19. *Id.* at 26.

20. *Id.* at vi.

21. CTR. FOR FOOD SAFETY, *supra* note 4, at 2.

22. *See Prescription for Trouble: Using Antibiotics to Fatten Livestock*, UNION OF CONCERNED SCIENTISTS, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/prescription-for-trouble.html#.VqufzMeCv9o (last visited Jan. 29, 2016).

23. *See* FOOD AND WATER WATCH, *supra* note 1, at 27.

24. *See* CTR. FOR DISEASE DYNAMICS, ECON. & POL'Y, THE STATE OF THE WORLD'S ANTIBIOTICS 2015, 48 (2015), http://cddep.org/sites/default/files/swa_2015_final.pdf.

25. 21 C.F.R. § 558.15(a) (2015).

26. *See Growth Promoting Antibiotics for Animals*, MICROBEWIKI, https://microbewiki.kenyon.edu/index.php/Growth_promoting_antibiotics_for_animals (last visited Dec. 18, 2015).

27. *See id.*

28. CTR. FOR FOOD SAFETY, *supra* note 4, at 30.

29. William M. McLaren, *The Death of the Duty to Apply: Limitations to CAFO Oversight Following Waterkeeper & National Pork Producers*, 11 J. ANIMAL & NAT. RES. L. 87, 92–93 (2015).

30. Jonathan Knutson, *FDA's New Prescription: Veterinarians Must Give Oversight on Drug Use*, AGWEEK (Nov. 30, 2015), http://www.agweek.com/news/north-dakota/3892847-fdas-new-prescription-veterinarians-must-give-oversight-drug-use.

antibiotics consumed in the United States are administered to animals rather than humans.[31] The United States is second only to China in antibiotic consumption.[32]

Antibiotic waste enters the ambient environment through a number of pathways. First, antibiotics can enter CAFO environments directly through animal feed, water, and excrement.[33] Over seventy-five percent of antibiotics can survive in animal urine and feces and can seep into the soil and groundwater right where the animals live.[34] Second, the massive amount of waste produced at CAFOs is most often repurposed as fertilizer for crops. Fields are substantially overfertilized in order to use extra waste, which increases the antibiotic seepage into soil and groundwater.[35] Third, antibiotics stay in animal tissue for some time before the body metabolizes and excretes them.[36] Although there are required waiting periods before an antibiotic-treated animal can be slaughtered for meat, drugs remaining in animal tissue can still be transferred to the general population within that window—as occurred in at least one case where an active antibiotic remaining in frozen beef caused anaphylactic shock in a man who was allergic to penicillin.[37]

The ARPs or "superbugs" developing from antibiotics in livestock, animal waste, and on manure-laden crops pose grave risks to public health and the environment. The World Health Organization ("WHO") considers antibiotic resistance as one of the most significant threats to human health today.[38] ARPs are dispersed from CAFOs and fields by trucks that transport animals, farmworkers who handle animals, fertilizer spread over crops, wind rising off facilities, water flow from hog lagoons, and flies attracted to manure.[39] Significantly, many of the antibiotics given to animals (sixty-two percent in 2013) are also considered medically

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31. CTR. FOR DISEASE DYNAMICS, ECON. & POL'Y, *supra* note 24, at 48.

32. *Id.* at 40.

33. *Id.* at 45.

34. *Id.*

35. *Id.*

36. *Id.*

37. *See* N. Raison-Payron et al., *Anaphylaxis to Beef in Penicillin-Allergic Patient*, 56 ALLERGY 796 (2001), http://onlinelibrary.wiley.com/doi/10.1034/j.1398-9995.2001.056008796.x/full.

38. "The direct consequences of infection with resistant microorganisms can be severe, including longer illnesses, increased mortality, prolonged stays in hospital, loss of protection for patients undergoing operations and other medical procedures, and increased costs . . . . The indirect impact of antimicrobial resistance, however, extends beyond increased health risks and has many public health consequences with wide implications, for instance on development." Margaret Chan et al., GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE, WORLD HEALTH ORGANIZATION [WHO] (2015), http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1.

39. *The Overuse of Antibiotics in Food Animals Threatens Public Health*, CONSUMERS UNION, http://consumersunion.org/news/the-overuse-of-antibiotics-in-food-animals-threatens-public-health-2/ (last visited Dec. 18, 2015); Kuldip Kumar et al., *Antibiotic Use in Agriculture and Its Impact on the Terrestrial Environment*, 87 ADVANCES IN AGRONOMY 1 (2005).

important to humans.[40] For humans infected with an ARP that has developed in response to a medically important antibiotic, the antibiotic is no longer effective and fewer options exist for human treatment.[41] ARPs contribute to at least two million infections and twenty-three thousand deaths per year.[42]

Strains of ARPs in food can migrate to humans through handling or consumption, and can last in human stool for up to two weeks.[43] The Centers for Disease Control and Prevention ("CDC") published a study showing that almost a quarter of all Methicillin-resistant Staphylococcus aureus ("MRSA") in the Netherlands could be traced to a single strain of the bacteria that had entered the human population from an animal reservoir.[44] Another recent report found that certain bacteria in China are becoming increasingly resistant to Colistin, an antibiotic of "last resort" for dangerous and otherwise-untreatable bacteria.[45] Even more alarming, scientists have reported that antibiotic-resistant bacteria can now easily transfer their resistance to other bacteria; such strains have been found in both animal meat and humans, and may be migrating between countries.[46]

The effects of antibiotic overuse are not felt evenly throughout the U.S. population. A recent study found that "people currently working with swine were six times more likely to be carrying some strain of drug-resistant staph, and 5.8 to 8.4 times more likely to be carrying strains that are specifically linked to hogs."[47] Much of the workforce that handles pigs and other factory-farmed animals is made up of low-income and minority populations, as are the communities surrounding many CAFOs.[48]

In addition to public health impacts, the accumulation of antibiotics in the biosphere "affects the structure and activity of environmental microbiota leading

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40. *62 Percent of 2013 Animal Antibiotics Sales Were Medically Important Drugs*, FOOD SAFETY NEWS (Apr. 13, 2015), http://www.foodsafetynews.com/2015/04/62-percent-of-2013-animal-antibiotics-sales-were-medically-important-drugs/#.VqulgseCv9o.

41. CARRIE HRIBAR, NAT'L ASS'N OF LOC. BOARDS OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 10 (Mark Schultz ed. 2010).

42. CTRS. FOR DISEASE CONTROL AND PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 11 (2013).

43. Bonnie Marshall & Stuart Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718 (2011).

44. Michael Pollan, *Our Decrepit Food Factories*, THE N.Y. TIMES MAG., Dec. 16, 2007, at 625.

45. Jason Beaubien, *E. Coli Bacteria Can Transfer Antibiotic Resistance to Other Bacteria*, NAT'L PUB. RADIO (Nov. 20, 2015), http://www.npr.org/sections/goatsandsoda/2015/11/20/456689272/e-coli-bacteria-can-transfer-antibiotic-resistance-to-other-bacteria.

46. Colistin is often used in animal feed in China because it is a relatively old drug, and therefore cheaper. *See* Maryn McKenna, *Apocalypse Pig: The Last Antibiotic Begins to Fail*, NAT'L GEOGRAPHIC (Nov. 21, 2015), http://phenomena.nationalgeographic.com/2015/11/21/mcr-gene-colistin/.

47. Maryn McKenna, *Is Drug-Resistant Staph a Work Hazard for Farm Workers?*, NAT'L GEOGRAPHIC (May 2, 2015), http://phenomena.nationalgeographic.com/2015/05/02/mrsa-swine-workers/.

