

ANTIBIOTIC RESISTANCE AND INEFFECTIVE REGULATIONS FOR FACTORY FARMING

MARVI ALI†

Factory farming practices in the United States are accelerating an antibiotic resistance, which will have disastrous effects on human health. Antibiotics were first used in food-producing animals in the 1940s.¹ Agricultural methods for managing livestock have changed dramatically since then, leading to the current reign of industrial factory farms.² Although factory farming³ operations have become more efficient, they generally sacrifice animal welfare to reduce expenses related to living conditions and nutrition.⁴ These animals lack proper food, space, ventilation, and hygiene, and are subjected to high stress.⁵ Poor living conditions weaken the animals' immunity, and housing high numbers of animals in close proximity raises the risk of infection

†. I am a 2017 graduate of the College of William & Mary, and I am now earning a J.D. and a Masters in Sustainability through Wake Forest University's Dual Graduate Degree Program. I would like to thank my parents for their endless love and support in all my endeavors, both including and well beyond academic pursuits. I am now serving as a Notes & Comments Editor for Wake Forest's *Journal of Law & Policy* and will graduate in 2020.

1. Haihong Hao et al., *Benefits and risks of antimicrobial use in food-producing animals*, 5 FRONTIERS IN MICROBIOLOGY 1, 1 (2014).

2. Caline Mattar et al., *One Health and Antimicrobial Resistance*, 62 WORLD MED. J. 108, 109 (2016); FOOD & WATER WATCH, FACTORY FARM NATION 2 (2015), <https://www.foodandwaterwatch.org/sites/default/files/factory-farm-nation-report-may-2015.pdf>.

3. A factory farm is an industrial facility that raises large numbers of farm animals in a confined environment. The animals' movements are prohibited to cages, crates, or being crowded in pens. *Factory Farms*, ASPCA, <https://www.aspc.org/animal-cruelty/farm-animal-welfare> (last visited Sept. 5, 2019).

4. Robert S. Lawrence, *The FDA Did Not Do Enough to Restrict Antibiotics Use in Animals*, ATLANTIC (Apr. 16, 2012), <https://www.theatlantic.com/health/archive/2012/04/the-fda-did-not-do-enough-to-restrict-antibiotics-use-in-animals/255878> (“[I]ndustrial operations that dominate modern food animal production confine hundreds and often thousands of animals in overcrowded and unsanitary facilities.”).

5. *Id.*

and disease.⁶ Factory farms administer antibiotics to animals for three main purposes: (1) disease treatment; (2) disease prevention; and (3) growth promotion.⁷ For disease prevention, animals are regularly fed low-dose antibiotics to ward off nonspecific risks of infection.⁸ Antibiotics used for growth promotion help animals grow quickly to yield more meat and products despite causing poor nutrition and health.⁹ In response to antibiotics, bacteria gradually develop resistant strains.¹⁰ This is most problematic when the antibiotics used for animals are similar to those used in human medicine. Consuming products from factory farms transmits resistant strains of bacteria to humans, rendering traditional medical treatment options for humans ineffective.¹¹

The primary federal agency responsible for regulating antibiotic use in animal products is the Food and Drug Administration (“FDA”), which is aware of the threat of resistance.¹² However, current FDA regulations fall short of providing adequate solutions. The United States Department of Agriculture (“USDA”) sets standards for animal welfare under the Animal Welfare Act (“AWA”), which currently does not cover farm animals, and through the Food Safety Inspection Service (“FSIS”), which reviews antibiotic residue in animal products.¹³ The Centers for Disease Control and Prevention (“CDC”) is tasked with addressing antibiotic resistance generally, but it lacks clarity on

6. CARRIE HRIBAR, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 10 (Mark Schultz ed., 2010), https://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf.

7. *Id.*

8. *Id.*

9. *Id.*; Peter Hughes & John Heritage, *Antibiotic growth-promoters in food animals*, in ASSESSING QUALITY AND SAFETY OF ANIMAL FEEDS 129, 133–34 (2004).

10. HRIBAR, *supra* note 6, at 10.

11. *Id.*

12. *Antimicrobial Resistance Information from FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance-information-fda> (last visited Sept. 5, 2019).

13. *Animal Welfare Act*, U.S. DEP’T OF AGRIC.: ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa (last visited Sept. 5, 2019); *The Food Safety and Inspection Service*, U.S. DEP’T OF AGRIC.: FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/wps/wcm/connect/22dd2ec9-2e85-46f8-8d81-32456616fbbf/QandA2018.pdf?MOD=AJPERES> (last visited Sept. 7, 2019).

how to enact effective directives through inter-agency action.¹⁴ The Environmental Protection Agency (“EPA”) regulates harmful discharges from factory farms, but it does not classify antibiotics or resistant bacteria as hazardous chemicals.¹⁵ Additionally, two proposed bills, Preservation of Antibiotics for Medical Treatment Act of 2017 (“PAMTA”) and Strategies to Address Antibiotic Resistance Act (“STAAR”), have the potential to reduce improper antibiotic use on factory farms by barring use of antibiotics in animals¹⁶ and by monitoring antibiotic resistance.¹⁷

Part I of this Comment explains antibiotic resistance, how factory farms contribute to it, and the need for responsive action. Part II explains current laws and regulations relating to the use of antibiotics in factory farms, critiques their shortfalls, and identifies viable solutions.

I. FACTORY FARMS IMPROPERLY ADMINISTER ANTIBIOTICS TO PREVENT INFECTION AND PROMOTE GROWTH IN FOOD-PRODUCING FARM ANIMALS, WHICH OVER TIME CREATES RESISTANCE AND RENDERS THE ANTIBIOTICS INEFFECTIVE TO HUMANS.

Industrial factory farms, such as Concentrated Animal Feeding Operations (“CAFOs”), have found enormous success in the United States as a way to raise animals quickly in massive proportions.¹⁸ To illustrate, “[i]n 1966, 57 million hogs lived on 1 million American farms; by 2001, roughly the same number of

14. See *U.S. Action to Combat Antibiotic Resistance*, CTR. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugresistance/us-activities.html> (September 10, 2018).

15. 42 U.S.C.A. § 11021(e)(5) (Westlaw through Pub. L. No. 99-499); *Why are CAFOs bad?*, MICH. SIERRA CLUB, <https://www.sierraclub.org/michigan/why-are-cafos-bad> (last visit ed Sept. 5, 2019).

16. Medically-important antibiotics are drugs that are important to treat human diseases. U.S. GOV’T ACCOUNTABILITY OFF., GAO-17-192, ANTIBIOTIC RESISTANCE: MORE INFORMATION NEEDED TO OVERSEE USE OF MEDICALLY IMPORTANT DRUGS IN FOOD ANIMALS (2017).

