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Eliminating Antibiotic Use in Animal Production: Responding to Scientific Evidence of an Impending Global Health Crisis

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Eliminating Antibiotic Use in Animal Production: Responding to Scientific Evidence of an Impending Global Health Crisis

By Sabrina R. Rearick*

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I. INTRODUCTION

The development of antibiotics has been marked as one of the greatest medical advances of the past century; their use has saved millions of lives, increased life expectancies, and led to a number of other important medical advances.¹ However, the effectiveness of antibiotics has become seriously threatened due to massive overuse and improper dosing, and as a result, antibiotic resistant bacteria have become one of the greatest threats to human health worldwide.² Yet, even though antibiotic resistance is widely recognized as an impending public health crisis, approximately 24.6 million pounds of antibiotics, roughly 70% of all antibiotics produced, are consumed by the meat industry each year.³ Despite decades of scientific research showing adverse human health consequences associated with antibiotic use in food animals and numerous pleas for binding regulations, the federal government has refused to mandate a reduction in the enormous amounts of antibiotics used in animal production.⁴

This article starts by providing background information on antibiotic resistance. It then explores the actions taken by the Food and Drug Administration (“FDA”) regarding the use of medically important antibiotics,⁵ traces the Second Circuit decision in *National Resources Defense Council, Inc. v. U.S. Food and Drug Administration* (“*NRDC III*”)⁶, which upheld the FDA’s actions, and presents

1. PRESIDENT’S COUNCIL OF ADVISORS ON SCI. AND TECH., EXEC. OFFICE OF THE PRESIDENT, REP. TO THE PRESIDENT ON COMBATING ANTIBIOTIC RESISTANCE, at 1 (2014) [hereinafter PCAST REPORT].

2. U.S. DEP’T OF HEALTH & HUMAN SERV., CTR. FOR DISEASE CONTROL AND PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, at 11 (2013) [hereinafter CDC REPORT]. Eradicating the world’s ability to fight routine infectious diseases such as pneumonia, meningitis, sore throat, general skin, bone and blood infections, foodborne illnesses, and many more, will result in higher death tolls from primary infections and unperformed procedures predicated on disease treatment. INTERAGENCY TASK FORCE ON ANTIMICROBIAL RESISTANCE (ITFAR), A PUBLIC HEALTH ACTION PLAN TO COMBAT ANTIMICROBIAL RESISTANCE, at 5 (2012) [hereinafter ITFAR REPORT].

3. MARGARET MELLON, CHARLES BENBROOK, AND KAREN LUTZ BENBROOK, HOGGING IT: ESTIMATES OF ANTIMICROBIAL ABUSE IN LIVESTOCK, at xi (Union of Concerned Scientists ed. 2001).

4. See generally THE PEW CHARITABLE TRUSTS, ANTIBIOTIC RESISTANCE AND FOOD ANIMAL PRODUCTION: A BIBLIOGRAPHY OF SCIENTIFIC STUDIES (1969–2014) (Antibiotic Resistance Project ed., 2013).

5. The term “medically important antimicrobial drugs” generally refers to antimicrobial drugs that are important for therapeutic use in humans. FOOD AND DRUG ADMIN., CTR. FOR VETERINARY MED., GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIBIOTIC DRUGS IN FOOD-PRODUCING ANIMALS, 3, n.1 (2012) [hereinafter GFI#209].

6. 760 F.3d 151 (2d Cir. 2014) [hereinafter “*NRDC III*”].

the proposed actions taken by Congress and the Obama Administration in the past decade. Finally, the article makes several proposals for the future based on the successes of other countries in removing the non-judicious use of antibiotics in food-producing animals.⁷ While this article focuses on a critique of the government's actions to date, it ultimately aims to highlight that non-judicious antibiotic use in food animals can and should be stopped in order to help preserve the effectiveness of one of the greatest advances in modern medicine.

II. BACKGROUND

A. *The Threat of Antibiotic Resistance*

The discovery of antibiotics as a means to combat bacterial infection was accompanied by the discovery that antibiotic use would also lead to increased bacterial resistance.⁸ In a simplified explanation, when an antibiotic is insufficient to kill off all of the bacteria in an organism, the surviving bacteria multiply and pass resistance traits to new bacteria through inheritance.⁹ Resistance traits can be combined through inheritance, creating new strains of bacteria that are resistant to a number of the antibiotics designed to treat them.¹⁰

Bacteria that are resistant to one or more classes of antibiotics have become increasingly common.¹¹ In fact, a number of bacterial

7. Carol Cogliani, Herman Goossens, & Christina Greko, *Restricting Antimicrobial Use in Food Animals: Lessons from Europe*, 6 MICROBE 274 (2011).

8. Richard A. Stein, *Antibiotic Resistance: A Global, Interdisciplinary Concern*, 73 THE AMERICAN BIOLOGY TEACHER 314, 317 (2011).

9. U.S. GOV'T ACCOUNTABILITY OFF., GAO-04-490, REPORT TO CONGRESSIONAL REQUESTERS, ANTIBIOTIC RESISTANCE: FEDERAL AGENCIES NEED TO BETTER FOCUS EFFORTS TO ADDRESS RISK TO HUMANS FROM ANTIBIOTIC USE IN ANIMALS 9 (2004) [hereinafter GAO REPORT ON ANTIBIOTIC RESISTANCE]. The problem of drug resistance is particularly threatening because of both the speed in which bacteria propagate and because bacterial transference between species can occur. Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 44-45 (2000).

10. See Charles W. Schmidt, *Antibiotic Resistance in Livestock: More at Stake than Steak*, 110 ENVTL. HEALTH PERSP., A396, A400 (2002); Stein, *supra* note 8, at 315. Bacterial strains that are resistant to multiple antibiotics are commonly known as superbugs. *Id.*

11. CDC REPORT, *supra* note 2, at 5. In the U.S. alone, at least 2 million people each year acquire bacterial infections that are resistant to one or more of the antibiotics designed to treat the infection. *Id.* at 11.

Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials include bacteria that cause pneumonia, ear infections, and meningitis [...], skin, bone, lung, and bloodstream infections [...], urinary tract infections (e.g., *Escherichia coli*), foodborne infections (e.g., *Salmonella* or *E. coli* acquired from meat, eggs, nuts, fresh produce etc.), and infections transmitted in healthcare settings [...].

ITFAR REPORT, *supra* note 2, at 5.

diseases are now almost entirely untreatable because the bacteria have acquired resistance to *all* of the antibiotics that have been used to combat them.¹² Consequently, thousands of people die each year either directly from antibiotic-resistant bacteria or indirectly from other conditions complicated by antibiotic resistant infections.¹³ The growth of antibiotic-resistant bacteria also demands extensive economic expenditures, both directly in the form of “prolonged and/or costlier treatments, extend[ed] hospital stays, [and] additional doctor visits and healthcare use,” as well as indirectly in the form of lost productivity.¹⁴

In an attempt to preserve antibiotic effectiveness in light of the severity of the problem, both national and international public health and animal health organizations have developed judicious-use guidelines that encourage selective use of antibiotics only for necessary treatment and use with doctor/veterinary oversight.¹⁵ However, despite these recommendations and knowledge of the consequences of overuse, antibiotics are still being misused at least 50% of the time.¹⁶ Thus, while antimicrobial resistance is not a new phenomenon, the current magnitude of the problem has elevated the issue of antibiotic resistance to a global crisis.¹⁷

Dr. Rima F. Khabbaz, Deputy Director of Infectious Diseases and Director of the Office of Infectious Diseases at the Center for Disease Control (“CDC”), summarized the potential costs of antibiotic-resistance in a 2014 symposium, stating that:

The cost of inaction is huge and unimaginable. It almost kind of sounds like a doomsday scenario, but it is real. People talk about returning to a pre-antibiotic era where simple infections, say a cut

12. PCAST REPORT, *supra* note 1, at 2. See Lena H. Sun and Brady Dennis, *The superbug that doctors have been dreading just reached the U.S.* THE WASHINGTON POST (May 27, 2016).

13. CDC REPORT, *supra* note 2, at 11; *The Richard & Hinda Rosenthal Symposium 2014: Antimicrobial Resistance: A Problem without Borders*. Washington, DC: The National Academies Press (2014) [hereinafter IOM Symposium on Antimicrobial Resistance], at 6–7.

14. CDC REPORT, *supra* note 2, at 11. The CDC has estimated \$20 billion in healthcare costs can be directly attributed to antibiotic-resistant infections, and estimates of the indirect costs to society—such as lost productivity—exceed \$35 billion per year (measured in 2008). *Id.* The CDC also estimates the annual impact of antibiotic-resistant infections to result in 8 million additional days in hospitals. PCAST REPORT, *supra* note 1, at 2.

15. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 14.

16. See CDC REPORT, *supra* note 2, at 41; Nancy E. Halpern, *Antibiotics in Food Animals: The Convergence of Animal and Public Health, Science, Policy, Politics and the Law*, 14 DRAKE J. AGRIC. L. 401, 407 (2009). In 1978, the WHO issued warnings about the impending global resistance of pathogens, “blaming the problem on ‘the widespread and indiscriminate use of antimicrobial drugs in man and animals.’” *Id.* (internal citation omitted).

17. PCAST REPORT, *supra* note 1, at 1; ITFAR REPORT, *supra* note 2, at 5.

of a finger, cannot be treated. That is real. We have some pathogens where we no longer have any antibiotic that fights them.¹⁸

Finally, it is worth noting that the cost of inaction burdens the global population, as drug resistant pathogens affect all people regardless of age, gender, ethnicity, geographic border, or socioeconomic background.¹⁹

B. *Antibiotic Use in Farm Animals*

The widespread use and misuse of antibiotics in human medicine may be the principal connection between antibiotic resistance and human disease; however, the use of antibiotics in animal production has been shown to contribute to antibiotic resistance in humans for over four decades.²⁰ Scientists have found that resistant bacteria bred in animals can be transferred to humans directly through ingestion of contaminated food products, directly through contact with animals or livestock, and indirectly when antibiotic resistant bacteria is released into the air, soil, or water—often occurring with the spreading of manure.²¹ While there is still some debate as to the degree of correlation between antibiotic use in animals and human antibiotic resistance,²² the scientific consensus is that antibi-

18. IOM Symposium on Antimicrobial Resistance, *supra* note 13, at 6. Scholars have noted that “incrementally tweaking what we are doing is not going to get the job done.” *Id.* at 15.