48. *See Environmental Racism*, FOOD EMPOWERMENT PROJECT, http://www.foodispower.org/environmental-racism/ (last visited Jan. 29, 2016).

to alteration of the ecosystem."[49] The indirect effects of antibiotics on the food web and other environmental systems have not been well studied, but information on related harms is beginning to come to light.[50] Antibiotic overuse is altering the environment at the ecosystem level, to the extent that ceasing to use any single antibiotic drug will not appreciably effect restoration efforts.[51]

B. POSSIBLE EFFECTS OF A BAN: DENMARK CASE STUDY

Eliminating a large portion of the antibiotics used in livestock, especially medically important antibiotics, is crucial for improving human health and the ability to treat diseases. Although the United States still has no mandatory regulations in place forbidding subtherapeutic use in animals, other countries, most notably Denmark, have had laws on the subject for a decade or more.[52] In 1998, Denmark banned the use of antibiotics for growth promotion in broiler chickens and pigs.[53] Although disease prevention usage is not entirely prohibited, veterinarians must prescribe the use of any antibiotic to animals and they cannot profit from sales of the drugs.[54] Even with a minor increase in therapeutic antibiotic use, overall use in Danish livestock decreased thirty-six percent by 2003 in response to the law.[55]

The ban did not come without some initial downsides for industry. In the years immediately following the law, young pigs experienced an increase in diarrhea and mortality, largely due to the initial failure of farmers to make adequate changes to their practices in response to the ban.[56] There were no similar effects on chickens.[57] Danish farmers were able to reverse those trends and improve animal welfare at the same time by altering on-farm conditions, such as cleaning more frequently, increasing facility ventilation, allowing more space for animal movement, vaccinating animals, allowing piglets to stay with their mothers longer, and adjusting and slightly increasing animal feed.[58] According to a study by the Pew Charitable Trusts, the economic impacts for the pork industry have been extremely low (slightly more than a one percent increase in production

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49. GODFREY BBOSA & NORAH MWEBAZA, GLOBAL IRRATIONAL ANTIBIOTICS/ANTIBACTERIAL DRUGS USE: A CURRENT AND FUTURE HEALTH AND ENVIRONMENTAL CONSEQUENCES 3 MICROBIOLOGY BOOK SERIES #4 1651 (2013), http://www.formatex.info/microbiology4/vol3/1645-1655.pdf.

50. *See* Kumar, *supra* note 39.

51. Bbosa & Mwebaza, *supra* note 49, at 1651.

52. U.S. GOV'T ACCOUNTABILITY OFF., ANTIBIOTIC RESISTANCE: AGENCIES HAVE MADE LITTLE PROGRESS ADDRESSING ANTIBIOTIC USE IN ANIMALS (2011), http://www.gao.gov/assets/330/323090.pdf.

53. THE PEW CHARITABLE TRUSTS, AVOIDING ANTIBIOTIC RESISTANCE: DENMARK'S BAN ON GROWTH PROMOTING ANTIBIOTICS IN FOOD ANIMALS, (Nov. 1, 2010), http://www.pewtrusts.org//media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/denmarkexperiencepdf.pdf.

54. *Id.*

55. *See* Marshall & Levy, *supra* note 43.

56. Young pig mortality increased for a few years "[b]y less than one percent, according to the WHO." *See* PEW CHARITABLE TRUSTS, *supra* note 53.

57. *Id.*

58. *Id.*

costs) and negligible for the poultry industry.[59] The overall loss to the Danish economy was around 0.03 percent.[60]

The ban has led to marked improvements in reducing ARPs in both farm animals and meat.[61] Studies show that the reform measure has "significantly reduced the prevalence of resistant bacteria and is helping to preserve antibiotics for human diseases."[62] Denmark's success helped persuade the European Union to ban antibiotic use for growth promotion in 2006, but some countries have made less progress than Denmark in reducing the amounts used in animals.[63] One reason for this is that other countries have failed to implement the same agricultural changes now commonplace on Danish farms.[64] Moreover, Danish farmers are subject to public shaming for noncompliance—if farmers skirt the law, they are given a yellow card, fined, and published on a public list.[65]

Still, concerns remain about banning all subtherapeutic uses of antibiotics. Importantly, animal welfare could be compromised—animals are likely to fall sick or die more easily, as seen in the early days of Denmark's ban. There also remains the possibility that an animal could be denied access to antibiotics needed to fight acute disease, especially for farmers without easy access to a veterinarian. Additionally, Denmark's success involved giving animals more room, such as by increasing the amount of land used for raising animals, which could endanger parts of existing forests and their attendant ecosystems. The possible time increase for animals to reach slaughtering weight may also increase the amount of waste produced per animal, which already outpaces the amount of fertilizer necessary for crops.[66] Furthermore, although production costs rose only minimally in Denmark, the United States uses more antibiotics per pound of meat. Consequently, a similar decrease in use could cause a larger increase in the price of meat.[67] One study by researchers at Iowa State University, however, found these fears to be overstated. The results show that a system similar to Denmark's would increase American pork production costs by only $4.50 per animal (not even $0.03 per pound of pork).[68] Even if drastic changes in the way

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59. *Id.*

60. *Id.*

61. Sharon Levy, *Reduced Antibiotic Use in Livestock: How Denmark Tackled Resistance*, 122 ENVTL. HEALTH PERSPS. 6 (2014), http://ehp.niehs.nih.gov/122-a160/.

62. *Denmark Spearheads Fight Against Antibiotic Resistance*, TECHNOLOGIST ONLINE (Aug. 4, 2015), http://www.technologist.eu/denmark-spearheads-fight-against-antibiotic-resistance/.

63. Dan Charles, *Europe's Mixed Record on Animal Antibiotics*, NAT. PUB. RADIO (Mar. 23, 2012), http://www.npr.org/sections/thesalt/2012/03/23/149221287/europes-mixed-record-on-animal-antibiotics.

64. *Id.*

65. Sarah Gonzalez, *Antibiotic Tracking: Do the Danes Have It Right?*, AGRI-PULSE COMM., INC. (July 4, 2013), http://www.agri-pulse.com/uploaded/Antibiotic_tracking_Do_the_Danes_have_it_right.pdf.

66. FOOD & WATER WATCH, *supra* note 1.

67. *See* Levy, *supra* note 61.

68. Barry Estabrook, *Denmark's Drug-Free Pigs*, N.Y. TIMES (Apr. 3, 2015), http://www.nytimes.com/2015/04/03/opinion/denmarks-drug-free-pigs.html.

that CAFO operators produce meat have heavy up-front costs, such costs would be counterbalanced by the improvements to environmental and human health resulting from reduced antibiotic use.

III. FEDERAL REGULATORY SYSTEM

The federal regulatory system surrounding antibiotic use in livestock is not located in one set of rules. Instead, livestock antibiotics are subject to federal law, guidance documents, and executive orders—each of which will be discussed and analyzed in this section.

A. NEW ANIMAL DRUG APPLICATIONS

Before CAFO operators can distribute antibiotics to livestock, the drugs must be approved to verify their safety and efficacy. Currently, hundreds of drugs are available for use in animals in oral, injectable, and other forms.[69]

The FDA, through its Center for Veterinary Medicine ("CVM"), is the main regulatory agency responsible for approving new drugs for use in livestock.[70]

New animal drugs are considered unsafe unless a drug sponsor goes through the approval process outlined in the statute. This process requires a report of investigations showing, among other criteria, the drug ingredients, method of manufacture, whether it is "safe and effective for use," and methods for determining how much of the drug will end up in or on food.[71] Every step of the approval process is conducted by the drug sponsor, including the decision of which drugs to research, the testing for safety and effectiveness, and the drafting of the environmental assessment.[72] The CVM's role is limited to reviewing the application. Importantly, the CVM can refuse to approve a drug if the New Animal Drug Application ("NADA") fails to adequately demonstrate that a drug meets certain safety criteria.[73] To determine safety, the CVM considers factors such as the probability that a person will consume the drug in or on his or her food as well as the drug's cumulative effect on people or animals; environmental effects are not considered.[74]

Though not included in direct safety considerations, approval of a NADA does require the completion of environmental review in accordance with the National

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69. *See generally* 21 C.F.R. pts. 510–58 (1997).

70. *About the Center for Veterinary Medicine (CVM)*, CTR. FOR VETERINARY MED., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm (last visited Jan. 29, 2016).

71. 21 U.S.C. § 360b(b)(1) (2015).

72. FROM AN IDEA TO THE MARKETPLACE: THE JOURNEY OF AN ANIMAL DRUG THROUGH THE APPROVAL PROCESS, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm (last visited Dec. 8, 2015).

73. 21 U.S.C. § 360b(d)(1)(A)−(I) (2015).

74. 21 U.S.C. § 360b(d)(2) (2015).