17. Strategies to Address Antibiotic Resistance Act (STAAR), S. 3176, 114th Cong., 2d Sess. (2016); Preservation of Antibiotics for Medical Treatment Act of 2017, H.R. 1587, 115th Cong. (2007).

18. JAMES MACDONALD & WILLIAM MCBRIDE, U.S. DEP’T OF AGRIC., EIB NO. 43, THE TRANSFORMATION OF U.S. LIVESTOCK AGRICULTURE: SCALE, EFFICIENCY, AND RISKS (2009); HRIBAR, *supra* note 6, at 1 (“The current agricultural system rewards larger farms with lower costs, which results in greater profit and more incentive to increase farm size.”).

hogs were on just over 80,000 farms, and fewer than 5,000 farms accounted for more than half of all hogs produced in the United States.”¹⁹ To accommodate consumer demand and increase profit, factory farms have become efficient at processing the most animals with the least possible expenditure.²⁰ Although these operations reap profits through economic efficiency and processing power, they sacrifice animal health, hygiene, and welfare. The animals are confined with little daylight, fresh air, or space to move, implicating significant animal welfare concerns.²¹ Keeping animals in close quarters creates a breeding ground for bacterial infections that can spread quickly.²² Factory farm animals are especially susceptible to disease because of weakened immunity resulting from stress, poor ventilation, confined spaces, close proximity between sick and healthy animals, and inadequate nutrition.²³

Antibiotics are naturally present in organisms to fend off infection.²⁴ Superfluous antibiotics disrupt natural processes and kill healthy bacteria, weakening an organism’s immune system.²⁵ If irregular concentrations of antibiotics are introduced to an organism’s system, both harmful and non-harmful bacteria respond by developing a resistance.²⁶ Antibiotic resistance is a recognized issue in human medicine, but an overwhelming majority of the antibiotics consumed worldwide is used for animals.²⁷ Nontherapeutic antibiotic use is largely unique to the

19. David Osterberg & David Wallinga, *Addressing Externalities from Swine Production to Reduce Public Health and Environmental Impacts*, 94 AM. J. PUB. HEALTH 1703, 1703 (2004).

20. MACDONALD & MCBRIDE, *supra* note 18, at iii.

21. *Inhumane Practices on Factory Farms*, ANIMAL WELFARE INST., <https://awionline.org/content/inhumane-practices-factory-farms> (last visited Sept. 5, 2019).

22. HRIBAR, *supra* note 6, at 10.

23. Tia Schwab, *Unhealthy Conditions for Farm Animals are—No Surprise—Bad for Humans*, STONE PIER PRESS (May 17, 2019), <https://stonepierpress.org/goodfoodnews/factory-farms-public-health>.

24. See NAT’L CTR. FOR EMERGING AND ZONOTIC INFECTIOUS DISEASES, CTRS. FOR DISEASE CONTROL AND PREVENTION, ANTIBIOTIC USE IN THE UNITED STATES: PROGRESS AND OPPORTUNITIES 7–8 (2017) [hereinafter ANTIBIOTIC USE IN THE U.S.].

25. *Id.* at 8.

26. PAUL EBNER, CAFOS AND PUBLIC HEALTH: THE ISSUE OF ANTIBIOTIC RESISTANCE 2 (2007), <https://www.extension.purdue.edu/extmedia/ID/cafo/ID-349.pdf>.

27. MEAGEN BOHNE & JEAN HALLORAN, CONSUMER REPORTS, MEAT ON DRUGS 2 (2012) (“Some 80 percent of all antibiotics sold in the United States are not used on people but on animals, to make them grow faster or to prevent disease in crowded and unsanitary conditions.”) [hereinafter CONSUMER REPORTS]; Mattar et al., *supra* note 2, at 108.

animal production industry.²⁸ In factory farming operations, antibiotics are administered for three main purposes: (1) disease treatment, (2) disease prevention, and (3) growth promotion.²⁹

As a solution to reduced immunity, facilities administer low-dose antibiotics therapeutically to combat microbial infections that can spread rampantly once introduced.³⁰ This practice constitutes the first use of antibiotics: disease treatment, which is comparable to the way antibiotics are used in human medicine. Second, to mitigate the potential for diseases and bacterial infections, factory farms continually administer low-dose antibiotics for disease prevention.³¹ Generally, even when just a few members of a herd are afflicted with a bacterial infection, antibiotics are administered to all members of the herd to prevent illness.³² Disease prevention constitutes a subtherapeutic use of antibiotics, which, though effective for a period of time, encourages bacteria to develop resistance, thus rendering the antibiotics ineffective in the future.³³ Third, antibiotics are used for growth promotion because they increase growth rate and weight gain, which induces higher yields of meat and products.³⁴ Growth promotion is a misuse of antibiotics because they are not used as “necessary for assuring animal health.”³⁵ Regularly feeding animals antibiotics to enhance growth and increase production of meat, milk, and eggs constitutes a nontherapeutic use of antibiotics.³⁶ Use in growth promotion also contributes to

28. Mattar et al., *supra* note 2, at 109.

29. Timothy F. Landers et al., *A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential*, 127 PUB. HEALTH REP. 4, 6 (2012).

30. See Polly Walker et al., *Public health implications of meat production and consumption*, 8 PUB. HEALTH NUTRITION 348, 352 (2005).

31. WORLD HEALTH ORG., WHO GLOBAL STRATEGY FOR CONTAINMENT OF ANTIMICROBIAL RESISTANCE 37 (2001), http://www.who.int/drugresistance/WHO_Global_Strategy_English.pdf [hereinafter WHO REPORT].

32. *Id.*

33. Walker et al., *supra* note 30, at 352.

34. Laura M. Cox, *Antibiotics shape microbiota and weight gain across the animal kingdom*, 6 ANIMAL FRONTIERS 8 (2016); David L. Smith et al., *Animal antibiotic use has an early but important impact on the emergence of antibiotic resistance in human commensal bacteria*, 99 PROCEEDINGS OF THE NAT'L ACAD. OF SCI. 6434 (2002).

35. U.S. FOOD & DRUG ADMIN., GFI #209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 21–22 (2012) [hereinafter GFI #209].

36. HRIBAR, *supra* note 6, at 10.

development of antibiotic-resistant bacteria which over time makes antibiotics ineffective in treatment for both animals and humans.³⁷

*A. Antibiotic Resistance in Food-Producing Animals
Threatens Human Health*

Subtherapeutic and nontherapeutic antibiotic use in food-producing animals is a public health concern because “[m]any of these antibiotics are closely related to those used to treat infections in humans.”³⁸ Resistant strains of bacteria that develop in factory farm animals threaten the value of antibiotics for human medical treatment.³⁹ The use of antibiotics in animal feed causing antibiotics to be less effective for human medicine is strongly supported by scientific evidence.⁴⁰ When administered to animals, antibiotics kill some bacteria, but resistant bacteria survive and multiply.⁴¹ Human consumers are exposed to harmful, resistant bacteria through food consumption and contact with animals.⁴² Animal waste also contains resistant bacteria and antibiotic residue, which can come into contact with humans through water supplies.⁴³

Antibiotic resistance is a well-established threat to public wellbeing in human medicine.⁴⁴ Clinical research shows that every antimicrobial agent produced has led to the development of

37. *Id.*; Smith et al., *supra* note 34, at 6434 (“[Agricultural antibiotic use] for animal growth promotion or for treatment or control of animal diseases generates reservoirs of antibiotic-resistant bacteria that contaminate animal food products.”).