19. ITFAR REPORT, *supra* note 2, at 5.

20. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 1; Goforth & Goforth, *supra* note 9, at 49. In 1969, the report of the Joint Committee, commissioned by the English Parliament to study the use of antibiotics in animal husbandry and veterinary medicine, and commonly known as the Swann Report, concluded that: “the administration of antibiotics to farm livestock, particularly at sub-therapeutic levels, poses certain hazards to human and animal health.” *Id.* (internal citation omitted). The final recommendation was that only antibiotics that are not used in human medicine should be used for growth promotion. Goforth & Goforth, *supra* note 9, at 49.

21. David C. Love, Meghan F. Davis, Anna Bassett, Andrew Gunther & Keeve E. Nachman, *Dose Imprecision and Resistance: Free-Choice Medicated Feeds in Industrial Food Animal Production in the United States*, 119 ENVTL. HEALTH PERSPS. 279, 280 (2011); Ariele Lessing, Note, *Killing Us Softly: How Sub-Therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 474–75 (2010); LEO HERRIGAN, JAY GRAHAM & SHAWN MCKENZIE, *Antibiotic Drug Abuse*, THE CAFO READER: THE TRAGEDY OF INDUSTRIAL ANIMAL FACTORIES, 259 (ed. Daniel Imhoff) (2010).

22. While still acknowledging that transference is possible, there is a small number of researchers that maintain that the health risks of the transference are minimal, or that more research is needed to understand the degree of transfer. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 6. These researchers note that restricting the use of antibiotics in meat could increase levels of infectious bacteria, potentially harming human health. See e.g. I. Phillips, M. Casewell, T. Cox, B. De Groot, C. Friis, R. Jones, C. Nightingale, R. Preston & J. Waddell, *Does the Use of Antibiotics in Food Animals Pose a Risk to Human Health? A Critical Review of Published Data*, 53(1) J. ANTIMICROBIAL CHEMOTHERAPY, 28 (2004). Notably, this is the sole article cited by the GAO Report, and was written by an advisory group

otic use in animals reduces the efficacy of the human antibiotic arsenal.²³ In light of such evidence, over 350 expert organizations, including the American Public Health Association and the World Health Organization, have called for a ban on the nontherapeutic use of antibiotics in food-producing animals.²⁴

Shockingly, the quantities of antibiotics sold for use in food-producing animals still dwarfs the amount used in human medicine; for every one pound of antibiotic used in human medicine, eight pounds are used for nontherapeutic purposes in livestock production.²⁵ Moreover, the list of antibiotics approved for use in animals includes a number of drugs that are either used themselves for human patients or are closely related to such human drugs.²⁶

The real problem is that almost all of the antibiotics used in livestock production are used in healthy animals for growth purposes or disease prevention.²⁷ To be sure, public health advocates do not object to treating *sick* animals with antibiotics, but they do not want to diminish the efficacy of these important drugs by feeding antibiotics to *healthy* animals.²⁸ Further compounding the problem,

to the Animal Health Institute. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 89.

23. Mellon, Benbrook, & Benbrook, *supra* note 3, at 1. In 2014, The PEW Charitable Trusts compiled a bibliography of the latest scientific studies and economic literature regarding “the contribution of routine antibiotic use in food animals to the growing public health crisis of human antibiotic resistance.” THE PEW CHARITABLE TRUSTS, *supra* note 4, at 1. The report concluded that current research supports the 2009 conclusion made by Dr. Frederick J. Angulo, then acting associate director of science in the CDC’s National Center for Environmental Health and the Agency for Toxic Substances and Disease: “[t]here is scientific consensus that antibiotic use in food animals contributes to resistance in humans. And there’s increasing evidence that such resistance results in adverse human health consequences at the population level. Antibiotics are a finite and precious resource, and we need to promote prudent and judicious antibiotic use.” *Id.*

24. Lynn M. Boris, Note, *The Food-Borne Ultimatum: Proposing Federal Legislation to Create Human Living Conditions for Animals Raised for Food in Order to Improve Human Health*, 24 J.L. & HEALTH 285, 291 (2011); HARRIGAN ET AL., *supra* note 21, at 260.

25. Terence J. Centner, *Regulating the Use of Non-Therapeutic Antibiotics in Food Animals*, 21 GEO. INT’L ENVTL. L. REV. 1, 1 (2008).

26. Goforth & Goforth, *supra* note 9, at 47. The list includes: amoxicillin, ampicillin, erythromycin, neomycin, penicillin, and tetracycline. *Id.* at 48; *see also* Carmen Cordova & Avinash Kar, NRDC Issue Brief, *Playing Chicken with Antibiotics: Previously Undisclosed FDA Documents Show Antibiotic Feed Additives Don’t meet the Agency’s Own Safety Standards*, 4 (Jan. 2014).

27. Mellon, Benbrook & Benbrook, *supra* note 3, at xii–xx; Centner, *supra* note 25, at 11. Growth promotion relies on the idea that feeding animals low levels of antibiotics reduces immune system activity, which would otherwise be tasked with combatting bad living conditions, to free more resources for growth and weight gain. Boris, *supra* note 24, at 291. Disease prevention relies on the idea that antibiotics can be applied preventatively to combat conditions associated with confined animal feeding operations or CAFOs. *Id.* at 291–92; *see* Barbara O’Brien, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Sub-therapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 415 (1996).

28. Michael Pollan, *Power Steer*, THE NEW YORK TIMES MAGAZINE, Mar. 31, 2002. It is worth noting that it currently remains unclear how much of an increase in meat production,

growth promotion and disease prevention rely on a form of preemp-
 tive application of antibiotics to healthy animals known as subther-
 apeutic dosing.²⁹ This involves the administration of low levels of
 antibiotics, “insufficient to kill an invading bacterial infection, but
 . . . effective in preventing bacterial infection from occurring.”³⁰
 Subtherapeutic doses of antibiotics, prescribed over long periods of
 time and which are not directed against a particular organism,³¹
 create reservoirs of antibiotic-resistant bacteria that can lead to
 new resistance traits and strains.³²

Dr. Spellberg summarized the principal point this article aims to
 make during the Institute of Medicine’s Richard & Hinda Rosenthal
 Symposium in 2014:

[Regarding] antibiotics in animal feed[,] [t]his is a national dis-
 grace. There is no scientific debate here . . . It needs to end. . . .
 More challenging to think about, scientifically, is how we prevent
 inappropriate antibiotic prescriptions among people.³³

III. AGENCY ACTION

A. *The FDA and the Federal Food, Drug, and Cosmetic Act*

The FDA was established to protect against impure and unsafe
 foods, drugs, cosmetics, and other potential hazards.³⁴ Accordingly,
 under the Federal Food, Drug, and Cosmetic Act (“FDCA”), the FDA
 has been charged with regulating antibiotic use in animals used for

if any, actually results from routine use of in-feed additives. Stein, *supra* note 8, at 317. Recent studies have shown remarkably modest weight gains and other benefits, indicating that growth-promoting antibiotics offer very limited benefits. Peter Collignon, Henrik C. Wegener, Peter Braam & Colin D. Butler, *The Routine Use of Antibiotics to Promote Animal Growth Does Little to Benefit Protein Undernutrition in the Developing World*, 41 CLINICAL INFECTIOUS DISEASES 1007, 1008–09 (2005). For example, a 2007 analysis of a study conducted by Perdue Farms concluded that the benefits of antibiotic use were too small to cover the cost of the drugs. Meghan F. Davis & Lainie Rutkow, *Regulatory Strategies to Combat Antimicrobial Resistance of Animal Origin: Recommendations for a Science-Based U.S. Approach*, 25 TUL. ENVTL. L.J. 327, 362 (2012). Additionally, the amount of antibiotics needed to promote growth has increased significantly over time, now requiring roughly ten to twenty times the amount used four decades ago. Goforth & Goforth, *supra* note 9, at 46–47.

29. Lessing, *supra* note 21, at 469.

30. *Id.*; see also Love et. al., *supra* note 21, at 280.

31. See Lauren Orrico, Note, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combating Antibiotic-Resistant Bacteria*, 27 J.L. & HEALTH 259, 264 (2014). For example, drugs used for growth promotion or disease prevention are often administered to food animals in the form of free-choice medicated feeds (FCMF), where each animal chooses how much feed to consume. Love et. al, *supra* note 21, at 280. FCMF often results in the inability to deliver predictable, uniform, or intended dose levels. *Id.*

32. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 2; Love et. al., *supra* note 21, at 279.

33. IOM Symposium on Antimicrobial Resistance, *supra* note 13, at 15.

34. 21 U.S.C. § 393(a)–(b) (2012).

food production.³⁵ Under the FDCA, the FDA must review scientific documentation on the safety and efficacy of a drug's proposed use and approve its label before drug companies can market a new animal drug.³⁶ The FDA considers an antimicrobial drug to be "safe" if the agency concludes there is a "reasonable certainty of no harm to human health from the proposed use of the drug in animals."³⁷ In considering the safety of a drug, the FDA considers both the direct toxic effects of the drug as well as indirect effects of the drug on human health, including the potential human health impact of antibiotic resistance stemming from the use of the drug in food-producing animals.³⁸

If safety issues arise after a drug's initial approval, the FDCA provides grounds for withdrawal of approval.³⁹ Section 360b(e)(1) of the FDCA states, "the Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . *if the Secretary finds—that experience or scientific data show that such drug is unsafe for use.*"⁴⁰ Under this provision, the FDA has the initial burden to produce evidence indicating that there are serious questions about the ultimate safety of the drug used in food-producing animals. If the agency meets this burden, the burden shifts to the sponsor to demonstrate the safety of the drug.⁴¹

B. The Emergence and Reaffirmation of Safety Concerns

In the mid-1960s, the FDA first became concerned that long-term use of antibiotics in food animals could pose a serious threat to human and animal health.⁴² As early as 1970, a special task force, created in response to those concerns, reported that the subtherapeutic use of antibiotics in animal feed favors the development of

35. 21 U.S.C. § 360 (2012).