Environmental Policy Act ("NEPA").[75] Generally, a drug sponsor must prepare an environmental assessment ("EA") to evaluate the potential risk that a drug's approval may pose to the environment.[76] If the CVM determines that the EA shows no significant environmental impact, the drug is issued a Finding of No Significant Impact ("FONSI").[77] If significant impacts on the environment are likely, the CVM must prepare an Environmental Impact Statement ("EIS") with possible alternatives to mitigate the impact.[78] It is rare, however, for the CVM to find an impact significant enough to require an EIS. Allowing the drug sponsors themselves to prepare the initial EA eliminates any incentive to find anything requiring an EIS; most EAs lead the CVM to issue a FONSI instead.

The NADA file is kept entirely confidential during the application process—even its very existence is undisclosed.[79] Only once a drug is approved is it published in the Federal Register.[80] Only at this point are the summaries of the NADA's safety and effectiveness data—which are written by either the sponsor or the CVM—made publically available.[81] NADA EAs and EISs are also

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75. 21 C.F.R. § 25.20(m) (2007). NEPA requires the evaluation of all major agency actions to determine their environmental impacts. 42 U.S.C. § 4332(C) (2015). This generally takes the form of an EA, but a sponsor can potentially avoid an EA by specifying a categorical exclusion.

76. *See* U.S. FOOD & DRUG ADMIN., *Environmental Impact Considerations*, http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/default.htm (last visited July 8, 2014); *see also* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #61, FDA APPROVAL OF NEW ANIMAL DRUGS FOR MUMS (May 29, 2008). A drug may also fall within the categorical exclusion category and be exempt from the preparation of an EA or an environmental impact statement. *See id*.

77. GUIDANCE FOR INDUSTRY #61, *supra* note 76.

78. *See From an Idea to the Marketplace*, *supra* note 72. In February 1994, President Clinton issued Executive Order (EO) 12,898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. Exec. Order No. 12,898, 59 Fed. Reg. 7,629 (Feb. 16, 1994). The accompanying memorandum directs agencies to "analyze the environmental effects, including human health, economic and social effects, of Federal actions, including effects on minority communities and low-income communities, when such analysis is required by the National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. § 4321 et seq." *Id.* As discussed above, the high instances of MRSA found in CAFO workers and those living in surrounding areas have a significant impact on the local population. Both of these populations are typically low-income and made up of predominantly minority members. *See, e.g.*, Wendee Nicole, *CAFOs and Environmental Justice: The Case of North Carolina*, ENVTL. HEALTH PERSPECTIVES (June 1, 2013), http://ehp.niehs.nih.gov/121-a182/; *see generally Antibiotic Resistance Fact Sheet: Latinos Living Healthy*, LEAGUE OF UNITED LATIN AM. CITIZENS ("LULAC") 2, http://lulac.org/programs/health/Pew_Factsheet_Final.pdf (last visited Jan. 29, 2016). There is no mention, however, of environmental justice considerations in FDA regulations describing the contents of FONSIs, EAs, or EISs. *See* 21 C.F.R. §§ 25.40–25.45. The NADA EAs do not contain any analysis of environmental justice. Unfortunately, EO 12,898 explicitly refuses to create any enforceable right, and attempts to require environmental justice analyses in EAs have been overall rejected by courts. *See, e.g.*, Morongo Bank of Mission Indians v. Fed. Aviation Admin., 161 F.3d 569, 575 (9th Cir. 1988). Since EAs are completed by drug sponsors, there is very little incentive to search for and find significant environmental impacts, and even less incentive to consider environmental justice concerns in light of EO 12,898's lack of enforcement right.

79. 21 C.F.R. § 514.11(b) (2014).

80. *Id.*

81. 21 C.F.R. § 514.11(e) (2014). All safety and effectiveness data that have been previously disclosed to the public are also made publically available. 21 C.F.R. § 514(e)(1) (2014).

protected from disclosure until the drug is approved. According to the regulations, "unless the existence of applications . . . has been [previously] made publicly available, the release of the environmental document before approval of [animal drugs] is inconsistent with statutory requirements imposed on the FDA."[82] If the CVM requires the drug sponsor to prepare an EIS, the statement is not released to the public until the drug approval is published in the Federal Register, and only then will the public have opportunity to comment.[83] Astonishingly, drug sponsors can make it through this process by providing only their own studies and analyses of the safety and efficacy of a drug that is likely to find its way directly onto the plates of consumers, while those very same consumers are essentially denied any opportunity to participate in the process.

After the FDA approves an antibiotic for use in animals, its sponsors are required to send the agency annual reports on the quantities distributed and the target animals, but not on who the buyers are or which animals actually receive the drugs.[84] The FDA summarizes the information from all of the drug sponsors each year and makes reports publically available.[85] But the public does not have access to the details of the reports, and even the FDA has noted the limitations of this data.[86] Currently, a proposed rule details administrative practices for drug sponsors who must report and requires them to submit "species-specific estimates

82. 21 C.F.R. § 25.50(b).

83. "Comments on the EIS may be submitted after the approval of the drug, animal drug, biologic product, or device. Those comments can form the basis for the agency to consider beginning an action to withdraw the approval of applications for a drug, animal drug, or biologic product, or to withdraw premarket notifications or premarket approval applications for devices." 21 C.F.R. § 25.52(b) (2003).

84. *See* 21 C.F.R. § 514.80.

85. *See id*. In December 2015, the agency published the public 2014 summary report. *See* U.S. FOOD & DRUG ADMIN., 2014 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS (Dec. 2015), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf.

86. "In accordance with statutory requirements designed to protect confidential business information, annual sales and distribution data are summarized by antimicrobial drug class and only those antimicrobial drug classes and other categories with three or more distinct sponsors of approved and actively marketed animal drug products are independently reported. Antimicrobial drug classes with fewer than three distinct sponsors are reported collectively as 'Not Independently Reported' ("NIR")." 2014 SUMMARY REPORT, *supra* note 85, at 8. The FDA does send the actual reports to the Antimicrobial Resistance Task Force. 42 U.S.C. § 247d-5(a). According to an FDA presentation at the September 30, 2015, public meeting about on-farm data collection, limitations on the information currently collected include:

- "Veterinarians (with certain exceptions) can legally use drugs in an extralabel manner
- Majority of animal feed drugs are approved for multiple indications
- Approved for use in both food- and nonfood-producing animals
- Approved for multiple routes of administration, and as OTC and prescription drugs
- Approved and labeled for use in:—multiple species
    - for multiple indications
    - with multiple dosage regimens
- Because of all these variations—assumptions cannot be made about actual product use
- Sales data represent summary of volume of product sold or distributed through various outlets by the manufacturer intended for sale to the end user
- And not the volume of product ultimately purchased by the end user for administration to animals."

of sales for cattle, swine, chickens, and turkeys."[87] Beyond summarizing the reports, the FDA is not heavily involved in a drug's oversight once it has been approved.[88] The agency typically relies on others to bring new evidence of a drug's safety or efficacy to its attention.[89]

If a drug is later found to be unsafe, the FDA must withdraw it from the market, but only after receiving sufficient notice.[90] *Natural Resources Defense Council v. FDA* controls the scope and requirements of the FDA's withdrawal procedures.[91] Public interest organizations sued the FDA for failing to withdraw approval for several antibiotics used in livestock after the FDA received new evidence that the drugs were unsafe.[92] The basis for the requested withdrawal was a 1972 Task Force finding that subtherapeutic uses of antibiotics led to higher levels of antibiotic-resistant bacteria, which in turn led to public health concerns.[93] In 1977, the FDA issued notices of opportunity for hearing on several drugs and concluded both that the drugs were "not shown to be safe," and that penicillin in particular "may be unsafe" under its approved conditions of use.[94] Almost immediately after this finding, Congress requested that the National Academy of Sciences conduct research in response to the concerns, and the FDA held off on the proposed hearings.[95]

By the time the lawsuit was filed in 2011, the FDA still had not held the proposed hearings—despite two separate petitions in 1999 and 2005 by groups requesting withdrawal of the drugs for subtherapeutic use.[96] A few months after the complaint was filed, the FDA denied both of those petitions.[97] The Second Circuit addressed the question of whether the statute required the FDA to hold the

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CTR. FOR VETERINARY MED., OVERVIEW OF FDA HISTORICAL AND CURRENT ANTIMICROBIAL SALES AND DISTRIBUTION DATA COLLECTION AND ANALYSIS, (Sep. 30, 2015), http://www.fda.gov/downloads/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/UCM464325.pdf.