38. MARGARET MELLON ET AL., UNION OF CONCERNED SCIENTISTS, HOGGING IT: ESTIMATES OF ANTIMICROBIAL ABUSE IN LIVESTOCK xi (2001) (“Tetracycline, penicillin, erythromycin, and other antimicrobials that are important in human use are used extensively in the absence of disease for nontherapeutic purposes in today’s livestock production.”); Jennifer Nomura, *Slowing Antibiotic Resistance by Decreasing Antibiotic Use in Animals*, 15 MINN. J.L., SCI., & TECH., 585, 593 (2014) (stating that the FDA has withdrawn approval to use Baytril® and cephalosporins for animals); Walker et al., *supra* note 30, at 352.

39. MELLON ET AL., *supra* note 38, at 2–3; Walker et al., *supra* note 30, at 352.

40. HRIBAR, *supra* note 6, at 10; Mark Kaufman, *Worries Rise Over Effect of Antibiotics in Animal Feed: Humans Seen Vulnerable to Drug-Resistant Germs*, WASH. POST (Mar. 17, 2000), http://www.upc-online.org/000317wpost_animal_feed.html.

41. CTRS. FOR DISEASE CONTROL AND PREVENTION, U.S. DEP’T OF HEALTH AND HUM. SERVS., ANTIMICROBIAL RESISTANCE FROM THE FARM TO THE TABLE (2017), <https://www.cdc.gov/foodsafety/challenges/from-farm-to-table.html>.

42. HRIBAR, *supra* note 6, at 10.

43. *Id.* at 3 (“[H]uman health can suffer because of contaminated air and degraded water quality, or from diseases spread from farms.”).

44. WHO REPORT, *supra* note 31, at 1.

strains of resistant bacteria.⁴⁵ Higher doses and more frequent use of antibiotics lead to higher levels of resistant bacterial subpopulations.⁴⁶ As a result, there are fewer treatment options available when humans are infected with antibiotic-resistant pathogens.⁴⁷ Consequently, antibiotic resistance increases healthcare costs worldwide,⁴⁸ as well as human suffering and deaths caused by antibiotic-resistant pathogens.⁴⁹ Once antibiotic resistance develops, it is generally slow, difficult and impossible to reverse.⁵⁰ The American Medical Association (“AMA”) opposes the use of antibiotics “at non-therapeutic levels in agriculture, or as . . . growth promoters, and urges that non-therapeutic use in animals of antimicrobials [that are also used in humans] should be terminated or phased out”⁵¹

B. International Responses to Antibiotic Resistance

Antibiotic resistance is an international public health concern, and factory farms are considered a main contributor due to their improper use of antibiotics on farm animals.⁵² The World Health Organization (“WHO”) began addressing the antibiotic resistance phenomenon in 1997.⁵³ WHO urged curtailing use of antibiotics in high population density farming to prevent increased resistance in humans.⁵⁴ WHO labeled antibiotic resistance a “global problem that needs urgent action.”⁵⁵ Although WHO does not have any binding authority in the United States, it encourages national governments to prioritize containment of antimicrobial resistance, develop regulations to limit administration of antibiotics to food-producing animals,

45. *Id.* at 15.

46. *Id.*

47. *Id.* at 12.

48. *Id.* at 11.

49. *Id.*

50. *Id.* at 11–12.

51. AM. MED. ASS’N, RESOLUTION 508 – ANTIMICROBIAL USE AND RESISTANCE (2001), https://www.iatp.org/sites/default/files/64_2_36325.pdf.

52. WHO Report, *supra* note 31, at 4, 37.

53. *Id.*

54. *Id.*

55. *Id.* at 11.

incentivize appropriate use of antibiotics, and research effects of antibiotic resistance in humans.⁵⁶

European countries started banning the use of antibiotics for livestock growth promotion in the 1970s.⁵⁷ The United Kingdom banned the use of penicillin and tetracycline as growth promoters in the early 1970s,⁵⁸ and Norway, Finland, Poland, Denmark, and Switzerland followed suit and banned the use of certain antibiotics as growth promoters in animal feed over the next several years.⁵⁹ In 2006, the European Union enacted a ban on all growth-promoter antibiotics.⁶⁰

II. FEDERAL AGENCIES AND CONGRESS SHOULD COMBAT ANTIBIOTIC RESISTANCE, SPECIFICALLY BY REGULATING USES OF MEDICALLY-IMPORTANT ANTIBIOTICS IN FACTORY FARMS, AND BY REFORMING THE ANTIBIOTIC APPROVAL PROCESS, AMENDING GUIDANCE DOCUMENTS, EXPANDING AGENCY ROLES, PROMULGATING NEW RULES, AND PASSING PROPOSED LEGISLATION.

Congress delegated statutory authority to the FDA to approve new antibiotics for use in food-producing animals.⁶¹ USDA reviews animal products placed on the market, looking at safety and antibiotic residue.⁶² The CDC focuses on antibiotic use and resistance in terms of impact to humans.⁶³ These three agencies, along with state and local public health departments, formed the National Antimicrobial Resistance Monitoring System

56. *Id.* at 5–7.

57. Carol Coglian et al., *Restricting Antimicrobial Use in Food Animals*, 6 MICROBE 274, 278 (2011).

58. STACY SNERINGER ET AL., U.S. DEP'T OF AGRIC., ERS NO. 200, ECONOMICS OF ANTIBIOTICS USE IN U.S. LIVESTOCK PRODUCTION 14 (2015).

59. *Id.*

60. Coglian et al., *supra* note 57, at 278.

61. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 360b(a) (Westlaw through Pub. L. No. 116-56).

62. *See* Animal Welfare Act, 7 U.S.C.A. §§ 2131–2159 (Westlaw through Pub. L. No. 116-56); *see also* Federal Meat Inspection Act (FIMA), 21 U.S.C.A. §§ 601–695 (Westlaw through Pub. L. No. 116-56).

63. Revitalizing the Centers for Disease Control and Prevention, 42 U.S.C. § 247d–4 (Westlaw through Pub. L. No. 116-56).