36. 21 U.S.C. § 360(a)(1) (2012). This is known as the New Animal Drug Approval process (NADA).

37. GAO REPORT ON ANTIBIOTIC RESISTANCE, *supra* note 9, at 15.

38. Davis & Rutkow, *supra* note 28, at 355.

39. 21 U.S.C. § 360b(e).

40. 21 U.S.C. § 360b(e)(1) (emphasis added).

41. Davis & Rutkow, *supra* note 28, at 355. Notably, this burden shifting is in contrast to regulatory efforts in other industries in which the burden of proof to demonstrate safety remains with the producer at every stage, i.e. chemical production which is "similar in that most antimicrobials are chemical compounds." *Id.*

42. See Nat. Res. Def. Council, Inc., v. U.S. Food and Drug Admin., 884 F. Supp. 2d 127, 132 (S.D.N.Y. 2012) [hereinafter NRDC I].

antibiotic-resistant bacteria, and recommended restrictions on antibiotic use in animal feed unless certain safety criteria were met.⁴³ In light of the task force's findings, the FDA issued a regulation stating that the agency proposed to withdraw approval of all subtherapeutic uses of antibiotics in animal feed, in accordance with Section 360b(e)(1) of the FDCA, unless interested parties could provide evidence that the drugs met particular safety criteria set by the FDA.⁴⁴

In reviewing data provided by the drug sponsors, the Director of the Bureau of Veterinary Medicine ("BVM")⁴⁵ found that the data failed to rebut findings indicating that the subtherapeutic use of antibiotics was leading to an increase in antibiotic-resistant bacteria, or that such resistant bacteria was being transferred from animals to humans. Subsequently, the Director of the BVM proposed to withdraw approval of the use of penicillin and tetracyclines in animal feed on the grounds "that the[se] drug products are not shown to be safe," because the specified human and animal health safety criteria had not been satisfied.⁴⁶ As part of the withdrawal process, the BVM then issued notices for an opportunity for hearing ("NOOHs") on proposals to withdraw approval of all subtherapeutic uses of certain antibiotics in animal feed.⁴⁷ Several drug sponsors and agricultural organizations objected to the withdrawal of these drugs, and the Commissioner of the FDA granted requests for hearings regarding withdrawal. At the requested hearing, the drug sponsors would have had the burden of proving that the drugs were safe.⁴⁸ If the drugs were in fact shown to be safe at the proposed hearings, the FDA would rescind the proposals for withdrawal and the drugs could continue to be used.

In the years between the FDA's grant of a hearing and its formal action regarding the NOOHs, the agency repeatedly affirmed both that certain antibiotic use in food-animals could be dangerous to

43. *Id.* The multi-agency task force consisted of scientists from the National Institute of Health, the U.S. Department of Agriculture, the CDC, universities, and the agricultural and pharmaceutical industries. *Id.*

44. *Id.* at 133. Some of the safety criteria included that subtherapeutic use of the drug would not increase salmonella in animals, increase the pathogenicity of bacteria, or increase the numbers of pathogenic bacteria or the resistance of pathogens to antibiotics used in human medicine. *Id.*

45. The Bureau of Veterinary Medicine is the subdivision of the FDA charged with reviewing animal drug applications and withdrawals. *Id.*

46. *Id.* at 134.

47. *NRDC I*, 884 F. Supp. 2d at 134.

48. *Id.* (citing FDA, Final Decision of the Commissioner, *Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry*, 70 Fed. Reg. 44105).

human health and that the issue of antibiotic resistance is of serious concern. For example, in 1983, the Commissioner of the FDA explicitly denied requests from several drug sponsors to rescind the NOOHs, explaining that the NOOHs “represent the Director’s [and Commission’s] formal position that use of the drugs is not shown to be safe.”⁴⁹ In 1996, the FDA and other health agencies collaborated to form the National Antimicrobial Resistance Monitoring System (“NARMS”) to monitor bacteria susceptibility.⁵⁰ In 1999, the FDA joined the Interagency Task Force on Antimicrobial Resistance (“ITFAR”), in an attempt to unify strategies regarding antimicrobial resistance.⁵¹ ITFAR recommendations have consistently suggested that agencies must increase regulatory action regarding antimicrobial use in food-producing animals.⁵² In 2003, the FDA released Guidance Document #152 (“GFI 152”), setting guidelines for new drug approval and again reaffirming its belief that antibiotic use in animals has safety consequences for human health.⁵³

C. FDA Action in Response to Findings

Ultimately, the hearings granted by the FDA in 1978 were never held.⁵⁴ Further, despite decades of data indicating the dangers of subtherapeutic use of antibiotics in livestock, the FDA formally rescinded the 1977 NOOHs for the withdrawal of approval certain antibiotics in animal feed on December 16, 2011.⁵⁵ At that time, the FDA also denied citizen suits from 1999 and 2005 that were filed under Section 512(e) of the FDCA seeking to withdraw regulatory approval for the subtherapeutic use of certain antibiotics in animal feed, which were also based on the agency findings that led to the 1977 NOOHs.⁵⁶

49. *Id.* at 135.

50. HHS, *The National Antimicrobial Resistance Monitoring System (NARMS) Strategic Plan*, 2 (2012–16)

51. ITFAR REPORT, *supra* note 2, at 3–4. The Task Force is co-chaired by the Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); and National Institutes of Health (NIH). *Id.* at 3.

52. *See* ITFAR REPORT, *supra* note 2, at 3–4.

53. FOOD AND DRUG ADMIN., CTR. FOR VETERINARY MEDICINE, GUIDANCE FOR INDUSTRY #152: EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN, 2 (2003) [hereinafter GFI #152].

54. NRDC I, 884 F. Supp. 2d at 131.

55. *Id.* at 136; Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697 (Dec. 22, 2011).

56. Section 512(e) of the FDCA has been previously referred to in this article as Section 360b(e)(1) of the FDCA. Nat. Res. Def. Council, Inc., v. U.S. Food and Drug Admin., 872 F. Supp. 2d 318, 324–27 (S.D.N.Y. 2012) [hereinafter NRDC II]. The list included penicillin and tetracyclines, similarly subject to the 1977 NOOHs. *Id.* *See* Letter from Leslie Kux, Acting

Although the FDA maintained that the drugs had not yet been proven safe, the agency reasoned that they were implementing alternative strategies for combating the negative effects of subtherapeutic use of antibiotics in animal feed that would be more efficient.⁵⁷ However, the alternative strategies being pursued by the FDA are the issuance of two guidance documents that carry no actual legal authority.⁵⁸ In April 2013, the FDA issued Guidance Document #209—The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (“GFI #209”)—to encourage judicious use of *all* medically important antimicrobial drugs.⁵⁹ The framework produced two principles: Medically important antibiotics should be limited to uses considered necessary for assuring health in food-producing animals, and, in the event that such use is necessary, it should be limited to that which includes veterinary oversight or consultation.⁶⁰ The FDA formally stated in GFI #209, “[i]n light of the risk that antimicrobial resistance poses to public health, [the] FDA believes the use of medically important antimicrobial drugs in food-producing animals for production purposes (e.g., to promote growth or improve feed efficiency) represents an injudicious use of these important drugs.”⁶¹ In December 2013, the FDA followed with Guidance Document #213 (“GFI #213”).⁶² GFI #213 was intended to provide recommendations, information and

Assistant Commissioner for Policy, Food and Drug Administration, to Ms. Sarah Klein, Esq., Food Safety Program, Center for Science in the Public Interest (Nov. 7, 2011) (issuing the final response from the FDA to the 1999 citizen petition) (hereinafter FDA denial of 1999 Citizen Petition); Letter from Leslie Kux, Acting Assistant Commissioner for Policy, Food and Drug Administration, to Andrew Macquire, Vice President, Environmental Health, Environmental Defense (Nov. 7, 2011) (issuing the final response from the FDA to the 2005 Citizen Petition) [hereinafter FDA denial of 2005 Citizen Petition].

57. *NRDC I*, 884 F. Supp. 2d at 136.

58. *See* *NRDC III*, 760 F.3d 151, 176 (2d Cir. 2014) (Katzmann, C.J., dissenting).

59. GFI #209, *supra* note 5, at 21–22. In GFI #209, the FDA cited a non-exhaustive summary of the scientific literature addressing questions regarding the use of antimicrobial drugs in food-producing animals. Each of the studies stated, in one form or another, that there is strong evidence of adverse human health consequences due to antibiotic-resistant bacteria resulting from the use of antibiotics in food animals. Virtually of the studies listed recommended that the U.S. ban the use of antimicrobials in growth promotion in animals if those classes of drugs are also used in humans. *Id.* at 5–17.

60. *Id.* at 21–22.

61. *Id.* at 21. In regards to the use of antimicrobial drugs for disease prevention purposes, the FDA deems it sometimes necessary and judicious as long as such use includes professional veterinary involvement. The Administration “believes it is important to phase-in the voluntary practice of including veterinary oversight or consultation in the use of these drugs.” *Id.* at 22.