87. *FDA Releases Proposed Rule to Collect Antimicrobial Sales and Distribution Information by Animal Species*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm446803.htm (last visited Mar. 19, 2016); Antimicrobial Animal Drug Sales and Distribution Reporting, 80 Fed. Reg. 28,863 (May 20, 2015) (to be codified at 21 C.F.R. pt. 514), https://www.federalregister.gov/articles/2015/05/20/2015-12081/antimicrobial-animal-drug-sales-and-distribution-reporting (last visited Jan. 22, 2016). The comment period for the proposed rule closed on August 18, 2015. A final rule has not yet been issued by the agency.

88. CTR. FOR FOOD SAFETY, *supra* note 4, at 7.

89. *Id.*

90. "The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds . . . that such drug is unsafe for use . . . ." 21 U.S.C. § 360b(e)(1) (2015).

91. Nat. Res. Def. Council v. U.S. Food & Drug Admin., 760 F.3d 151 (2d Cir. 2014).

92. These antibiotics included penicillin and tetracycline. *Id.* at 156.

93. *Id.* at 154.

94. *Id.*

95. *Id.* at 155.

96. *Id.* at 156.

97. *Id.*

withdrawal hearings once it found subtherapeutic uses of the antibiotics in animal feed to be unsafe.[98] The court held:

> [1] Congress has *not* required the FDA to hold hearings whenever FDA officials have scientific concerns about the safety of animal drug usage, [2] that the FDA retains the discretion to institute or terminate proceedings . . . , and [3] the statutory mandate . . . limit[s] the FDA's remedial discretion by requiring withdrawal . . . *only* when the FDA has made a final determination, after notice and hearing . . . .[99]

Currently, then, the statute's withdrawal mandate applies once the FDA has held withdrawal hearings and found drugs to be unsafe. Actually holding these withdrawal hearings, however, is not required, even in the face of compelling safety concerns from the agency itself. Since public comments on a NADA EIS are allowed only *after* a drug has been approved, and since evidence of safety concerns post-approval does not require the FDA to take any action, drug sponsors face almost no checks and balances in assuring their drugs can be manufactured, marketed, and sold for use in animal feed.[100]

Besides approving new drug applications, the FDA is also involved in the National Antimicrobial Resistance Monitoring System ("NARMS"), along with the U.S. Department of Agriculture ("USDA") and the CDC. NARMS monitors antibiotic data and trends in the United States.[101] Although it provides useful information on the spread of antibiotic-resistant bacteria and foodborne pathogens, the partnership has no rulemaking authority.

B. ORGANIC FOOD PRODUCTION ACT

The only federal law that prohibits antibiotic use in livestock to some degree is the Organic Food Production Act, which controls farm certification as "organic."[102] Producers of a certified organic farm cannot use antibiotics in feed for growth promotion,[103] subtherapeutic doses of antibiotics,[104] or any drugs in the

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98. *Id.* at 158.

99. *Id.* at 171–72 (emphasis added).

100. In fact, the EPA has listed the drug Erythromycin on its Contaminant Candidate List, which is a list of contaminants that are not yet regulated, but may be in the future because they "present the greatest public health concern related to exposure from drinking water." *Basic Information on the CCL and Regulatory Determination*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/ccl/basic-information-ccl-and-regulatory-determination (last updated Nov. 25, 2015). Erythromycin was issued a FONSI and is currently approved for use in cattle. *Listing of Environmental Assessments and Findings of No Significant Impact*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm (last updated Jan. 7, 2016). *See, e.g.*, Ctr. for Food Safety v. Hamburg, 2015 WL 6755596 (N.D. Cal. Nov. 5, 2015).

101. *See National Antimicrobial Resistance Monitoring System for Enteric Bacteria*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/narms/reports/index.html (last updated Sept. 17, 2015).

102. 7 U.S.C. § 6509 (2015).

103. 7 U.S.C. § 6509(c)(3) (2015).

absence of illness, except vaccines.[105] No antibiotic is on the National List of allowed substances,[106] although, bizarrely, there is a loophole for chickens to receive antibiotics on their first day of life.[107] If a sick animal requires the use of antibiotics, the producer may not withhold treatment, and the resulting animal products cannot be sold with an organic label.[108] This creates an economic loss for farmers when animals get sick and need antibiotics because the animal's meat can no longer be sold at a premium. The requirement can give rise to animal welfare concerns; when non-antibiotic treatments are available for sick animals, farmers have no incentive to also provide painkillers (at additional cost) when the alternative treatments are painful or take longer for animals to heal.[109] When other treatments are unavailable, farmers are incentivized to rush sick animals to slaughter.[110]

C. GUIDANCE FOR INDUSTRY #209 AND #213

The FDA published two guidance documents on medically important antibiotic use in livestock in December 2013: (1) Guidance for Industry ("GFI") #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; and (2) GFI #213, Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209.[111] GFI #209 recommends limiting the use of medically important antimicrobial drugs[112] to those necessary to protect animal health.[113] It attempts to limit use for growth promotion and feed efficiency by specifying that they are not necessary to

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104. 7 U.S.C. § 6509(d)(1)(A) (2015).

105. 7 U.S.C. § 6509(d)(1)(C) (2015).

106. 7 C.F.R. § 205.603 (2016).

107. "(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: Except, [t]hat [. . .] [p]oultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life . . . ." 7 C.F.R. § 205.236 (2016); *see also* Tom Philpott, *Wait, We Inject Antibiotics Into Eggs for Organic Chicken?!*, MOTHER JONES (Jan. 15, 2014, 5:55 AM), http://www.motherjones.com/tom-philpott/2014/01/organic-chicken-and-egg-antibiotics-edition.

108. 7 C.F.R. § 205.238(c)(7) (2016).

109. Robert Grillo, *No Antibiotic Use Means More Pain and Suffering for Organic Dairy Cows*, FREE FROM HARM (Jan. 23, 2013), http://freefromharm.org/animal-cruelty-investigation/no-antibiotic-use-means-more-pain-and-suffering-for-organic-dairy-cows/.

110. *Id.*

111. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY [GFI] #209 THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS (Apr. 13, 2012), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #213, RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 (Dec. 12, 2013).

112. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #152, EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN, APP. A (Oct. 23, 2003), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf.

113. *See* U.S. FOOD & DRUG ADMIN., GFI #209, *supra* note 111, at 21.

safeguard animal health, but does not include limitations for disease prevention purposes.[114] The guidance further recommends bringing animal drug usage under veterinarian supervision.[115] GFI #213 merely gives drug sponsors more specific recommendations on how to voluntarily align their NADAs with GFI #209. Full implementation of the guidance would make use of medically important antibiotics for growth promotion or feed efficiency illegal, and would require a licensed veterinarian to authorize use for "prevention, control, or treatment of a specifically identified disease."[116] To assist veterinarians in following GFI #209 and #213, the FDA published the Veterinary Feed Directive ("VFD") final rule in June 2015.[117]

The guidance documents have two major weaknesses. First, they are "guidance" documents, and drug producers are not required by law to adhere to the recommended practices. Each page of the guidance documents states in bold: "Contains Nonbinding Recommendations."[118] Second, the documents do not recommend a limitation on the prophylactic use of antibiotics, even though, as discussed above, the line between using antibiotics for growth promotion or for prophylaxis is a blurry one.

D. EXECUTIVE ORDER 13,676 AND THE NATIONAL ACTION PLAN

President Obama issued Executive Order ("EO") 13,676 on combating antibiotic-resistant bacteria on September 18, 2014.[119] EO 13,676 directs the federal government to "work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections."[120] Importantly, it establishes the Task Force for Combating Antibiotic-Resistant Bacteria ("Task Force") made up of various agency heads.[121] The Task Force was required to

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114. *Id.*

115. *Id.* at 22.

116. Collecting On-Farm Antimicrobial Use and Resistance Data; Public Meeting; Request for Comments, 80 Fed. Reg. 50,638 (Aug. 20, 2015), http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2768-0001 [hereinafter Collecting On-Farm Antimicrobial Use and Resistance Data].