(“NARMS”) address antibiotic resistance through data collection and monitoring.⁶⁴

The FDA’s and USDA’s current policies governing factory farming practices should be amended to reduce the spread of antibiotic resistance.⁶⁵ The CDC has explicitly articulated its goal to reduce antibiotic resistance, and Congress should grant clearer authority on inter-agency action to support this goal.⁶⁶ The EPA should also use authority from the Clean Water Act (“CWA”) to label antibiotic discharge from CAFOs as a pollutant. The following sections analyze the limitations of current agency authority and regulations and propose suggestions to more effectively combat antibiotic resistance by banning improper antibiotic uses in factory farming.

A. The Food and Drug Administration

Although the FDA has authority over antibiotics administered to food-producing animals,⁶⁷ it has been ineffective in banning the use of antibiotics in factory farms. Under the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”), the FDA approves and regulates antibiotics for animals, monitors safety and effectiveness, and monitors manufacturing and marketing.⁶⁸ The FDA should promote reform in the food-producing industry by expediting the process for recalling antibiotics used in animals, especially for those used in humans, and strengthening Guidance for Industry documents (“GFI”) regarding antibiotic use in animals.

FDA regulation of antibiotics in farm animals was criticized in two noteworthy cases. The Animal Legal Defense Fund of Boston brought one of these cases against a veal producer that failed to disclose to customers the use of antibiotics in its

64. *National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/narms/index.html> (last updated Mar. 15, 2019).

65. *See infra* Parts II.a–II.b.

66. *See infra* Part II.c.

67. *What the FDA Does and Does Not Regulate*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm374203.htm> (last updated Oct. 19, 2017) [hereinafter *FDA Regulations*].

68. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301–399 (Westlaw through Pub. L. No. 116-56); *FDA Regulations*, *supra* note 67.

products.⁶⁹ The Massachusetts state court determined that state courts did not have jurisdiction over this dispute because the FDA is the regulatory agency in charge of antibiotic use.⁷⁰ The Natural Resources Defense Council (“NRDC”) brought the second case in 2012, claiming that the FDA should have withdrawn its approval of penicillin and tetracycline (antibiotics used in both humans and animals).⁷¹ The FDA proposed withdrawing approval in 1977, but Congress required further studies before approving the measure, which led to several years of research.⁷² The FDA withdrew the proposal after releasing GFI documents in 2010 in which the FDA concluded the use of antibiotics was not in the interest of public health and should be limited.⁷³ The GFIs, however, fall short of providing an effective solution.⁷⁴ The court agreed with NRDC and ordered the FDA to initiate withdrawal proceedings for nontherapeutic use of penicillin and tetracycline in animals.⁷⁵

i. Antibiotic Approval and Recall

The FDA should remove antibiotics from the livestock feed market. Better drug assessment, necessary recall, and more stringent approval requirements can reduce antibiotic resistance derived from improper uses in factory farms. In GFI #152, the FDA listed antibiotics considered important to human medicine and directed pharmaceutical companies to assess the risks of antibiotic resistance before issuing approval for use in food-producing animals.⁷⁶ GFI #213 highlighted the importance of periodically reassessing and updating this list.⁷⁷ Updating the list of approved

69. *Animal Legal Def. Fund Bos., Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 279 (D. Mass. 1986).

70. *Id.* at 283.

71. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 131–32 (S.D.N.Y. 2012).

72. *Id.* at 133–35.

73. *Id.* at 136.

74. *See infra* Part II.a.2.

75. *Nat. Res. Def. Council*, 884 F. Supp. 2d at 151.

76. U.S. FOOD & DRUG ADMIN., GFI #152, EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN 2 (2003).

77. U.S. FOOD & DRUG ADMIN., GFI #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 (2013) [hereinafter GFI #213].

antibiotics is easier said than done, however, because the antibiotic approval process is extensive, and recalling a previously approved antibiotic for use in animal feed is difficult and time-consuming.⁷⁸ There has been limited success, however, such as with the FDA's 2005 recall of enrofloxacin for use in poultry after a five-year-long effort.⁷⁹ The FDA should utilize rulemaking to expedite the process for recalling antibiotics that are already on the market.

Furthermore, GFI #152 does not cover antibiotics approved before 2003.⁸⁰ The Infectious Diseases Society of America ("IDSA") pointed out that "almost all antibiotics being used for growth promotion and other non-therapeutic purposes in livestock production were approved by FDA before 2003," so they have not been reviewed for likelihood of antibiotic resistance.⁸¹ Because the recall process is burdensome,⁸² the FDA should expedite the process for identifying and banning antibiotics used on animals that are medically important for treating human diseases, even if previously approved for animal use. The FDA should also conduct post-market safety reviews for antibiotics on the market.⁸³ To more effectively decrease antibiotic resistance, the FDA should reassess antibiotics used on food-producing animals and recall those that are used in human medicine.

ii. Suggestions for GFI Documents #209 and
#213: Mandate Compliance, Proscribe
Preventative Use, and Clarify Language

GFI #209 from 2012 states antibiotics should be used judiciously and limited to "those uses that are considered necessary for assuring animal health."⁸⁴ Specifically, GFI #209

78. U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-801, ANTIBIOTIC RESISTANCE: AGENCIES HAVE MADE LIMITED PROGRESS ADDRESSING ANTIBIOTIC USE IN ANIMALS 25 (2011) [hereinafter GAO-11-801].

79. *Id.*

80. *See id.* at 22.

81. Brad Spellberg et al., *Combating Antimicrobial Resistance: Policy Recommendations to Save Lives*, 52 CLINICAL INFECTIOUS DISEASES (IDSA PUB. POL'Y SUPPLEMENT 5) S397, S420 (2011).

82. *See generally* U.S. FOOD & DRUG ADMIN., ENFORCEMENT MANUAL: APPENDIX IV (2019).

83. Spellberg, *supra* note 81, at S420–21.

84. GFI #209, *supra* note 35, at 21–22.

condemns the use of medically-important antibiotics for growth promotion purposes.⁸⁵ GFI #209 also encourages “veterinary oversight or consultation” for using antibiotics on farm animals.⁸⁶ Antibiotic use for “treatment, control, and prevention of disease” is still permitted.⁸⁷ The accompanying GFI, #213 from 2013, instructs pharmaceutical manufacturers to align their approved antibiotics with #209.⁸⁸ Both GFIs are voluntary, and the phrase “contains nonbinding recommendations” is printed across the top of every page.⁸⁹

There are three main problems with the FDA’s GFIs #209 and #213 as they are currently drafted. First, the guidelines are voluntary.⁹⁰ To have a meaningful effect, the FDA should issue mandatory regulations that industry members are compelled to follow. In addition, the FDA should collect “the antibiotic use data, including the purpose of use, needed to measure the strategy’s effectiveness.”⁹¹ Issuing mandatory rules restricting and monitoring antibiotic use would deter factory farming operations from committing violations and create avenues for enforcing rules and adjudicating disputes.