62. . FOOD AND DRUG ADMIN., CTR. FOR VETERINARY MEDICINE, GUIDANCE FOR INDUSTRY #213: NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI#209, 2 (2013) [hereinafter GFI #213].

guidance to sponsors of antimicrobial animal drugs who are interested in voluntarily revising their conditions for use of products consistent with GFI #209.⁶³

While the FDA has secured initial support from drug companies to voluntarily cease nonjudicious use,⁶⁴ it is yet to be seen whether substantial reductions in nontherapeutic uses will actually result. The FDA has asserted that the voluntary approach will be the fastest way to achieve the goal of removing nonjudicious antibiotic use, because “initiating regulatory action would require that the agency proceed on a product-by-product basis, [which] would likely create significantly more disruption to the animal health/agriculture industry, and would require significantly more resources and time to implement.”⁶⁵

However, actors outside the agency have expressed concerns that GFI #209 and GFI #213 will not be effective in ultimately controlling antibiotic misuse because of the voluntary nature of the strategies.⁶⁶ Many argue that it is irrational to think that those who benefit economically from the use of antibiotics would voluntarily cease use without further legal mandate or enforcement.⁶⁷ In this

63. *Id.* at 3. Judicious use principles include preventative strategies (such as appropriate husbandry, hygiene, and immunization), optimization of current pharmacological information and principles; limiting antibiotic use to animals who are ill or at risk; minimizing environmental contamination; and keeping accurate records of treatment and outcome kept for evaluation. FDA, *Judicious Use of Antimicrobials*, U.S. DEP’T OF HEALTH AND HUM. SERV., <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/>. The FDA established a 3-year timeframe for stakeholders to comply with the guidance by voluntarily phasing-in or implementing judicious use principles and modifying product labels for sponsors of affected products. GFI #213, *supra* note 62, at 9.

64. FDA, *FDA Secures Full Industry Engagement on Antimicrobial Resistance Strategy*, U.S. DEP’T OF HEALTH AND HUM. SERV. (June 30, 2014), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm403285.htm>.

65. FDA, *FDA’s Strategy on Antimicrobial Resistance—Questions and Answers*, U.S. DEP’T OF HEALTH AND HUM. SERV. (June 11, 2015), <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm#question5>. Note that the FDA’s argument that the formal withdrawal process would be too expensive and time-consuming is rather paradoxical, given that the agency itself has delayed starting the process for thirty-seven years and has spent a substantial amount of money on defending their discretion to do so. This argument was made by Judge Katzmann in his dissent in *NRDC III*, 760 F.3d at 180 (Katzmann, C.J., dissenting).

66. Both GFI #209 and GFI #213 are non-binding and suggest only voluntary compliance by the drug companies and agricultural producers; neither provides a legal mandate of enforcement, and failure to comply with the endorsed judicious use principles does not result in a penalty for noncompliance. See Cordova & Kar, *supra* note 26, at 9. Both GFI #209 and GFI #213 are introduced by the following statement: “This Guidance represents the [FDA’s] current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.” See GFI #209, *supra* note 5, at 3; GFI #213, *supra* note 62, at 3.

67. See Davis & Rutkow, *supra* note 28, at 348; see also Lydia Zurlaw, *Will FDA’s Voluntary Plan Actually Reduce Antibiotics in Animal Feed?*, FOOD SAFETY NEWS (Dec. 12, 2013), <http://www.foodsafetynews.com/2013/12/fda-finalizes-guidance-for-phasing-out-antibiotics->

regard, it is worth noting that despite the widespread acknowledgement of the impending public health crisis of antibiotic resistance and various recommendations to reduce nontherapeutic use in animal production, drug companies have done shockingly little to reduce or remove antibiotics from livestock.⁶⁸ Additionally, scholars have pointed out that antibiotic use has become a custom in modern agriculture, stating that “the use of antibiotics is so ingrained in this country that it will almost certainly be necessary to implement regulations phasing out the subtherapeutic use of antibiotics in agriculture.”⁶⁹

Finally, while GFI #209 and GFI #213 do encourage drug manufacturers to discontinue selling drugs for “growth promotion”, they do not discourage the continuation of “disease prevention.”⁷⁰ By failing to distinguish between therapeutic and nontherapeutic uses, the guidance documents leave open the possibility for medically important drugs to continue being used at subtherapeutic levels under the label of disease prevention.⁷¹ While the products affected by the plan will be placed under veterinary oversight, there is no explicit suggestion that veterinarians not prescribe antibiotics for disease prevention.⁷²

Overall, while the FDA maintains that the voluntary approach it has instituted will be the best means of reducing the subtherapeutic use of antibiotics in animal production, it has ultimately done very little to eliminate unsafe dosing practices.

in-food-animals/#.Vuh1vOZ9l60. The article quotes University of Texas law Professor and Center for Progressive Reform scholar Tom McGarity, stating that “[v]oluntary regulations are merely suggestions . . . The reason that we have regulatory agencies is because the public cannot rely on promises by industry to do better.” *Id.* Rep. Louise Slaughter said the guidance is “an inadequate response [with] no mechanism for enforcement and no metric for success.” *Id.*

68. See Goforth & Goforth, *supra* note 9, at 46. Rather, in the face of serious threats of resistance, the amount of antibiotics used nonjudiciously has increased exponentially. *Id.*

69. Goforth & Goforth, *supra* note 9, at 70.

70. Greg Cima, *Senators Doubt FDA Can Control Antimicrobial Use*, J. AM. VETERINARY MED. ASS'N (Jan. 28, 2015), <https://www.avma.org/News/JAVMANews/Pages/150215o.aspx>. The FDA defines disease prevention as “involv[ing] the administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease, in a situation where disease is likely to occur if the drug is not administered.” Cordova & Kar, *supra* note 26, at 9 (citing GFI #209, *supra* note 5).

71. See generally Cima, *supra* note 70; see also Zurlaw, *supra* note 67.

72. See generally GFI #213, *supra* note 62.

IV. JUDICIAL INTERPRETATION: *NRDC v. FDA*A. *Background and District Court Holding*

On May 25, 2011, a group of advocacy organizations⁷³ filed suit against the FDA in a federal district court alleging that the FDA withheld agency action in violation of the FDCA⁷⁴ and the Administrative Procedure Act (“APA”).⁷⁵ Plaintiffs’ first claim for relief asserted that FDCA § 360b(e)(1) compelled the FDA to hold the hearings proposed in the 1977 NOOHs and, if appropriate after the hearing, to withdraw approval for the antibiotic uses the NOOHs listed.⁷⁶ Plaintiffs’ second claim stated that under APA § 706(1), the FDA’s failure to issue final responses to the citizen petitions filed in 1999 and 2005 constituted unreasonably delayed agency action under the APA and the FDA’s implementing regulations.⁷⁷ The second claim became moot when the FDA issued final responses denying the 1999 and 2005 citizen petitions and formally withdrew the 1977 NOOHs.⁷⁸ Plaintiffs then filed a supplemental complaint alleging a third claim for relief, asserting that FDA’s denial of the citizen petitions was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” in violation of FDCA §360b and APA §706(2).⁷⁹

District Court Judge Theodore H. Katz granted the Plaintiffs’ motion for summary judgment on their first claim for relief and ordered the FDA to initiate the § 360b(e)(1) mandatory withdrawal proceedings.⁸⁰ The court dismissed the Defendant’s argument that Plaintiffs’ claim was moot based on the rescission of the 1977

73. Plaintiffs consisted of a group of advocacy organizations, consisting of the Natural Resources Defense Council, Inc, The Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, Inc., Union of Concerned Scientists, Inc. *NRDC I*, 884 F. Supp. 2d at 130.

74. (1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized . . . 21 U.S.C. § 360b(e)(1).

75. “The reviewing court shall—(1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706.

76. *NRDC I*, 884 F. Supp. 2d at 140.

77. *NRDC II*, 872 F. Supp. 2d at 330.

78. *Id.*; Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Food, 76 Fed. Reg. 79,697 (Dec. 22, 2011);

79. *NRDC II*, 872 F. Supp. 2d at 330. Under FDA regulations, the denial of a citizen petition is a final agency action subject to judicial review. See 21 C.F.R. § 10.45(d) (2016).

80. *NRDC I*, 884 F. Supp. 2d at 151.

NOOHs, stating that formal withdrawal of the 1977 NOOHs did not rescind the original findings that subtherapeutic use of the drugs in food producing animals has not been shown to be safe.⁸¹ The FDA was instructed to issue a withdrawal order unless the manufacturers could rebut the finding by proving that the use of the drugs did not pose a threat to human health.⁸² The court also granted the Plaintiff's request for relief under APA §706(2).⁸³ The court found first that the FDA's denial of the citizen suits was subject to judicial review, and second, that the FDA's proffered grounds for denying the petitions—the time and expense required for a formal hearing and the recent adoption of GFI #209 and #213—were arbitrary and capricious.⁸⁴

B. *Second Circuit Opinion*

On review, the Second Circuit Court of Appeals reversed the opinion of the District Court on both counts.⁸⁵ Circuit Judge Gerard E. Lynch, writing for the majority, stated that the text of § 360b(e)(1) does clearly require the FDA to proceed with withdrawal proceedings for certain uses of antibiotics *if* the FDA makes a finding that those uses are not shown to be safe for humans.⁸⁶ However, the statute does not clearly specify *when* such a finding is officially made.⁸⁷ Therefore, the issue turns on when a finding becomes formalized enough to trigger the mandatory withdrawal process. The Plaintiffs argued that the mandatory withdrawal process is triggered by an internal agency finding based on scientific evidence.⁸⁸ The FDA's position, in contrast, was that the mandatory withdrawal process is triggered only after a finding reached at the end of a hearing.⁸⁹

The court agreed with FDA's statutory interpretation that Congress does not require the FDA to hold hearings based on internal agency deliberations, even when they indicate scientific concerns

81. *Id.*

82. *Id.*

83. *NRDC II*, 872 F. Supp. 2d at 342.

84. *Id.* at 338–42.

85. *NRDC III*, 760 F.3d 151, 153 (2d Cir. 2014).

86. *Id.* at 158.

87. *Id.* The opinion states, “The Parties dispute the circumstances under which the mandatory language ‘shall ... issue an order withdrawing approval’ comes into play. In particular, they dispute what it means for the Secretary to make a finding, and when that finding occurs.” *Id.*

88. *Id.* at 159.