117. 21 C.F.R. pt. 558. In June of 2015, the FDA published the Veterinary Feed Directive ("VFD") final rule. The VFD requires veterinarians to "engage with the client (i.e., the animal producer) to assume responsibility for making clinical judgments about patient (i.e., animal) health, have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and provide for any necessary follow-up evaluation or care." Over-the-counter medically important antibiotics will now be subject to veterinary oversight. *Fact Sheet, Veterinary Feed Directive Final Rule and Next Steps*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm449019.htm (last updated Dec. 17, 2015).

118. *See* U.S. FOOD & DRUG ADMIN., GFI #209, *supra* note 111.

119. Exec. Order 13,676, 184 Fed. Reg. 56,931 (Sept. 18, 2014), https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria.

120. *Id.* § 1.

121. Membership includes Secretaries of Defense, Agriculture, Health & Human Services as well as representatives from the Department of State, Department of Justice, and the Environmental Protection Agency, among others. *Id.* § 3(a).

submit a National Action Plan to the President by the spring of 2015.[122] Section 4 of the EO also creates an Advisory Council to make recommendations to the President whose members are appointed by the Secretary of Health and Human Services ("HHS").[123]

EO 13,676 is woefully inadequate to address the crisis of antibiotic oversue.[124] Even its substantive provision on improved antibiotic stewardship is weak with regard to antibiotic use in livestock.[125] While the order directs HHS to review existing regulations and propose new ones for hospitals to "implement robust antibiotic stewardship programs," it merely directs the FDA to "continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals."[126] Further, there are concerns that the Presidential Advisory Council members lack adequate expertise in animal agriculture.[127]

Pursuant to EO 13,676, the White House released the President's National Action Plan for Combating Antibiotic-Resistant Bacteria ("National Action Plan") in March 2015.[128] The plan identifies five goals: slow the emergence of antibiotic-resistant bacteria, increase surveillance, develop better tests, advance research for new antibiotics and other drugs, and collaborate internationally.[129] The goals are broken down into objectives, two of which are relevant to regulating antibiotic use:

- 1.2—Eliminate the use of medically-important antibiotics for growth promotion in food-producing animals and bring other agricultural uses of antibiotics, for treatment, control, and prevention of disease, under veterinary oversight;

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122. *Id.* § 3(c)(i).

123. *Id.* § 4; *see also Membership: Presidential Advisory Council on Combating Antibiotic Resistant Bacteria*, U.S. DEP'T OF HEALTH AND HUMAN SERVS. http://www.hhs.gov/ash/carb/membership/index.html (last updated Sept. 15, 2015).

124. Exec. Order 13,676, *supra* note 119, § 10(c).

125. *Id.* § 5.

126. *Id.*

127. Congresswoman Louise M. Slaughter, *Slaughter, Advocates Decry Unbalanced White House Antibiotics Taskforce* (Sept. 17, 2015), https://louise.house.gov/media-center/press-releases/slaughter-advocates-decry-unbalanced-white-house-antibiotics-taskforce. Currently, three of the four members with veterinary degrees have downplayed the severity of antibiotic resistance. *See, e.g.*, Peter Davies & H. Scott Hurd, *Antibiotics for Animals: Dangerous for Humans?*, BESTFOODFACTS.ORG (Feb. 29, 2012), http://www.bestfoodfacts.org/food-for-thought/animalantibioticsdangerous; *see generally Advances in Animal Health in the Livestock Industry: Hearing Before the Subcomm. on Livestock, Dairy and Poultry of the H. Comm. on Agriculture*, 110th Cong. (2008) (statement of Dr. Randall Singer, Associate Professor of Epidemiology, Univ. of Minnesota); Kindra Gordon, *Antibiotics Issue Must Remain Science-based*, ANGUS PRODUCTIONS, INC. (2011), http://www.rangebeefcow.com/2011/summaries/MikeApleyAntibiotics.html.

128. THE WHITE HOUSE, NATIONAL ACTION PLAN FOR COMBATTING ANTIBIOTIC-RESISTANT BACTERIA, https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf (2015) [hereinafter NATIONAL ACTION PLAN].

129. *Id.*

- 2.4—Enhance monitoring of antibiotic-resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain for food animals and retail meat.

Section 1.2 mirrors GFI #209 and #213 and encourages drug sponsors to curb the use of their medically important antibiotics for growth promotion. Three drug companies have already announced new commitments under Section 1.2; on June 2, 2015, President Obama signed a Presidential Memorandum directing federal agencies to preference contracts with those producing meat in accordance with the guidance.[130] An FDA update notes that "[a]ll of the affected drug sponsors have committed in writing to making the changes described in the guidance."[131]

The National Action Plan also outlines its goal to increase surveillance efforts and includes Objective 2.4 to "[e]nhance monitoring of antibiotic-resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain for food animals and retail meat."[132]

Once a drug has been approved for use in livestock, a drug sponsor is free to sell it according to its label.[133] While CAFO operators technically can only use the drug according to its restrictions, they are not required to report detailed usage to any government agency.[134] The USDA's National Animal Health Monitoring System periodically collects some information on antimicrobial resistance from operators, but the surveys are voluntary and kept confidential.[135]

In response to the National Action Plan, and in recognition of the dearth of information on how antibiotics are used in CAFOs and how precisely they are contributing to antibiotic resistance, the FDA collaborated with the USDA and the CDC to hold a public meeting on September 30, 2015, on possible approaches for collecting this on-farm data.[136] Once again, the National Action Plan's sub-objectives dealing with on-farm data specify that sampling and monitoring will be voluntary and confidential.[137] The information available on the meeting

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130. OFFICE OF THE PRESS SECRETARY, EXEC. OFFICE OF THE PRESIDENT, FACT SHEET: OVER 150 ANIMAL AND HEALTH STAKEHOLDERS JOIN WHITE HOUSE EFFORT TO COMBAT ANTIBIOTIC RESISTANCE (2015).

131. *FDA Releases Biannual Progress Report, Announces Public Meeting on Use of Antimicrobials in Food Producing Animals*, U.S. FOOD & DRUG ADMIN., (Aug. 21, 2015), http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm459365.htm.

132. *See* NATIONAL ACTION PLAN, *supra* note 128.

133. Generally, this means over-the-counter, although steps are being taken to require a veterinarian's prescription for medically important antibiotics. *Phasing Out Certain Antibiotic Use in Farm Animals*, U.S. FOOD & DRUG ADMIN., (Feb. 25, 2015), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm.

134. *Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan*, U.S. DEP'T OF AGRIC., ANIMAL & PLANT HEALTH INSPECTION SERV., (Apr. 2015), https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf [hereinafter Proposed Initiatives].

135. *Id.*; *National Animal Health Monitoring System: National Studies of U.S. Livestock and Poultry*, U.S. DEP'T OF AGRIC., ANIMAL & PLANT HEALTH INSPECTION SERV., program aid no. 2039 (Apr. 2010), https://www.aphis.usda.gov/animal_health/nahms/downloads/NAHMS_brochure.pdf.

136. *See* Collecting On-Farm Antimicrobial Use and Resistance Data, *supra* note 116.

137. *See* NATIONAL ACTION PLAN, *supra* note 128.

notice webpage includes a PowerPoint presentation by the USDA that gives an overview of its proposed initiatives for complying with Objective 2.4. The presentation again highlighted the confidential nature of its surveys.[138] The public comment period closed on November 30, 2015, and there have been no updates as of yet.[139]

Unfortunately, there are still major weaknesses in the National Action Plan. First, this commitment remains voluntary. The voluntary status of the guidance documents is peppered throughout the Plan, EO 13,676 is lacking substantively to combat antibiotic overuse, and Objective 1.2 is just that—an objective. Second, even if every drug company embraces the guidance documents, prophylactic use will still be allowed, though it will need to be prescribed by a veterinarian, rather than being available over-the-counter. Third, the policy still allows antibiotic use without requiring any mitigation of problematic CAFO conditions, such as overcrowding or dirty facilities, which often lead to animal disease in the first place. Fourth, the line between disease prevention and growth promotion is often unclear and the guidance does not prohibit drug sponsors from using ambiguous language on their labels. For instance, "[a]bout one quarter of medically important antibiotics (66 of 287) can be used in one species for disease prevention at levels fully within the range of growth promotion and with no limit on the duration of treatment."[140] Drug sponsors will likely ask FDA for a change in their directions of use, which can include the same dosages for prophylaxis as for growth promotion and will do very little to curtail antibiotic use. Lastly, the application process stays the same; there is no additional transparency, and EISs can be challenged only after a drug is approved.

E. PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT

Rep. Louise Slaughter (D-NY), the only microbiologist in Congress, has introduced the Preservation of Antibiotics for Medical Treatment Act ("PAMTA") every year since she became its primary sponsor in 2007.[141] PAMTA amends the NADA process to prohibit drug approval for nontherapeutic use if it leads to antimicrobial resistance, and puts the onus on the sponsors to demonstrate that it does not.[142] The act contains strong language banning the nontherapeutic use of

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138. *See USDA APHIS Proposals for Collection and Analysis of Antimicrobial Use and Resistance Data*, U.S. DEP'T OF AGRIC., (Sept. 30, 2015), http://www.fda.gov/downloads/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/UCM464315.pdf.

139. *See* Collecting On-Farm Antimicrobial Use and Resistance Data, *supra* note 116.

140. *Gaps in FDA's Antibiotics Policy: Many Drugs May Still be Available for Food Animals at Growth-Promotion Levels*, THE PEW CHARITABLE TRUSTS (Nov. 30, 2014), http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2014/11/gaps-in-fdas-antibiotics-policy.

141. *Antibiotic Resistance*, CONGRESSWOMAN LOUISE M. SLAUGHTER, https://louise.house.gov/issues/antibiotic-resistance (last visited Dec. 18, 2015); Preservation of Antibiotics for Medical Treatment Act of 2015, H.R. 1552, 114th Cong. (2015) [hereinafter PAMTA].

142. PAMTA, *supra* note 141.

antimicrobials, while still allowing for the treatment of sick animals, and requires affirmative withdrawal of drugs failing to meet the standards by the FDA within two years.[143] It pins the definition of "medically important antimicrobial" to the WHO's WHO publicized list.[144]

PAMTA has been introduced in Congress since 1999 and is currently sponsored by sixty Democrats, sixteen of whom are from California, and no Republicans.[145] In 2011, ninety-two representatives signed on as cosponsors, showing a decrease in support of about a third.[146] Likely because of the strong prohibitions and affirmative mandates the bill contains, the bill-tracking website govtrack.us gives the bill a zero percent chance of passage this year.[147] Unsurprisingly, PAMTA faces strong opposition from industry.[148]

IV. RECENT MISSED OPPORTUNITIES

Limiting the use of antibiotics in livestock in the United States has been largely unsuccessful. Two recently passed laws were prime opportunities to strengthen the system: California's partial ban on certain types of livestock antibiotic use and a new federal rule on produce safety. California's state ban did somewhat improve the current federal system, but did not go far enough. The federal produce rule missed the mark entirely.

A. CALIFORNIA'S LIVESTOCK ANTIBIOTICS LAW

On October 10, 2015, California passed Senate Bill 27, titled Livestock: Use of Antimicrobial Drugs ("SB 27").[149] SB 27 is the first state ban on some uses of medically important antibiotics for use in livestock.[150] Interestingly, California is

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143. *Id.*

144. *Id.* § 6(a)(II); WORLD HEALTH ORGANIZATION, CRITICALLY IMPORTANT ANTIMICROBIALS FOR HUMAN MEDICINE (3rd Rev. 2012), http://www.who.int/foodsafety/publications/antimicrobials-third/en/.

145. PAMTA, *supra* note 141.

146. Helena Bottemiller, *Rep. Slaughter Reintroduces PAMTA, Criticizes FDA Strategy for Tackling Resistance*, FOOD SAFETY NEWS (Mar. 15, 2013), http://www.foodsafetynews.com/2013/03/rep-slaughter-reintroduces-pamta-criticizes-fdas-strategy-for-tackling-antibiotic-resistance/#.Vk8taYSCsXM.

147. *See* PAMTA, *supra* note 141.

148. *Preservation of Antibiotics for Medical Treatment Act (PAMTA) - H.R. 1150*, AM. VETERINARY MED. ASS'N, https://www.avma.org/Advocacy/National/Documents/IB_PAMTA_4-1-2014.pdf (last visited Dec. 18, 2015).

149. CAL. FOOD & AGRIC. CODE § 14400 (2015).

150. *See* Or. Legis. H.B. 2598, Relating to the Provision of Antibiotics to Food-Producing Animals; Declaring an Emergency (2015), https://olis.leg.state.or.us/liz/2015R1/Measures/Overview/HB2598 ("A livestock producer may not provide a medically important antibiotic to a food-producing animal for a nontherapeutic purpose unless: (1) There is a significant risk of a disease or infection that is present on the premises being transmitted to the food-producing animal; (2) The administration of the medically important antibiotic to the food-producing animal is necessary to prevent transmission of the disease or infection; (3) The medically important antibiotic is provided to the food-producing animal for the shortest duration necessary to prevent transmission of the disease or infection; and (4) The medically important antibiotic is provided to the smallest

one of the top five states for livestock production, making it an especially good "petri dish" to determine what parts of the law work.[151] The law is set to take effect January 1, 2018 to allow livestock producers time to adjust their practices, and is administered by the California Department of Food and Agriculture.[152] So far, no lawsuits have been filed challenging the ban.

Substantively, the law bans medically important antimicrobial[153] drugs for use in livestock unless a veterinarian determines that the drugs are necessary to treat or control the spread of disease or to perform animal surgery.[154] Medically important antimicrobials are prohibited from being administered "in a regular pattern" *unless* a veterinarian has prescribed them for such a purpose.[155] A separate provision allows a veterinarian to prescribe a drug prophylactically "to address an elevated risk of contraction of a particular disease or infection."[156] Drugs used for this purpose are never permitted to be administered in a regular pattern.[157] Another provision bans outright the use of these drugs for weight gain or feed efficiency improvements.[158] Violators are subject to daily fines of up to $500 and are required to attend an educational program on antibiotics.[159]

Some reporting is also considered under the new law. While the required reporting is confidential and does not mandate on-farm data, representative samples of information from the food production chain, major livestock segments, and regions with considerable livestock production are still mandatory.[160] Required information includes "drug sales and usage, as well as antimicrobial resistant bacteria and livestock management practice data."[161] This language was significantly watered-down from the bill as originally introduced in December 2014, which required reporting "on the administration of each medically important antimicrobial drug," including the number and species of livestock, the type

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number of food-producing animals necessary to prevent transmission of the disease or infection."); *see also* Alex Zielinski, *The States Trying to Regulate the Use of Human Antibiotics in Livestock*, THINK PROGRESS (Oct. 22, 2015), http://thinkprogress.org/health/2015/10/22/3715031/antibiotic-state-map/.

151. *See Factory Farm Map*, FOOD & WATER WATCH, http://www.factoryfarmmap.org/#animal:all;location:US;year:2012 (last visited Dec. 18, 2015).

152. CAL. FOOD & AGRIC. CODE § 14400-14408 (2015).

153. "Antimicrobial drugs include all drugs that work against a variety of microorganisms, such as bacteria, viruses, fungi, and parasites. An antibiotic drug is effective against bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics." *FDA's Strategy on Antimicrobial Resistance—Questions and Answers*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm#question9 (last updated June 11, 2015).

154. CAL. FOOD & AGRIC. CODE § 14402(a) (2015).

155. *Id.* § 14402(d).

156. *Id.* § 14402(b).

157. *Id.* § 14402(d).

158. *Id.* § 14402(c).

159. *See id.* § 14408 (2015).

160. *Id.* § 14405(b).

161. *Id.* § 14405(b)(1).

of drug and disease, the duration of use, and why it was used.[162]

Another section of the law mandates the development of antimicrobial stewardship guidelines and best management practices.[163] The California Department of Food and Agriculture must consult with the Veterinary Medical Board, the State Department of Public Health, universities, and cooperative extensions to address the proper use of antibiotics in livestock.[164] It highlights alternatives to antibiotic use like vaccines and good hygiene.[165] The provision also emphasizes using antibiotics only when necessary and for the shortest possible duration.[166] There are no due dates for any of the anticipated guidelines or practices.