Second, although the FDA disapproves of the use of antibiotics for growth promotion, it continues to allow subtherapeutic doses to be administered for disease prevention.⁹² The FDA has taken an important first step by stating that “production use indications such as ‘increased rate of weight gain’ or ‘improved feed efficiency’ are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs.”⁹³ However, the FDA should exclude disease prevention from “therapeutic uses that are necessary for assuring the health of food-producing animals.”⁹⁴ Preventative use is not “necessary for assuring animal health,” and therefore should not be included

85. *Id.* at 21.

86. *Id.* at 22.

87. *Id.*

88. GFI #213, *supra* note 77, at 3–5.

89. *Id. passim.*

90. *Id.*

91. GAO-11-801, *supra* note 78.

92. *Id.* at 7.

93. GFI #213, *supra* note 77, at 4.

94. *Id.*

as an acceptable use.⁹⁵ As Congressman Henry Waxman stated to the House of Representatives Subcommittee on Health, “we would be shocked if a pediatrician ever ordered antibiotics for an entire nursery school class to keep the children from being infected with strep throat.”⁹⁶ Waxman explained this is exactly the approach factory farms take, as he criticized using antibiotics for disease prevention and growth promotion, and urged the FDA to adopt stronger regulations.⁹⁷ The FDA should condemn preventative antibiotic use by either revising GFIs, issuing rules reflecting policy statements, or issuing regulations that specifically exclude disease prevention from “necessary use.” Animal health can be improved without preventatively administering antibiotics, by improving living conditions and hygiene practices on factory farms.⁹⁸ Further, allowing preventative use disincentivizes the industry from improving animal welfare conditions.⁹⁹ The Consumers Union¹⁰⁰ recommended the FDA “strengthen these guidelines and establish a mandatory ban on the use of antibiotics in animal production except to treat sick animals.”¹⁰¹ Antibiotic use for disease prevention is a significant contributor to antibiotic resistance and should not be an accepted industry practice, especially when the antibiotics are also used to treat humans.¹⁰²

Third, the language of the GFIs is inconsistent with reducing antibiotic resistance because disease prevention is neither “necessary” for animal health nor a “judicious use” of

95. GFI #209, *supra* note 35, at 3.

96. *Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong., 8 (2010) (statement of Henry A. Waxman, Chairman, H. Comm. on Energy and Commerce) [hereinafter *Antibiotic Resistance Hearing*].

97. *Id.* at 8–9.

98. *Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong., 130 (2010) (statement of Gail R. Hansen, Senior Officer, Pew Charitable Trusts).

99. *See Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance*, WORLD HEALTH ORG. (Nov. 7, 2017), <https://www.who.int/news-room/detail/07-11-2017-stop-using-antibiotics-in-healthy-animals-to-prevent-the-spread-of-antibiotic-resistance>.

100. Consumers Union is the advocacy division of Consumer Reports, which is a large independent product-testing organization. CONSUMER REPORTS, *supra* note 27, at 1. Consumers Union focuses on consumer concerns, including health care and food safety. *Id.*

101. *Id.* at 23.

102. *Stop Using Antibiotics in Healthy Animals*, *supra* note 99.

antibiotics.¹⁰³ Improving living conditions and hygiene would prevent the spread of diseases on factory farms,¹⁰⁴ and would render the use of preventative antibiotic unnecessary. Using antibiotics in food-producing animals reduces effectiveness in human medicine, and thus is not a judicious use.¹⁰⁵ Therefore, to truly restrict antibiotic use in animals to what is necessary and judicious, the FDA should prohibit the use of antibiotics for disease prevention. The American Veterinary Medical Association (“AVMA”) explains that the “judicious use” provision means that veterinarians are obligated to “optimize therapeutic efficacy and minimize antimicrobial resistance.”¹⁰⁶ One of the AVMA’s principles is considering other management and intervention strategies before antimicrobial treatment.¹⁰⁷ The FDA should include other strategies in its GFIs and provide ways the industry can avoid using antibiotics for disease prevention, such as maintaining cleaner facilities and naturally promoting animal health.¹⁰⁸

Implementing these revisions will balance the interests of the industry and pharmaceutical companies with the public interest in preserving effective antibiotics. Additionally, while the GFIs “call for ending the use of antibiotics to make animals grow faster,” FDA continues to endorse “use of [antibiotics] to compensate for overcrowded and unsanitary conditions.”¹⁰⁹ Instead, the FDA should suggest improvements in living conditions for animals in factory farms. Although this may increase costs for industry members, the money saved from the cost of antibiotics can be redirected to improve management practices and animal living conditions.¹¹⁰ That being said, “the cost of producing meat in systems that do not use growth

103. GFI # 213, *supra* note 77, at 4.

104. *General Disease Prevention Practices for Farms*, CTR. FOR FOOD SEC. & PUB. HEALTH, http://www.cfsph.iastate.edu/Animal_Response/English/pdf/H6a_GeneralDiseasePreventionPractices.pdf (last visited Sept. 7, 2019).

105. *Stop Using Antibiotics in Healthy Animals*, *supra* note 99.

106. *Judicious Therapeutic Use of Antimicrobials*, AM. VETERINARY MED. ASS’N, <https://www.avma.org/KB/Policies/Pages/Judicious-Therapeutic-Use-of-Antimicrobials.aspx> (last visited Sept. 7, 2019).

107. *Id.*

108. *General Disease Prevention Practices for Farms*, *supra* note 104.

109. Lawrence, *supra* note 4.

110. See, e.g., Guillaume Lhermie et al., *The farm cost of decreasing antimicrobial use in dairy production*, 13 PLOS ONE, Mar. 22, 2018, at 9 (2018).

promoters [is comparable] with the cost of conventional meat production in the United States.”¹¹¹ Data from Consumer Reports indicates that “‘no antibiotics’ meat and poultry is not as costly as many might assume.”¹¹²

Subtherapeutic and nontherapeutic uses in factory farming are contributing to antibiotic resistance;¹¹³ thus, these industry practices require reform. The FDA has the authority to mitigate antibiotic resistance in humans by strengthening existing regulations regarding antibiotic use in animals and expediting the antibiotic recall process for antibiotics that are creating risks of resistance in human medicine.¹¹⁴

B. The U.S. Department of Agriculture

The USDA should regulate antibiotics by including food-producing animals in their existing regulations or passing new regulations that cover them. The USDA is tasked with developing regulations and directives “to ensure compliance with all relevant federal laws, executive orders, directives, and policies.”¹¹⁵ The USDA regulations cover the following subjects: food distribution, rural development, grain inspection, animal and plant health, crop and livestock insurance, quality assurance, exports, and biotechnology.¹¹⁶ The USDA created the Animal and Plant Health Inspection Service (“APHIS”) in 1972 to govern treatment and care aspects of animal and agriculture management.¹¹⁷ APHIS is tasked with protecting animal health, health and welfare of the United States public, economic interests of livestock industries, the United States environment, and interstate and foreign commerce of animals.¹¹⁸ Current laws that rely on the issue of

111. CONSUMER REPORTS, *supra* note 27, at 6.

112. *Id.* at 15.