89. *Id.*

about the safety of animal drug use. Rather, the FDA retains discretion to institute or terminate proceedings to withdraw approval of animal drugs, unless a finding that the drug poses a threat to human health and safety is reached at the conclusion of a hearing.⁹⁰ Because internal FDA findings do not meet the requirements of a formal finding under § 306(b), the court dismissed plaintiffs' first claim for relief and remanded the issue to the district court to grant the defendant's motion for summary judgment.⁹¹

The majority also dismissed the Plaintiffs' second claim for relief asserting that the denial of the citizen petition was arbitrary or capricious agency action in violation of § 706(2)(A) because the denials were based on factors not mentioned in the statute.⁹² The court concluded that the decision of whether to institute or terminate a hearing process for an animal drug is a discretionary decision left to the choice of the FDA. Consequently, the court found it "relatively easy" to accept the FDA's justifications denying the Petitions, including considerations of "cost, time, and a preference for voluntary compliance over adversary proceedings."⁹³

Chief Judge Katzmann issued a dissenting opinion, asserting that § 360b(e)(1) requires the FDA to continue the proposed withdrawal proceedings based on the formal declarations of the FDA as contained in the 1977 NOOHs. Further, he argued that the FDA's denial of the citizen petitions was arbitrary and capricious because it relied on outside factors and failed to address the statutory requirement that the drug use is shown to be safe.⁹⁴

C. Analysis

The Second Circuit erred in two respects: first in holding that a *finding* which would mandate the withdrawal process occurs only after a hearing is held, and second in awarding the FDA discretion in denying the citizen petitions.

Regarding the first issue, although the text of §360b(e)(1) clearly requires withdrawal of approval once such a finding has been made, the statute does not clearly specify exactly what type of finding mandates the withdrawal process or when that finding occurs.⁹⁵ While the Court acknowledged that the textual placement of the

90. *Id.* at 171–72.

91. *NRDC III*, 760 F.3d at 176.

92. *Id.* at 173.

93. *Id.* at 173, 175.

94. *Id.* at 176–77.

95. *Id.* at 158.

notice and hearing provision is awkward under either interpretation, it supported the FDA's interpretation that the finding provision is structurally linked with the mandatory withdrawal provision and not linked to the mandatory hearing provision.⁹⁶ However, several points support the Plaintiffs' argument that an internal agency finding is linked to the mandatory hearing provision.

First, consider that an identical congressional design for approval and withdrawal of drugs exists for non-animal drugs under § 355.⁹⁷ Both, in identical syntax, indicate that the FDA is required to withdraw approval for the drug once it provides a hearing and makes a finding that a particular drug is not shown to be safe.⁹⁸ The available evidence indicates that courts have construed § 355 for non-animal drugs to require the FDA to move forward with withdrawal proceedings (by holding the necessary hearing) if a preliminary finding is made that a drug is not shown to be safe.⁹⁹ Thus, it is logical that a hearing on the withdrawal of animal drugs would proceed when a preliminary finding that the drug is not shown to be safe.

Second, nothing in the FDCA explicitly requires the FDA to “cling so tenaciously to formal procedures,” or to insist that a decision be made on substantial evidence of the record.¹⁰⁰ Section 512(e)(1) of the FDCA does not contain any particular format for the required hearing, and does not say the agency's decision must be made on the record.¹⁰¹ In contrast, another provision of the FDCA, §701(e)(1), identifies FDA decisions that are to be accompanied by a public hearing and made on substantial evidence of record at such

96. *Id.* at 161.

97. *NRDC III*, 760 F.3d at 180. The minimum due process protections—notice and opportunity to be heard—are the same as those for the approval and withdrawal of approval for non-animal drugs under 21 § 355(c)–(d).

98. *Id.* at 180–81. For comparison, the first sentence of § 355(e) reads: “The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds that [any of the listed statutory grounds apply].” 21 U.S.C. § 355(e) (2015).

99. *NRDC III*, 760 F.3d at 180–81. In *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the precise interpretation of § 355(e) was not at issue. But the Court's analysis proceeded under the assumption that once the FDA determines a product under its jurisdiction is not shown to be safe, it is statutorily required to begin withdrawal proceedings. *See id.* at 135; *see also Am. Pub. Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1315–16 (D.D.C. 1972) (holding that the FDA must commence withdrawal proceedings after announcing in the Federal Register that certain drugs were not shown to be effective for their approved uses).

100. Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1019 (2013). She also highlights that FDA has failed to recognize the availability of generic rulemaking to address the risks posed by antibiotics in animal feed as a whole class, rather than on a “drug by drug” basis. *Id.* at 1019–20.

101. *See id.* at 1020.

hearing under § 701(e)(3).¹⁰² Yet, of all the regulatory decisions contemplated by the FDCA, Congress decided *not* to include the decisions to withdraw approval for animal drugs in the § 701(e)(1) exclusive list of those decisions that require a formal hearing.¹⁰³ Further evidencing this intent, another provision of the FDCA not included on the § 701(e)(1) list explicitly imported the requirements of a formal hearing (expressly stating that § 701(e) applies).¹⁰⁴ In contrast, section 512(e)(1) does not adopt § 701(e) or its reference to a full formal evidentiary hearing (or an “evidence of record”).¹⁰⁵

The third point involves the traditional understanding of an administrative “finding.” The FDA claimed that a finding typically represents an official determination or reflects a final, deliberative decision; is issued at the conclusion of a process; or takes a fixed form embodied in an identifiable document.¹⁰⁶ However, other areas of the law have defined “findings” to mean written conclusions based on factual investigations, and other congressional statutes that refer to only a single finding have been found to imply both a pre-hearing and post-hearing finding.¹⁰⁷ Agency action frequently begins with a preliminary agency finding that triggers notice and opportunity for hearing rather than beginning with a hearing.¹⁰⁸ As mentioned by the dissent, “agencies do not arbitrarily decide to initiate hearings; instead, they begin the hearing process only when they find there is some reason to do so.”¹⁰⁹

Finally, mandating action upon a preliminary finding (or one that is not the result of the required hearing) does not necessarily present future problems in terms of identifying when and how such a

102. *Id.* at 1021. The selective list of § 701(e)(3) thus names specific FDA decisions that are to be accompanied by a hearing on the evidence of record, which includes, among others, the labeling of food offered for special dietary uses and tolerance for poisonous ingredients in food. *Id.*

103. *Id.*

104. “The provision on color additives for foods, drugs, and cosmetics expressly states that section 701(e) applies to the issuance, amendment, or repeal of regulations under that provision. The provision also expressly adopts the APA’s requirements on burdens of proof and other matters in formal hearings.” Heinzerling, *supra* note 100, at 1022.

105. *Id.*

106. *NRDC III*, 760 F.3d at 167. The opinion reads, “Judicial or administrative findings most commonly are adopted not as a prerequisite but as a consequence of a hearing or other official proceeding.” *Id.*

107. *Id.* at 183; see 15 U.S.C. §2603(c)(4)(B); 20 U.S.C. §1099b(l)(1); 26 U.S.C. § 7518(e)(2); and 42 U.S.C. § 6947(a)(2). The procedure often runs “preliminary finding, hearing, final finding, order,” rather than “hearing, finding, order.” *NRDC III*, 760 F.3d at 184 (Katzmann, C.J., dissenting).

108. *NRDC III*, 760 F.3d at 184.

109. *Id.*

finding has been made.¹¹⁰ The Plaintiffs did not contend that the withdrawal process should be initiated based on the subjective belief of the FDA; rather, they pointed to the 1977 NOOHs, which set forth the scientific conclusions of the CVM regarding safety issues.¹¹¹ Even though the NOOHs were eventually withdrawn, the agency itself explicitly stated that the withdrawal of the NOOHs did not withdraw its concerns for the safety of antibiotic use in animal feed, and the FDA repeatedly and consistently reaffirmed the findings produced in the 1977 NOOHs.¹¹² The court overlooked the fact that that these were not merely subjective beliefs of the FDA, but were beliefs that were published in a formal document and repeatedly reaffirmed by the agency.

The court also erred in holding that the decision to initiate the withdrawal process was an enforcement action that is awarded agency discretion.¹¹³ Accordingly, the court deferred to the FDA's determination that voluntary compliance would offer greater possibilities for reductions in animal antibiotic use than would pursuing a hearing to determine if the drug is in fact detrimental to human health.¹¹⁴ Unfortunately, the Court overlooked an important exception to agency discretion in enforcement actions, and further misclassified the FDA's decision as an enforcement decision when it more closely resembles rulemaking action.¹¹⁵

First, while the APA contains a presumption for judicial review, there is a narrow exception to the presumption; "judicial review is not available for 'agency action that is committed to agency discretion by law,'" such as when an agency refuses to institute investigative or enforcement proceedings.¹¹⁶ However, the exception can be

110. *Id.* at 169. The court stated, "[...] if the NOOHs embody (or contain) the requisite findings, and revocation of the NOOHs does not suffice to withdraw them, where do the findings exist? In the thoughts and beliefs of the Secretary or Commissioner? Scattered across various agency documents reflecting such thoughts?" *Id.* at 170.

111. *Id.* at 185 (Katzmann, C.J., dissenting).

112. *Id.* In fact, the FDA has yet to issue a single statement undermining the findings contained in the 1977 NOOHs.

113. *See Id.* at 175.

114. *See NRDC III*, 760 F.3d at 176. The majority wrote:

It is not for us to determine whether the agency has been prudent or imprudent, wise or foolish, effective or ineffective in its approach to this problem. Whether the agency's long inaction in the face of the dangers highlighted in the 1977 NOOH's represented politically-inspired foot-dragging or wise caution in developing a cost-effective approach, it was for the agency, and not the courts, to determine how best to proceed.

Id.

115. For a more in depth discussion of the administrative law issues and the standards governing review of agency action, see Case Comment, *Administrative Law—Reviewability—Second Circuit Upholds FDA's Decision Not to Withdraw Approval from Potentially Dangerous Animal Drugs*: Nat. Res. Def. Council, Inc., v. FDA, 128 HARV. L. REV. 1011 (2015).