The new law is certainly a step in the right direction. Most importantly, Section 14402(c) prohibits the use of medically important antimicrobials for growth promotion or improving feed efficiency. Moreover, moving the drugs from over-the-counter status to requiring veterinary oversight is likely to reduce their use at least to some degree. Also, the enforcement section finds that any "person" in violation of the new law can be punished, which could theoretically include not only the livestock producers and farmworkers, but also veterinarians who administer drugs. Additionally, if the guidance and best practices documents on minimizing antibiotic use are written, they may help encourage a transition to farm practices like those used in Denmark.

Other sections of the law, however, remain weak. For instance, although an attempt is made to close the prophylactic use loophole, it does not go far enough. Section 14402(b) specifically allows the use of an antimicrobial for prophylaxis.[167] Although the law prohibits prophylactic use in a "regular pattern" and adds the word "particular" to modify "disease or infection," neither phrase is defined. Because a drug ostensibly will always be administered in a regular pattern, unless one pill is sufficient for treatment, it is unclear if this prohibition has any meaning whatsoever. Also unclear is Section 14402(a)(2), which permits usage "[n]ecessary to control the spread of a disease or infection" and does not purport to prohibit it in a "regular pattern."[168] The language is ambiguous and could be read to allow for subtherapeutic dosages of medically important antimicrobials to be administered to entire herds or flocks of healthy animals. The prophylactic loopholes remain in the law and can be used as a back-door way to

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162. *See SB-27 Livestock: Use of Antimicrobial Drugs*, CAL. LEGIS. INFO., https://leginfo.legislature.ca.gov/faces/billVersionsCompareClient.xhtml?bill_id=201520160SB27&cversion=20150SB2799INT (last visited Dec. 18, 2015). Changes to the bill included references to the National Action Plan published after the bill's introduction. *Id.*

163. CAL. FOOD & AGRIC. CODE § 14404 (2015).

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.* § 14402(b).

168. *Id.* § 14402(a)(2).

feed antibiotics to animals for growth promotion. Alarmingly, these subtherapeutic dosages are of precisely the type that lead to ARPs.

Alternatively, this unclear language also has the potential to be highly restrictive in the hands of an active agency. This is demonstrated by the law's requirement that the department develop stewardship guidelines to reduce use to only that which is *necessary* to control, and only in some cases to prevent, disease.[169] In particular, the section requires the development of "practical alternatives," such as vaccines and changes to hygiene and management practices.[170] The law also prohibits antibiotic use for weight gain or feed efficiency.[171] More aggressive agency enforcement could rely on construing "regular pattern" in Section 14402(d) as a total ban on any prophylactic use of antimicrobial drugs. This interpretation could represent major progress toward a significant reduction in the use of antimicrobial drugs.

With an active agency interpreting California's law as strictly as possible, however, the same potential problems noted in the Denmark case study discussion remain. Reducing the use of antibiotics without adequately offsetting the change with altered management practices, such as increased ventilation, hygiene, space, and modified feed ratio, could lead to animal welfare concerns. The new law, however, does seem to anticipate this potential issue in the required "practical alternatives" section.[172] Sufficient use of this section could alleviate animal welfare concerns by implementing changes before January 1, 2018.

Beyond failing to conclusively ban prophylactic use, the law also does not implement mandatory surveillance or on-farm reporting of antibiotic use.[173] Instead, the California Department of Agriculture will consult with "willing participants," before reporting to the California legislature by January 2019 on whether there is sufficient participation for statistically relevant data.[174] Without requiring this information, finding and fining violators will be a much more onerous task.[175]

B. PRODUCE SAFETY RULE

Factory farming produces an enormous quantity of animal manure. Food and Water Watch estimated that in 2012, the largest factory farms produced nearly 370 million tons of livestock and poultry manure.[176] After temporary storage in

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169. *See id.* § 14404.

170. *Id.* § 14404(a).

171. *Id.* § 14402(c).

172. *Id.* § 14404(a).

173. *See SB-27 Livestock: Use of Antimicrobial Drugs Bill Analysis*, CAL. LEGIS. INFO. https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201520160SB27 (last visited Dec. 18, 2015).

174. *See* CAL. FOOD & AGRIC. CODE § 14405(c).

175. In contrast, the Danish "yellow and red card system ensures producers who use antibiotics in a non-compliant way will be fined and published on a public list." Gonzalez, *supra* note 65.

176. FOOD & WATER WATCH, *supra* note 1, at 5.

manure pits or lagoons, the waste is typically spread over farm fields as fertilizer.[177] Smaller farms have used manure as fertilizer for years, but the sheer amount of manure produced by CAFOs leads to over-application in an attempt just to get rid of the waste.[178] The excessive application allows manure and its ingredients to seep into the surrounding soil and groundwater.[179] Crops grown in animal manure fertilizer absorb crucial nutrients from it, but have been found to also absorb the antibiotics fed to livestock.[180] While, according to one study, "[l]ess than 0.1 percent of antibiotics applied to soil were absorbed into the corn, lettuce and other plants," consistent low-level amounts of antibiotics are exactly the type most likely to lead to ARPs.[181]

On November 13, 2015, the FDA released a new rule on produce safety in response to concerns about food-borne illnesses.[182] It covers a wide range of "science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption."[183] The rule focuses on those fruits and vegetables that can be eaten raw, as opposed to, for instance, beans grown for canning.[184] It includes standards for, among many other things, "biological soil amendments of animal origin," ("BSAs"), which is essentially fertilizer made from animal manure.[185] The rule's 319 pages, however, do not contain any standards for limiting antibiotics in manure-based fertilizer.[186] In fact, the word "antibiotic" is mentioned only once in the rule, in a response to a comment filed by the CFS.[187] Any discussion of "antimicrobials" is related to cleaning produce or adding them to produce wash water, rather than noting concerns about ARPs.[188]

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177. *Id.* at iv.

178. *Id.*

179. *Id.* at 2.

180. *See* Matthew Cimitile, *Crops Absorb Livestock Antibiotics, Science Shows*, ENVTL. HEALTH NEWS (Jan. 6, 2009), http://www.environmentalhealthnews.org/ehs/news/antibiotics-in-crops.

181. *Id.* Of particular concern are types of produce typically eaten raw, given that antibiotics can be broken down using heat, as well as produce such as carrots or potatoes that grow in direct contact with soil and may take up more antibiotics. *Id.*

182. *See* FSMA Final Rule on Produce Safety, *supra* note 15; *see also FDA Releases Groundbreaking Food Safety Rules for Produce Farms and Imported Food to Modernize and Strengthen Food Safety System*, U.S. FOOD & DRUG ADMIN., (Nov. 13, 2015), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472426.htm.

183. *Id.*

184. *See* Mary Clare Jalonick, *New Produce Safety Rules Aim to Prevent Illness Outbreaks*, SCI-TECH TODAY (Nov. 16, 2015), http://www.sci-tech-today.com/news/New+Produce+Safety+Rules+Announced/story.xhtml?story_id=0030002AC8BC.

185. *See* FSMA Final Rule on Produce Safety, *supra* note 15 (to be codified at 21 C.F.R. pts. 112.51 and 112.52).

186. *Fact Sheets on the Subparts of the Original FSMA Proposed Rule for Produce Safety*, U.S. FOOD & DRUG ADMIN., (Jan. 2013), http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334552.htm#F.

187. *See* FSMA Final Rule on Produce Safety, *supra* note 15.

188. *See id.* at 74,399.