113. *Stop Using Antibiotics in Healthy Animals*, *supra* note 99.

114. *FDA Regulations*, *supra* note 67.

115. *Regulations and Directives*, U.S. DEP’T OF AGRIC., <https://www.usda.gov/our-agency/about-usda/laws-and-regulations/regulations-and-directives> (last visited Sept. 7, 2019).

116. *Id.*

117. *History of APHIS*, U.S. DEP’T OF AGRIC.: ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/banner/aboutaphis/SA_APHIS_History (last modified Aug. 3, 2015).

118. *See About APHIS*, U.S. DEP’T OF AGRIC.: ANIMAL & PLANT HEALTH INSPECTION SERV., <https://www.aphis.usda.gov/aphis/banner/aboutaphis> (last modified Aug. 22, 2019).

antibiotic resistance are the Animal Welfare Act (“AWA”) and duties of the Food Safety Inspection Service (“FSIS”).

i. Expanding the AWA to Regulate Farm Animals

Congress should expand the AWA to cover food-producing animals, which would allow it to set standards for their care and treatment.¹¹⁹ The AWA, enacted in 1966, covers only certain animals and establishes standards for transport, sale, and handling as well as for humane treatment in exhibition, sale, research, and transportation.¹²⁰ The AWA does not regulate farm animals, such as livestock or poultry used or intended for use as food or fiber; rather, it regulates domestic animals.¹²¹ The USDA is responsible for setting AWA standards and APHIS enforces them.¹²² Because improper care and treatment of farm animals has directly increased the use of antibiotics in factory farms,¹²³ the USDA should have authority to set standards for living conditions and management practices of regulated animals.

Including farm animals in the AWA would also extend its provisions for the inspection of facilities and the enforcement of USDA standards to factory farms. APHIS inspectors are authorized to regularly conduct unannounced inspections of facilities covered by the AWA.¹²⁴ If the AWA included farm animals, APHIS would be able to promote better living conditions, monitor the factory farming practices, and deter noncompliance with USDA standards.¹²⁵

Redesigning factory farming practices to mitigate the emergence and spread of diseases will reduce the need for antibiotics both in treatment and prevention by improving

119. See Animal Welfare Act, 7 U.S.C.A. § 2132 (Westlaw through Pub. L. No. 116-56) (excluding food-producing animals from the list of animals the Act authorized for regulation).

120. *Animal Welfare Act*, U.S. DEP’T OF AGRIC.: NAT’L AGRIC. LIBRARY, <https://www.nal.usda.gov/awic/animal-welfare-act> (last visited Sept. 7, 2019).

121. Animal Welfare Act § 2132.

122. Tadlock Cowen, CONG. RESEARCH SERV., RS22493, THE ANIMAL WELFARE ACT: BACKGROUND AND SELECTED ANIMAL WELFARE LEGISLATION 1 (2016).

123. CONSUMER REPORTS, *supra* note 27, at 5.

124. *Animal Welfare Act*, *supra* note 13.

125. *Id.*

management practices.¹²⁶ The National Research Council suggests improving living conditions, increasing biosecurity, and providing better nutrition.¹²⁷ These reforms will boost farm animals' immunity via stress reduction and disease control.¹²⁸ Improving living conditions by installing better ventilation, allowing more space per animal, removing dead animals promptly, and implementing better hygiene practices will increase biosecurity and strengthen immunity to help animals fight diseases without antibiotics.¹²⁹

ii. Labeling “No Antibiotics” Products

Congress granted the USDA authority to inspect meat and ensure safety for human consumption through the Federal Meat Inspection Act (“FMIA”),¹³⁰ which the USDA delegated to this FSIS, the agency that reviews safety and proper labeling of animal products.¹³¹ While inspecting food for safety, FSIS tests for residual antibiotics.¹³² The FDA requires minimum intervals between the last dose of an antibiotic given to a farm animal and the time of slaughter to prevent antibiotic residue in meat.¹³³ To enforce these requirements and ensure compliance, FSIS conducts facility inspections.¹³⁴ APHIS and the National Animal Health Monitoring System (“NAHMS”) collect information about how and when antibiotics are given to livestock.¹³⁵ In addition to monitoring approved use, NAHMS should report to the USDA when

126. SNEERINGER ET AL., *supra* note 58, at 8.

127. *Id.* (defining “biosecurity” as “the protection of agricultural animals from any type of infectious agent”).

128. *Id.*

129. *Id.*

130. Federal Meat Inspection Act (FMIA), 21 U.S.C.A. §§ 601–695 (Westlaw through Pub. L. No. 116-56).

131. *Inspection for Food Safety: The Basics*, U.S. DEP’T OF AGRIC.: FOOD SAFETY & INSPECTION SERV., <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/inspection-for-food-safety-the-basics/inspection-for-food-safety-basics> (last visited Aug. 9, 2013).

132. FOOD SAFETY & INSPECTION SERV., 2019 NRP RESIDUE SAMPLING PLANS 6 (2018), <https://www.fsis.usda.gov/wps/wwc/connect/394f0bd4-2c5d-47bc-ba4f-f65992972e43/2019-blue-book.pdf?MOD=AJPERES>.

133. SNEERINGER ET AL., *supra* note 58, at 4.

134. *Inspection for Food Safety: The Basics*, *supra* note 131.

135. GAO-11-801, *supra* note 78, at 13.

unapproved antibiotics are used or when antibiotics are improperly used for growth promotion or disease prevention.

The USDA should authorize FSIS to issue a “no antibiotics” products label that indicates to consumers when no antibiotics were used in raising an animal.¹³⁶ This solution is comparable to the USDA’s “organic” label, which is reserved for animal products with no antibiotics present at slaughter.¹³⁷ Approving and labeling products as “organic” communicates to the public that the products are generally of better quality, justifying slightly higher prices.¹³⁸ If the AWA included farm animals, industry members may suffer financial setbacks to accommodate reforms in animal living conditions and facility management.¹³⁹ Adding a “no antibiotics” label and charging slightly higher prices for products would offset the cost of reforms and communicate to customers that the products are healthier than counterparts produced using antibiotics.¹⁴⁰

Although the USDA lacks authority to approve or remove antibiotics for animal use, it has the power to combat antibiotic resistance through other avenues.¹⁴¹ First, the USDA should authorize FSIS to inspect facilities to ensure compliance with pre-slaughter antibiotic withdrawal intervals and authorize NAHMS to collect more data on antibiotic use in factory farms. Second, the USDA should improve living conditions for farm animals by either amending the AWA to include a section on treatment of farm animals or passing new regulations to govern treatment of animals in factory farms. Third, the USDA should grant FSIS authority to label animal food products as “antibiotic free” after testing them for antibiotic residue.