116. *NRDC III*, 760 F.3d at 186 ((Katzmann, C.J., dissenting) (internal citation omitted).

rebutted where the statute provides clear guidelines regarding the exercise of enforcement powers.¹¹⁷ Here, the text of § 360b(1)(e) places clear limits on agency discretion by requiring the FDA to commence withdrawal proceedings whenever it finds a particular drug is not shown to be safe.¹¹⁸

Second, the withdrawal proceedings of § 360b(e)(1)(B) more appropriately fall into the category of rulemaking action than enforcement action.¹¹⁹ Therefore, the review of agency action should be held to the standard established for rulemaking actions in *Massachusetts v. EPA*.¹²⁰ *Massachusetts v. EPA* forbids an agency from relying on outside factors when refusing to make a particular statutory determination.¹²¹ When the presumption against judicial review is removed, it is easy to determine that the FDA denial of the citizen petitions was arbitrary and capricious because the reasons for denying the petitions were “divorced from the statutory text.”¹²² The FDA cannot refuse to make a determination required by statute because it prefers a different regulatory strategy; it must respond to the citizen petition by addressing whether the drug uses at issue are shown to be safe.¹²³

On September 8, 2014, the Plaintiffs petitioned for a rehearing *en banc* of the Second Circuit’s 2–1 decision, listing two reasons for rehearing.¹²⁴ The Plaintiffs’ Petition states that the Plaintiffs seek a rehearing *en banc* because the case involves questions of exceptional importance; the majority’s conclusion that the agency is not required to carry out its statutory mandate “leaves unremedied a health problem of critical importance.”¹²⁵ Second, the Petition as-

117. *Id.*

118. *Id.* at 177, 187 (Katzmann, C.J., dissenting). “The Secretary **shall**, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . if the Secretary finds—...(B) that new evidence . . . shows that such drug is not shown to be safe for use. . . .” 21 U.S.C. § 360b(e)(1) (emphasis added).

119. *Id.* at 188–89 (Katzmann, C.J., dissenting).

120. 549 U.S. 497 (2007). See *NRDC III*, 760 F.3d at 188 (Katzmann, C.J., dissenting) (asserting the *Massachusetts* holding). See generally *Massachusetts*, 549 U.S. 497 (2007) (holding that the statute allowed the administrator initial discretion, but that once an endangerment finding was made, action became mandatory and could not be justified by reasons divorced from the statute.)

121. See *NRDC III*, 760 F.3d at 188 (Katzmann, C.J., dissenting).

122. *Massachusetts*, 549 U.S. at 531–34 (reasons for action or inaction must be grounded in the statute).

123. See *NRDC III*, 760 F.3d at 192–93 (Katzmann, C.J., dissenting).

124. *NRDC III*, 760 F.3d 151 (2d Cir. 2014), petition for rehearing *en banc* filed, (September 18, 2014) No. 12–2106.

125. *Id.*

serts that the majority decision conflicted with Supreme Court decisions in *Massachusetts* and *Chevron*.¹²⁶ As of this writing, the Second Circuit has yet to grant rehearing.

V. THE LEGISLATIVE AND EXECUTIVE RESPONSE

A. Proposed Legislation

Based on the FDA's failure to address concerns over growing antibiotic resistance and armed with a growing body of scientific evidence, over 300 organizations and groups have expressed support for legislation that would phase out non-therapeutic use of antibiotics in farm animals and ban antibiotics vital to human health.¹²⁷ Accordingly, there have been numerous attempts to introduce reform legislation by both houses of Congress. For example, Representative Louise Slaughter (D-NY) has introduced versions of H.R. 1150—The Preservation of Antibiotics for Medical Treatment Act of 2013 (PAMTA)¹²⁸—to Congress in 2003, 2005, 2007, 2009, and 2013.¹²⁹ Senator Dianne Feinstein (D-CA) introduced a similar bill in 2013 titled Senate Bill 1256—Preventing Antibiotic Resistance Act of 2013 (PARA).¹³⁰

PAMTA and PARA have several similar provisions designed to preserve the use of medically important antibiotics. These provisions specify the need to: (1) amend the FDCA so that drug manufacturers have the initial burden of proof of safety of the nontherapeutic antibiotic use; (2) reduce and eventually eliminate the nontherapeutic use of antibiotics in animal feed and water; (3) prohibit antibiotic use for animals that are not diseased; (4) prohibit the practice of routine antibiotic use for disease prevention, and (5) ensure that veterinarians administering antibiotics have a connection

126. *Id.*; See also Andrew Westney, *NRDC Urges 2nd Circ. To Rehear Livestock Antibiotic Suit*, LAW 360 (Sept. 10, 2014), http://www.law360.com/articles/575628?utm_source=rss&utm_medium=rss&utm_campaign=articles_search.

127. *Preservation of Antibiotics for Medical Treatment Act: Hearing on H.R. 1549 Before the HR Committee on Rules*, 111th Cong., 4 (2009) (statement of Robert P. Martin, Senior Officer, The Pew Environment Group).

128. Preservation of Antibiotics for Medical Treatment Act of 2013, H.R. 1150, 113th Cong. (2013).

129. See H.R. 1549, 111th Cong. (2009); H.R. 962, 110th Cong. (2007); H.R. 742, 109th Cong. (2005); H.R. 2932, 108th Cong. (2003).

130. Preventing Antibiotic Resistance Act of 2013, S. 1256, 113th Cong. (2013). Additionally, the Strategies to Address Antimicrobial Resistance Act, H.R. 2400, 111th Cong. (2009), was introduced to Congress in 2007 and 2009. See Davis & Rutkow, *supra* note 28, at 358. The Strategies to Address Antimicrobial Resistance (STAAR) Act would amend the Public Health Service Act to create an Office Antimicrobial Resistance modeled after the Task Force established in 1999. *Id.*

with the animals they are prescribing to.¹³¹ PAMTA, for example, defines nontherapeutic use as, “[the] administration of antibiotics to an animal through feed or water [...] for purposes (such as growth promotion, feed efficiency, weight gain, or disease prevention) other than therapeutic use or nonroutine disease control.”¹³²

Additionally, Representative Henry Waxman (D–CA) introduced H.R. 820—The Delivering Antimicrobial Transparency in Animals Act—in 2013.¹³³ H.R. 820 enhances the reporting requirements pertaining to antimicrobial drug use in food animals. It would require all major industrial farmers to submit detailed reports to the FDA regarding the type and amount of antibiotics used in animal feed.¹³⁴

B. *The Executive Response – PCAST Report, Executive Order and National Strategy*

The Obama Administration has stated that it considers the development and spread of antibiotic resistance to be a “top national security and public health priority.”¹³⁵ To address the issue, on September 18, 2014, the Obama Administration released a set of federal actions to combat the rise of antibiotic-resistant bacteria, including an Executive Order¹³⁶ and *A National Strategy for Combating Antibiotic-Resistant Bacteria* (“CARB Strategy”).¹³⁷ Both actions were based on a new report from the President’s Council of Advisors on Science and Technology (“PCAST”) entitled *Combating Antibiotic-Resistant Bacteria* (“PCAST Report”).¹³⁸

131. Brian Krans, *Politics Stall Antibiotics Ban in Congress*, HEALTHLINE (July 24, 2014), <http://www.healthline.com/health/antibiotics/politics-pork-and-poultry-why-legislation-has-not-passed>. For example, the current PAMTA bill proposes to amend Sections 201 and 512 of the FDCA to withdraw approval for certain critically important antimicrobials for nontherapeutic use, thus requiring the FDA to eliminate the nontherapeutic use of eight classes of antimicrobials in food producing animals within two years.

132. Preservation of Antibiotics for Medical Treatment Act of 2013, *supra* note 128, at 4(a).

133. Delivering Antimicrobial Transparency in Animals Act of 2013, H.R. 820, 113th Cong. (2013).

134. *Id.*

135. Press Release, The White House Office of Communications, Fact Sheet: Obama Administration Takes Actions to Combat Antibiotic-Resistant Bacteria, (Sept. 18, 2014), <https://www.whitehouse.gov/the-press-office/2014/09/18/fact-sheet-obama-administration-takes-actions-combat-antibiotic-resistan> [hereinafter White House Press Release].

136. Exec. Order No. 13676184, 184 Fed. Reg. 56,931 (2014).

137. THE WHITE HOUSE, NAT’L STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA (Sept. 2014) [hereinafter CARB STRATEGY]. The actions also included the launch of a twenty-million-dollar prize to “facilitate the development of rapid, point-of-care diagnostic tests for health care providers to identify highly resistant bacterial infections.” White House Press Release, *supra* note 135.

138. PCAST REPORT, *supra* note 1. The Report was publicly released along with the Executive Order and National Strategy on September 18, 2014. *See Id.*

The PCAST Report recommendations for action occur in three focused areas: improving the surveillance and research of antibiotic-resistant bacteria, improving appropriate use of existing antibiotics to increase longevity, and developing and discovering new antibiotics and alternatives.¹³⁹ Despite the fact that the Report devoted little space to antibiotics in animal agriculture, it noted that “the risks to human health posed by the agricultural use of antibiotics are . . . a matter of very serious concern.”¹⁴⁰ Recommendations included development of more research through additional funding and strong support of the “FDA’s new Guidances 209 and 213, designed to promote the judicious use of antibiotics in agriculture.”¹⁴¹ PCAST concluded that the FDA should monitor the sales of medically important antibiotics and collect data, concluding that, “[i]f the FDA guidances are not effective in mitigating the risk of antibiotic resistance associated with antibiotic use in animal agriculture, [the] FDA should take additional measures.”¹⁴²

The Executive Order initially established the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to provide advice, information, and recommendations to the Secretary on combating antibiotic resistance.¹⁴³ It then directed the federal government to implement the national strategy and address the PCAST Report in order to address antibiotic resistance threats.¹⁴⁴ It established a new interagency Task Force for Combating Antibiotic-Resistant Bacteria with the mission of identifying actions to implement and monitor the Executive Order and the National Strategy.¹⁴⁵ The Task Force was given one year to submit a five-year National Action Plan to the President outlining goals, metrics, and timelines for implementation.¹⁴⁶ In regards to antibiotic use in food animals, Section 5(e), generally titled *Improved Antibiotic Stewardship*, instructs the FDA to “continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.”¹⁴⁷ Additionally, the USDA, EPA, and FDA should coordinate on research, findings, and

139. *Id.* at 2–7.