The rule does specify some procedures for the application of raw sewage to crops.[189] The Key Requirements section on the rule's webpage notes that the FDA is assessing the amount of time necessary between the application of raw manure to a field and the harvesting to minimize contamination.[190] Further, raw manure must be applied without coming into contact with produce, and in a way that minimizes the potential for contact afterwards.[191]

Discussion of antibiotics in fertilizer, however, is almost nonexistent. The rule's accompanying EIS includes only one such comment in its "substantive comments" section.[192] This comment was in response to the Draft EIS and was filed by the CFS.[193] CFS spent most of its comment on other topics, but in regards to livestock antibiotic and manure fertilizer, it stated:

> In fact, soil compaction, concentrated waste, and increased chemical use are all significant environmental hazards that could have direct adverse impacts on water, soils, and ecological and biological resources despite their temporal reality. This may be especially true, for example, if the concentrated livestock are routinely treated with antibiotics, which can enter local environments from animal wastes and promote the spread of antibiotic resistant bacteria. The concentration of animal wastes may be a short-term issue, but the impacts from the runoff of wastes with high prevalence of bacteria resistant to medically-important antibiotics are much longer lived and certainly significant. The EIS's failure to consider impacts as significant solely on the grounds that they may not be permanent is an insufficient assessment of environmental impacts and falls short of NEPA requirements.[194]

The FDA's response in the EIS is largely not a response at all—it merely says the rule will not change anything about either current antibiotic use in livestock or about existing conditions of antibiotic residue in the fertilizer, and "[t]herefore, FDA made no changes."[195] The EIS also sidesteps concerns about livestock

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189. *See id.* at 74,353–74,672.

190. *FSMA Final Rule on Produce Safety*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm (last updated Dec. 3, 2015).

191. *Id.* The FDA further discussed stabilized compost: "Microbial standards that set limits on detectable amounts of bacteria (including Listeria monocytogenes, Salmonella spp., fecal coliforms, and E. coli 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards." *Id.*

192. *Final Environmental Impact Statement for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, U.S. FOOD & DRUG ADMIN., E−22 (Oct. 2015), http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM470749.pdf [hereinafter EIS].

193. *Id.* (Letter from Cameron Harsh, Research Assoc., Ctr. for Food Safety, Comments Re: Draft Environmental Impact Statement on Food Safety Modernization Act (FSMA) Produce Rule, to Leslie Kux, Assoc. Comm'r for Policy, U.S. Food & Drug Admin. (Mar. 13, 2015) (affixed to EIS) at 5.).

194. *Id.* at E−32.

195. According to the FDA, "the treatment of animals on livestock operations with antibiotics would not change as a result of any proposed requirements in the [new rule], if finalized. Further, the minimum application intervals between BSA application and harvest are not expected to result in any changes to existing conditions

antibiotics in a section on composting, by noting that the Clean Water Act may regulate raw manure where there is a potential to release pollutants, including antibiotics.[196]

In the final rule, concerns about raw manure and antibiotics are noted in the "Comments on Non-Biological Hazards."[197] The FDA acknowledges there were comments about human health concerns involving antibiotics and that there is minimal "research on the risks presented by pharmaceuticals present in produce-growing soils that have been treated with biosolids, and any subsequent uptake into plants."[198] The agency's response is simply that it is limiting the scope of the rulemaking to biological hazards:

> As discussed previously, FDA's analysis of the potential for chemical hazards (including heavy metals and drug residues) to contaminate produce and cause serious adverse health consequences or death, as well as the adequacy of existing regulatory programs to address such potential, did not demonstrate that additional regulation was reasonably necessary. We conclude that it is not reasonably necessary to establish controls for physical or chemical (including radiological) hazards in this rulemaking in light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards.[199]

The FDA missed a key opportunity to limit the spread of antibiotic-resistant bacteria through this rule.[200] Even with a required time interval between application of manure and harvest, antibiotic-resistant bacteria can spread if the manure had antibiotics in it at any point. If the agency had limited the amount of allowable antibiotics in raw manure fertilizer, livestock producers would have been incentivized to either reduce antibiotic use in their animals or be forced to treat manure before spreading it on fields. Either way, a limit on antibiotics in manure could have minimized antibiotic release into the environment near croplands, at the very least. Unfortunately, CFS's comment was the only one involving livestock antibiotic use that was included in the EIS's "substantive comments" section.[201] Judicial review requires possible plaintiffs to exhaust other administrative remedies before bringing a complaint against an agency

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with respect to antibiotic residues in BSAs on a regional or national level. Therefore, FDA made no changes in response to [the] comment." *Id.* at E−22.

196. *Id.* at E−83.

197. FSMA Final Rule on Produce Safety, *supra* note 15.

198. *Id.*

199. *Id.*

200. Furthermore, the EIS environmental justice analysis did not address the concerns with heightened health impacts on farmworkers or the threat posed by ARPs. Instead, "significant" environmental justice was defined in terms of farmworker employment availability and ability to own a farm as a minority. EIS, *supra* note 192, at 4–7.

201. *Id.* at E–22.

decision.[202] For an EIS conducted under NEPA, this means the comments must include enough detail so that the FDA, in this case, is on notice and had the opportunity to consider any claims a plaintiff brings in a lawsuit.[203] Since comments about raw manure and antibiotics were voiced before the rule was officially issued, groups like CFS should be able to cross an exhaustion hurdle in any future challenge to the rule.

If a group did bring a suit against the FDA for failing to adequately address concerns about antibiotics in raw manure fertilizer, the challenge would have to be brought under the Administrative Procedure Act.[204] Under this Act, courts apply an arbitrary and capricious standard to agency action.[205] The court would have to ensure that the agency took a "'hard look' at the environmental consequences of a project before taking a major action."[206] The FDA's response in its EIS to comments about antibiotics is circular and does not adequately consider the potential environmental ramifications of allowing raw sewage. This failure should fall into the "arbitrary and capricious" category and could be an important vessel for the public to strengthen the current voluntary measures that are in place.

V. CONCLUSION

The regulatory framework surrounding antibiotic use in livestock is weak and does not effectively address the substantial health and environmental concerns raised by the issue. A recently released FDA summary report highlights the disconnect between meat producers' promises under the National Action Plan to cut back on drug use and data showing increases in antibiotics sales to producers.[207] California's new law, while a step in the right direction, is not strong enough to entirely foreclose the backdoor prophylactic loophole. The FDA's new produce rule almost entirely ignores problems with antibiotic residue in raw manure fertilizer. If meat producers are truly going to reduce livestock antibiotic use, mandatory rules regulating subtherapeutic dosages are imperative. The FDA should take note of Denmark's success, which was the result of a strategy that

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202. *See* Kleissler v. U.S. Forestry Serv., 183 F.3d 196, 200 (3d Cir. 1999).

203. *See id.* at 202.

204. 5 U.S.C. § 706(2)(A).

205. *See* Dubois v. U.S. Dep't of Agric., 102 F.3d 1273, 1284 (1st Cir. 1996).

206. *Id.*

207. *FDA Annual Summary Report on Antimicrobials Sold or Distributed in 2014 for Use in Food-Producing Animals*, U.S. FOOD & DRUG ADMIN., (Dec. 10, 2015), http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm476256.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery; *see also* Maryn McKenna, *Farm Antibiotics: Still Headed in the Wrong Direction*, NAT'L GEOGRAPHIC (Dec. 14, 2015), http://phenomena.nationalgeographic.com/2015/12/14/adufa-2014/; Dan Charles, *Antibiotic Use on Farms Is Up, Despite Promises to Kick the Drugs*, NAT'L PUB. RADIO (Dec. 11, 2015), http://www.npr.org/sections/thesalt/2015/12/11/459274335/antibiotic-use-on-farms-is-up-despite-promises-to-kick-the-drugs.

mandated limits, closed the prophylactic loophole, and fined and published public records of farmers who break the law.

At the very least, the FDA should follow California's attempt to first outlaw medically important antimicrobial use in animals without an acute infection. It could also require states to set their own regulations, or give out starter subsidies for a few years to farmers who restyle their practices to reduce antibiotic use. To help farmers follow new mandatory rules, the FDA should issue guidance on Danish farming practices that reduce animal illness, such as increasing space, hygiene, and ventilation, and changes in feed. As an incentive to make these changes, farmers should be fined for surpassing antibiotics limits and face public disclosure of violations.

The FDA should also supplement the Produce rule with standards on antibiotic residue in manure. Longer wait periods where antibiotics are fully broken down by the time of manure application will not be enough. Even when antibiotic residue is gone, ARPs developed in raw manure will still remain and transfer from CAFOs to crop fields and the surrounding environment. Limits should be placed on the amount of antibiotic residue at the beginning of the wait period instead.

Scientists, consumers, reporters, and the public have been voicing concern about the overuse of medically important antibiotics in livestock for decades. The regulatory scheme that has grown around the issue is insufficient and must be remedied. Using Denmark as a success story and California's new law as a template, the federal government can and should act to mitigate the human health and environmental impacts of livestock antibiotic overuse.