136. See CONSUMER REPORTS, *supra* note 27, at 23 (except for treatment when necessary).

137. See 7 C.F.R. § 205.238(c)(1) (2017).

138. See EMILY OAKLEY, NAT’L YOUNG FARMERS COAL., VEGETABLE FARMER’S GUIDE TO ORGANIC CERTIFICATION 12 (2014), https://www.youngfarmers.org/wp-content/uploads/2014/02/N_YFC-Organic-Certification-Guide.pdf.

139. See generally *Costs to Farmers and Consumers – Produce Rule*, NAT’L SUSTAINABLE AGRIC. COAL., <http://sustainableagriculture.net/fsma/learn-about-the-issues/costs-to-farmers-and-consumers-produce-rule> (last updated Oct. 2014).

140. See Trisha Calvo & Rachel Meltzer-Warren, *What ‘No Antibiotics’ Claims Really Mean*, CONSUMER REP., <https://www.consumerreports.org/overuse-of-antibiotics/what-no-antibiotic-claims-really-mean> (last updated Nov. 30, 2018).

141. See GIL H. HARDEN, OFFICE OF INSPECTOR GEN., USDA’S RESPONSE TO ANTIBIOTIC RESISTANCE 3–4 (2016).

C. Centers for Disease Control and Prevention

Congress should grant the CDC stronger authority to fulfill its mission of preventing disease and combatting health threats. The CDC focuses on infectious diseases and promoting human health under the Department of Health and Human Services (“HHS”).¹⁴² The CDC first implemented the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria in 2016.¹⁴³ The main goals of the plan are to “rapidly detect emerging antibiotic-resistant threats in healthcare, food, and the community” and to “understand these deadly threats to quickly contain them.”¹⁴⁴

NARMS is an inter-agency organization comprised of the CDC, USDA, FDA, and both state and local public health departments.¹⁴⁵ NARMS is primarily a research group that monitors antibiotic resistance, but it lacks enforcement mechanisms.¹⁴⁶ The FDA has sole authority over the antibiotics themselves, whereas the FDA and USDA have joint authority over industry practices, and the sole USDA has authority over food products for human consumption.¹⁴⁷ The CDC is in a unique position to identify human health risks and set goals to reduce antibiotic resistance.¹⁴⁸ To strengthen NARMS’s ability to implement policy and enforce federal regulations, Congress should delegate broad authority to the CDC to tackle the issue of antibiotic resistance. To join each of the agencies’ component roles, Congress should authorize the CDC to identify areas of concern, propose action, and issue directives through NARMS that

142. *About CDC Organization*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/organization/cio.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fabout%2Forganization%2Findex.html (last updated Sept. 5, 2019).

143. *What CDC is Doing: Antibiotic Resistance (AR) Solutions Initiative*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/solutions-initiative/Index.html> (last updated July 30, 2019).

144. *Lab Capacity: AR Lab Network*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html> (last updated July 29, 2019).

145. TOM FRIEDEN, CTRS. FOR DISEASE CONTROL & PREVENTION, *ANTIBIOTIC RESISTANCE THREATS IN THE U.S.* 36 (2013).

146. *See id.*

147. *See* Anastasia S. Stathopoulos, *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, 433–35 (2010).

148. *See generally Mission, Role and Pledge*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/about/organization/mission.htm> (last updated May 13, 2019).

would shape FDA and USDA policy regarding antibiotic approval and use.

The CDC labeled antibiotic resistance one of the most urgent threats to public health and identified antibiotic use as its greatest cause worldwide.¹⁴⁹ A significant percentage of antibiotics in human medicine and most antibiotics used in animal production are not necessary and proliferate resistant bacteria.¹⁵⁰ The CDC states antibiotic use is appropriate and safe “only when . . . needed to treat disease,” as explained in the CDC’s antimicrobial stewardship program.¹⁵¹ Despite having this knowledge, the FDA approves antibiotics for disease prevention purposes.¹⁵² Because the CDC has conducted studies indicating that using antibiotics for disease prevention contributes to antibiotic resistance,¹⁵³ it should be able to influence the FDA to issue regulations consistent with these findings.

The CDC created the Get Smart program to implement its antimicrobial stewardship program, which is tailored toward health care providers and patients.¹⁵⁴ To protect against antibiotic resistance in humans, the CDC instructs people to “take antibiotics only when needed” and explains that “when a patient takes an antibiotic when it is not needed, the patient gets no benefit and is unnecessarily exposed to preventable, and potentially serious, health problems.”¹⁵⁵ It follows that the same instruction should apply to food-producing animals, especially because they are a key link between antibiotic-resistant bacteria and humans.¹⁵⁶ The CDC should issue stewardship guidance for antibiotic use for farm animals that explains to industry members the impact of preventative antibiotic use and identifying solutions to help reduce the risk of diseases.¹⁵⁷

149. See FRIEDEN, *supra* note 145, at 36.

150. See Landers, *supra* note 29, at 5.

151. FRIEDEN, *supra* note 145, at 31.

152. *Id.*

153. *Id.* at 37.

154. Spellberg et al., *supra* note 81, at S414.

155. ANTIBIOTIC USE IN THE U.S., *supra* note 24, at 2, 5.

Antibiotic Resistance and Food Safety, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/foodsafety/challenges/antibiotic-resistance.html> (last updated Sept. 5, 2018).

156. See Landers et al., *supra* note 29, at 11.

157. See CTRS. FOR DISEASE CONTROL AND PREVENTION, NAT’L PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 9, 21–23 (2015), https://www.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf (“Goal 1: Slow

To more effectively address antibiotic misuse and overuse in factory farms, Congress should clarify the interaction among the CDC, FDA, and USDA, and identify the CDC as the primary agency that governs NARMS and issues policy regarding antibiotic resistance.

D. Environmental Protection Agency

The EPA does not have authority over the administration of antibiotics to farm animals, but it can reduce antibiotic use by labeling antibiotics and resistant bacteria as pollutants to water sources.¹⁵⁸ The CWA requires point sources to obtain a National Pollutant Discharge Elimination System (“NPDES”) permit for discharging pollutants into U.S. waters and gives EPA authority to set pollution control programs.¹⁵⁹ The CWA includes CAFOs as a “point source,” and the definition of “pollutant” includes biological materials.¹⁶⁰ Using antibiotics in animal production causes antibiotics and resistant bacteria to be released into the environment.¹⁶¹ Antibiotic residue and resistant bacteria from animal waste contaminate water supplies that humans use.¹⁶² Including antibiotics and resistant bacteria as pollutants to water supplies under the CWA would allow the EPA to restrict antibiotic use in CAFOs by setting limits for discharge, requiring permits, and enforcing standards. Therefore, the EPA should define antibiotics and resistant bacteria as biological pollutants under the CWA to help reduce antibiotic resistance.

the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections”; “Objective 1.3: Identify and implement measures to foster stewardship of antibiotics in animals.”).