140. *Id.* at 2.

141. *Id.* at 7.

142. *Id.* at 7. PCAST acknowledged while all 26 animal-drug companies affected by Guidance #213 have agreed to comply with the voluntary changes, “it will be important to see how the voluntary changes actually impact antibiotic use and stewardship in agriculture.” *Id.* at 53–55.

143. 3 C.F.R. 13676 § 4(c).

144. *Id.* § 1–2.

145. *Id.* § 3(b).

146. *Id.* § 3(c)(i).

147. *Id.* § 5(e).

surveillance of antibiotic use and resistance patterns in food-producing animals.¹⁴⁸

The National Strategy provides actions for five goals related to combatting antibiotic resistance that are to be achieved by 2020.¹⁴⁹ The goals include:

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections;
2. Strengthen national One-Health surveillance efforts to combat resistance;
3. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria;
4. Accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines; and
5. Improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control, and antibiotic research and development.¹⁵⁰

Pertaining to antibiotic use in food animals, Goal 1, Objective 1.2 recommends the elimination of use of medically important antibiotics for growth promotion in animals, and bringing other in-feed uses of antibiotics under veterinary oversight in line with GFI #213.¹⁵¹ Goal 4 has certain objectives that indicate the need for research on the relationship between antibiotic use in livestock and the development of antibiotic resistance, as well as research into resistance and its spread among zoonotic pathogens.¹⁵²

148. 3 C.F.R. 13676, § 5(f). Section 6 includes further requirements for Strengthening National Surveillance Efforts For Resistant Bacteria. “USDA, EPA, and FDA shall work together with stakeholders to monitor and report on changes in antibiotic use in agriculture and their impact on the environment.” *Id.* § 6(c).

149. CARB STRATEGY, *supra* note 137, at 5.

150. *Id.*

151. *Id.* at 8. Other in-feed uses include treatment and disease control and prevention of disease. *Id.*

152. *Id.* at 17–19.

C. Reception and Analysis

The proposed bills have been met with strong opposition, and none of them have even neared the floor for debate.¹⁵³ Key stakeholders such as agricultural and pharmaceutical companies have spent a great deal of time and money lobbying against the legislation.¹⁵⁴ These stakeholders argue that the proposed legislation is flawed for three reasons. First, they claim that the proposed bills too narrowly define therapeutic use by failing to include the “prevention of disease” in the definition of therapeutic uses; therefore, the legislation is not aligned with the FDA’s recommendations under GFI #209.¹⁵⁵ Second, opponents claim there is a need for further research and planning regarding the degree of connection between antibiotic use in food animals and antibiotic resistance in humans before binding regulations are implemented.¹⁵⁶

Regarding the Executive action, both the drug and animal production industries and the FDA have praised the recent actions taken by the Obama Administration.¹⁵⁷ In contrast, critics had hoped President Obama would go further in regards to antibiotics used in food animals, and believe the “PCAST recommendations fall

153. See Krans, *supra* note 131. Krans notes that—according to GovTrack—PAMTA has a one percent chance of ever being enacted, and PARA has a zero percent chance. *Id.*

154. For example, lobbying efforts have come from the National Beef Packing Company; the National Pork Producers Council; The Animal Health Institute; the Food Marketing Institute; Merck & Co., Eli Lilly & Co.; and Pfizer. *Id.* The economic incentives make opposition inevitable. For example, the National Research Council estimated that the animal health industry produced \$3.3 billion for pharmaceutical companies in 1995 alone. Davis & Rutkow, *supra* note 28, at 362.

155. AMERICAN VETERINARY MED. ASS’N, AVMA ISSUE BRIEF: PRESERVATION OF ANTIBIOTICS FOR MEDICAL TREATMENT ACT—H.R. 1150 (2014), https://www.avma.org/Advocacy/National/Documents/IB_PAMTA_4-1-2014.pdf, [hereinafter AVMA ISSUE BRIEF]; see GFI #209, *supra* note 5, at 4.

156. Halpern, *supra* note 16, at 419. “The correlation between [the two] must be more extensively explored before a definitive cause and effect can be established.” *Id.* The concern in this regard is that further harm to human health could result if antibiotics were entirely prohibited from use in food animals since alternatives have not been extensively explored. *Id.* See also AVMA ISSUE BRIEF, *supra* note 155, at 2.

157. Nat’l Pork Producers Council, American Meat Institute, *Groups Respond to White House Executive Order on Antibiotic Resistance* (Sept. 18, 2014), <http://nationalhogfarmer.com/health/groups-respond-white-house-executive-order-antibiotic-resistance>; Margaret A. Hamburg, *FDA’s Take on the Executive Order and National Strategy to Combat Antibiotic-Resistant Bacteria*, FDA VOICE (Sept. 18, 2014), <http://blogs.fda.gov/fdavoices/index.php/2014/09/fdas-take-on-the-executive-order-and-national-strategy-to-combat-antibiotic-resistant-bacteria/>. The FDA Voice Blog is available at <http://blogs.fda.gov/fdavoices/index.php>.

short in addressing the critical need to reduce antibiotic use, especially in livestock.”¹⁵⁸ They point out that while the executive actions generally endorse better antibiotic stewardship in agriculture, they do not require that regulatory or legislative action be taken.¹⁵⁹ Thus, FDA retains the ultimate discretion to refuse to withdraw the approval of certain animal drugs, and drug producers and consumers’ compliance with judicious use principles remains entirely voluntary. The critics also point out that the Executive’s primary recommendation regarding antibiotics used in agriculture authorized more expensive and time-consuming research on the correlation between antibiotic use in animals and human health.¹⁶⁰ Finally, they are displeased that the Executive actions include disease prevention in the description of permitted uses.¹⁶¹

In attacking the critiques of the proposed bills and simultaneously supporting critics of the Executive action, the following points are worth making. First, including disease prevention in the definition of therapeutic uses may permit drug producers to re-label antibiotics intended for growth promotion as antibiotics for disease prevention.¹⁶² If this re-labeling is done, it would undermine any efforts to reduce overall antibiotic use.

158. Press Release, Health Care Without Harm and Healthy Food Action, White House Report on Antibiotic Resistance Disappoints (Sept. 18, 2014), <http://www.marketwatch.com/story/white-house-report-on-antibiotic-resistance-disappoints-2014-09-18>.

David Wallinga, MD, Director of Healthy Food Action, stated, “For the White House to punt leadership on this critical medical and national security issue to the FDA [is] a tragic mistake. . . . For four decades, the FDA has failed to take action to reduce antibiotics used in livestock feed.” *Id.*

159. See Exec. Order No. 13676184 § 10, 184 Fed. Reg. 56,931 § 10 (2014). The relevant part of the Executive Order § 10 reads:

Nothing in this order shall be construed to impair or otherwise affect . . . the authority granted by law to an executive department or agency . . . This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Id. at § 10(b)(i), 10(c).

160. PCAST REPORT, *supra* note 1, at 5. For example, the PCAST report recommends that a USDA multidisciplinary Innovation Institute be employed to develop alternatives to antibiotics in agriculture; PCAST projects that the Institute will require \$25 in annual funding. *Id.*

161. See, e.g., Mae Wu, *Breaking Down the President’s Plan on Combating Antibiotic Resistance*, NRDC (Sept. 18, 2014), <https://www.nrdc.org/experts/mae-wu/breaking-down-presidents-plan-combating-antibiotic-resistance>; Lisa Schnirring, *White House Releases plan to curb antibiotic resistance*, CENTER FOR INFECTIONS DISEASE RESEARCH AND POLICY, <http://www.cidrap.umn.edu/news-perspective/2015/03/white-house-releases-plan-curb-antibiotic-resistance>.

162. The PCAST Report briefly addressed concerns that antibiotic use intended for growth promotion could be redesignated as intended for disease prevention, stating that the practice would be “unethical and illegal.” PCAST REPORT, *supra* note 1, at 54. Unfortunately, this would likely be hard to monitor with a degree of certainty, and enforcement would remain another issue entirely.

Second, demands for more, optimal, or consistent data are only a means of stalling the implementation of binding regulations. As a starting point, the tracking of bacterial resistance is markedly difficult; for example, in the U.S., the current surveillance systems to collect data from both human and animal populations have been described as “remain[ing] suboptimal and yield[ing] inconsistent results.”¹⁶³ Further, the drastic consequences of eliminating antibiotic effectiveness combined with the speed at which resistance is developing should outweigh the need for a precise measurement regarding a *degree* of harm caused to humans from animal antibiotic use.¹⁶⁴ The current scientific consensus has established that antibiotic use in animals results in adverse consequences for human health;¹⁶⁵ the reality is that harm, to whatever degree, will result from continued use. Instead, economic expenditures and research time should be focused on educating animal producers, veterinarians, and the like on alternatives to antibiotics, and any further resources should be devoted to the study of antibiotic resistance in humans.