158. See Shane Snyder et al., PHARMACEUTICALS IN THE WATER ENVIRONMENT 9 (2010), <https://www.acs.org/content/dam/acsorg/policy/acsonthehill/briefings/pharmaceuticalsinwater/nacwa-paper.pdf>.

159. Federal Water Pollution Control Act (Clean Water Act), 33 U.S.C.A. § 1342 (Westlaw through Pub. L. No. 116-56).

160. Clean Water Act § 1362(6), (14) (“‘[P]oint source’ means any discernible, confined, and discrete conveyance, including . . . concentrated animal feeding operation . . . from which pollutants are or may be discharged.”).

161. Amy Pruden et al., *Management Options for Reducing the Release of Antibiotics and Antibiotic Resistant Genes to the Environment*, 121 ENV’T HEALTH PERSP. 878, 879 (2013).

162. *Id.* at 878.

E. Non-Regulatory Suggestions

Non-regulatory solutions for combatting antibiotic resistance caused by misuse and overuse of antibiotics in factory farms include passing federal legislation, amending animal cruelty statutes, and educating the public on the risk of antibiotic resistance from food sources.¹⁶³ Congress passed the Generate Antibiotic Incentives Now (“GAIN”) Act in 2012 as part of the FDA’s Safety and Innovation Act to incentivize development of new antibiotics.¹⁶⁴ However critical it is to develop new antibiotics, it is also “essential to preserve the antibiotics we already have” by slowing antibiotic resistance.¹⁶⁵ Therefore, Congress should pass the Preservation of Antibiotics for Medical Treatment Act of 2017 (“PAMTA”) and the Strategies to Address Antibiotic Resistance Act (“STAAR”).

PAMTA would prohibit the use of medically-important antibiotics in animal farming practices except when needed to treat diseases in order to protect efficacy of antibiotics for human treatment.¹⁶⁶ PAMTA would also introduce a more stringent approval standard: applicants seeking approval of an antibiotic for animals use must show “reasonable certainty of no harm to human health due to development of antimicrobial resistance attributable . . . to the nontherapeutic use [of the drug].”¹⁶⁷ Members of Congress members have introduced PAMTA repeatedly since 1999.¹⁶⁸ Louise Slaughter, the main sponsor of the bill, stated, “to prevent a nightmarish post-antibiotic future, citizens of this country need to . . . demand that their leaders enact enforceable, verifiable limits on the use of antibiotics on the farm.”¹⁶⁹ PAMTA is the only bill that specifically focuses on

163. *Antibiotic Resistance*, WORLD HEALTH ORG. (Feb. 5, 2018), <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>.

164. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 801–806, 126 Stat. 1077 (2012).

165. *Antibiotic Resistance Hearing*, *supra* note 96, at 9.

166. Preservation of Antibiotics for Medical Treatment Act (PAMTA), H.R. 1150, 113th Cong. § 5 (2013).

167. *Id.* at § 4.

168. *See, e.g.*, H.R. 1587, 115th Cong. (2017); H.R. 1552, 114th Cong. (2015); S. 1211, 112th Cong. (2011); H.R. 962, 110th Cong. (2007); H.R. 2932, 108th Cong. (2003); S. 2508, 107th Cong. (2002).

169. Lydia Zurow, *Rep. Slaughter Reintroduces Preservation of Antibiotics Legislation*, FOOD SAFETY NEWS (Mar. 25, 2015), <https://www.foodsafetynews.com/2015/03/rep-slaughter-reintroduces-preservation-of-antibiotics-legislation>.

restricting non-judicious uses of antibiotics in animal agriculture.¹⁷⁰ STAAR supports reducing antibiotic resistance and reinforces CDC's role in collecting data, monitoring resistance, and preventing spread of resistant bacteria.¹⁷¹ Passing these two bills will support a federal response to antibiotic resistance by providing binding authority over federal regulatory bodies to take further action against antibiotic resistance.¹⁷²

Another suggestion to reduce improper antibiotic use is to include standards of care for farm animals in animal cruelty statutes.¹⁷³ Farm animals are generally exempt from such requirements or are subject to far fewer standards regarding living conditions and veterinary care.¹⁷⁴ The Prevention of Farm Animal Cruelty Act ("PFACA"), introduced in 2010, included provisions such as "adequate space to stand up, lie down, and turn around" and "fully extend all limbs," but Congress did not pass the legislation.¹⁷⁵ If state or federal animal cruelty statutes were amended to include more space per animal, sanitation, and veterinary oversight, disease transmission would decrease as would the need for antibiotics.¹⁷⁶

Lastly, it is imperative to educate the public—including consumers of animal products, lawmakers, and farm industry members—about antibiotic resistance. Medical researchers and professionals should persuade legislators and farm industry members to take action against antibiotic resistance by limiting antibiotic use in food-producing animals.

III. CONCLUSION

Subtherapeutic and nontherapeutic uses of antibiotics in animals should be prohibited to preserve the efficacy of antibiotics for use in human medicine. Specifically, antibiotic use for growth

170. Spellberg et al., *supra* note 81, at S405.

171. Strategies to Address Antibiotic Resistance Act (STAAR), S. 3176, 114th Cong., 2d Sess. (2016).

172. YOLISA NALULE, CTR. FOR DISEASE DYNAMICS, ECON. & POLICY, ANTIBIOTIC RESISTANCE AND THE 111TH CONGRESS 1–2 (2011), https://www.cddep.org/wp-content/uploads/2017/06/po_licy_brief_12_8-2.pdf.

173. See Stathopoulos, *supra* note 147, at 411.

174. *Id.* ("[A]nimals raised for food production receive virtually no protection under federal law and only ineffective protection under state anti-cruelty laws . . .").

175. Prevention of Farm Animal Cruelty Act, H.R. 4733, 111th Cong. § 3(b) (2010).

176. Stathopoulos, *supra* note 147, at 418–19.

promotion should be proscribed, and use for disease prevention should be significantly restricted to those antibiotics that do not have medical significance for humans. Some federal agencies have authority to enact rules limiting antibiotic use in animals by regulating antibiotics (FDA) or industry practices (USDA, APHIS, FSIS), but they have thus far been ineffective in doing so. Antibiotics and resistant bacteria that develop in factory farms travel to humans not only through food consumption, but also through environmental sources; therefore the EPA should regulate discharge into water supplies. Other groups, such as CDC and NARMS, need greater authority from Congress to address antibiotic resistance. Two proposed bills, PAMTA and STAAR, should be passed to spur impactful responses to antibiotic resistance. Reforming agency procedures and passing new regulations, have the potential to restrict and monitor antibiotic use, thereby curtailing antibiotic resistance and promoting both human and animal welfare.