Finally, as an additional note regarding further research, opponents of binding regulatory or legislative action have advocated for the consideration of risk factors that go beyond the appropriate parameters of a public health risk assessment.¹⁶⁶ These opponents claim that the harm resulting from eliminating antibiotic use—the loss of the economic and animal health benefits that the drugs provide—would outweigh the benefit to human health.¹⁶⁷ However, only the human safety of the drug may be considered. As is con-

163. Halpern, *supra* note 16, at 432. For example, the FDA, CDC, and USDA have six ongoing surveillance activities pertaining to resistant bacteria, each monitoring different bacterial varieties and using different laboratory testing methods. *Id.*

164. This argument is possible because the US requires a risk assessment. In contrast, the European Union rejected the need for such precise measurements and instead relied on the precautionary principle to avoid delay in banning five antibiotics in 1998; “[N]o [risk assessment] predicting human (or animal) health consequences was considered necessary.” Halpern, *supra* note 16, at 430 (alteration in original). The European Union decided that the risk of future antibiotic resistance outweighed the risk of increased animal production costs. Centner, *supra* note 25, at 30. The precautionary principle states that when the health of humans is in danger, it may not be necessary to wait for scientific certainty to take remedial or protective action. David Kriebel, et. al., *The Precautionary Principle in Environmental Science*, 109 ENVTL HEALTH PERSP. 871 (2001).

165. Indeed, the task forces that have come to this conclusion have not demonstrated success in blunting the overuse of antibiotics. Grover, *supra* note 57. See, e.g., ITFAR REPORT, *supra* note 2.

166. This analysis includes risk factors such as increased rates of mortality and infectious disease among animals, and decreased animal production. Halpern, *supra* note 16, at 416–17.

167. Halpern, *supra* note 16, at 435.

tained in the Final Decision of the Commissioner to withdraw approval for Baytril®, “FDA is not authorized, under the FDCA, to weigh economic, health or other benefits that the drug provides against a health risk to the ultimate human consumers of food from or contaminated by treated animals.”¹⁶⁸ While the opponents have attempted to reclassify the detriments to animal health as human safety considerations, their argument can be dismissed when one considers that antibiotics are not the only method of maintaining healthy food animals to ensure safe food for human consumption.¹⁶⁹ Case studies from outside of the U.S. have demonstrated that antibiotic bans have been successfully accomplished, allowing only brief increases in animal mortality and disease, when antibiotic alternatives are effectively implemented.¹⁷⁰

VI. CONCLUSION

D. Moving Forward, Possibilities for Reform—Leading Examples

Over the past decades, various countries in the European Union have taken regulatory action to ban the use of antibiotics as growth promoters in food animals.¹⁷¹ When faced with the same scientific data available to the U.S., the EU concern prompted enactment of a legislative ban on nonessential, or nontherapeutic, antibiotic use

168. FDA, Final Decision of the Commissioner, *Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry*, 70 Fed. Reg. 44105–01, at 120. In regards to enrofloxacin, the Commissioner stated, “[e]ven if I were to attempt to weight the benefits of enrofloxacin against its risks, the record before me is not sufficient to show that the alleged benefits outweigh the risks.” *Id.*

169. Alternatives typically involve improved production practices such as ensuring better ventilation, more space per animal, and better hygiene and sanitation standards. *C.f.* Lessing, *supra* note 21, at 468 (explaining that antibiotics are used to combat infections that only arose as a result of poor living conditions).

170. Davis & Rutkow, *supra* note 28, at 361; In some cases, reduced antibiotic dosing and improved hygienic practices resulted not only in lower mortality rates but actually increased the value of the production. Increased value will typically be generated because of the consumer demand for antibiotic free meat. For example, McDonald’s one of the largest meat purchasers in the world, only accepts chicken raised without medically-important antibiotics used for non-therapeutic purposes, and preferences other meat suppliers who comply with this policy. Other companies have banned all use of non-therapeutic antibiotics in the poultry they purchase. Vanessa K.S. Briceño, Note, *Superbug Me: The FDA’s Role in the Fight Against Antibiotic Resistance*, 9 N.Y.U. J. LEGIS. & PUB. POL’Y 521, 527–28 (2005–06). Moreover, the costs of improved sanitation and living conditions used to combat increased mortality can likely be offset by the decrease in the cost of antibiotics. Lessing, *supra* note 21, at 478. Therefore, the negative human health consequences that may arise from a decline in animal health can be mitigated by spending to improve farming production practices.

171. Cogliani et. al., *supra* note 7, at 274. The first ban on antibiotic growth promoters was enacted in Sweden in 1986, followed by Denmark, The United Kingdom, and The Netherlands. *Id.*

in food animals in an attempt to reduce pools of resistant genes.¹⁷² Importantly, “the full arsenal of antibiotics remains available to veterinarians to treat sick animals and herds.”¹⁷³ Using Denmark as the primary example, the bans do not limit all antibiotic use. Rather, they limit antibiotic use by requiring a veterinarian prescription, and mandating that certain drugs found to be particularly important for human medicine only be administered by injection instead of through feed additives.¹⁷⁴

On January 1, 2000, Denmark, one of the world’s major pork providers, banned the use of non-therapeutic antibiotics at all stages of pork production.¹⁷⁵ The “Danish experience” standing alone should raise serious skepticism regarding industry claims that efficient animal production without antibiotics could not be achieved.¹⁷⁶ The reports monitoring the ban have revealed at least four positive and inspiring conclusions. First, the ban was successful in reducing the amount of antibiotics consumed by food animals; the total antibiotic usage per pound of pork decreased by greater than 50 percent.¹⁷⁷ While antibiotic use gradually increased for a period of time due to the emergence and spread of new diseases, levels quickly returned to pre-ban levels.¹⁷⁸ The reduction of antimicrobial use has also led to reductions in the average duration of exposure of animals to antimicrobials.¹⁷⁹

Second, Denmark’s antibiotic ban has had minimal, if any, negative impact on the nation’s pork industry. While antibiotic use per kilogram of pig raised decreased, overall productivity increased from 18.4 million weaned pigs in 1992, to 27.1 million in 2008 (a 43

172. *Id.* at 274–75.

173. Kathy Talkington, *What Can Danish Hogs Teach Us About Antibiotics?*, THE PEW CHARITABLE TRUSTS (Oct. 13, 2009), <http://www.pewtrusts.org/en/about/news-room/opinion/2009/10/13/what-can-danish-hogs-teach-us-about-antibiotics>.

174. Preservation of Antibiotics for Medical Treatment Act of 2009: Hearing on H.R. 1549 Before the HR Committee on Rules, 111th Cong. 1, at 1–2 (2009) (statement of Dr. Frank Møller Aerestrup and Dr. Henrik Wegener, National Food Institute, Technical University of Denmark) [hereinafter Møller & Wegener Statement].

175. *Id.* Prior to the mandatory ban, the Danish government instituted a voluntary ban on the non-therapeutic use of antimicrobials at the finishing stage of production, adding a \$2.00 tax per pig for noncompliance. *Id.* at 2.

176. *Id.*

177. *Id.* at 2. Use in Denmark reached only 47 mg/kg during the peak of use, whereas the U.S. uses 250–300 mg/kg. *Id.*

178. 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.

179. WORLD HEALTH ORGANIZATION, IMPACTS OF ANTIMICROBIAL GROWTH PROMOTER TERMINATION IN DENMARK, 6 (Nov. 2002) [hereinafter WHO REPORT].

percent increase in production).¹⁸⁰ The average number of pigs produced per sow increased by four, which is a positive indicator of swine health and welfare.¹⁸¹ To be sure, pig mortality increased for a short period immediately following the withdrawal of antibiotics, creating a short-term need to increase therapeutic antibiotic use. However mortality rates fell sharply as of 2004, and as of 2008, they have returned to pre-antibiotic ban levels.¹⁸² Danish scientists claim that, overall, swine productivity has increased even as antimicrobial use has decreased.¹⁸³

Third, data from Denmark has shown a marked decline in the prevalence of antibiotic resistant bacteria in both food animals and healthy humans.¹⁸⁴ In some cases, the levels of a particular resistant bacteria declined only two years after the cessation of a particular antibiotic.¹⁸⁵ Extensive data has shown that the termination of antimicrobial growth promoters has fundamentally reduced the food animal reservoir of antibiotic resistant bacteria, and therefore reduced a reservoir of resistant genes that can transfer to several clinically important antibiotics for humans.¹⁸⁶

Fourth, the cost of raising pigs has not drastically risen despite critics' claims that the removal of antibiotics cannot be done cost effectively. According to a veterinarian with the Danish Agricultural and Food Council, "the cost of raising pigs has gone up by about €1 per animal, from birth to slaughter, since the ban."¹⁸⁷ The 2003 WHO report also found that overall economic impacts were minimal, translating to a production cost increase of just over one percent in swine and a zero percent increase in poultry.¹⁸⁸ This has been accomplished through more efficient production and husbandry practices that lead to less disease.¹⁸⁹

180. Sharon Levy, *Reduced Antibiotic Use in Livestock: How Denmark Tackled Resistance*, 122 ENVTL HEALTH PERSP. A160, A162 (2014).

181. Møller & Wegener Statement, *supra* note 175, at 2.

182. Levy, *supra* note 180, at A162. *But see* Mark Casewell, et al., *The European Ban on Growth-Promoting Antibiotics and Emerging Consequences for Human and Animal Health*, 52 J. OF ANTIMICROBIAL CHEMOTHERAPY 159, 161 (2003) (highlighting some of the adverse consequences to a widespread ban of antibiotics as growth promoters that occurred in years immediately following the ban).

183. Møller & Wegener Statement, *supra* note 175, at 2.

184. Levy, *supra* note 180, at A162.

185. *Id.*

186. WHO REPORT, *supra* note 179, at 6. However, further studies are needed to determine the effect the discontinued use of antibiotics in animal agriculture will have on antibiotic resistance in humans. *Id.*

187. Levy, *supra* note 180, at A162.

188. THE PEW CHARITABLE TRUSTS, *supra* note 178, at 3.

189. *Id.* at 2. Some of the methods included altering production systems by adopting other feed ingredients, tightening biosecurity, increasing weaning weight, improving sanitation, reducing density, and more. *Id.* at 5. Another of these methods includes allowing piglets to

Additionally, some U.S. research has already indicated that the costs of production are reduced when antibiotics are *not* used when considering the increased cost of feed containing antibiotics.¹⁹⁰ And importantly, the cost-benefit analysis swings even more in favor of alternatives to subtherapeutic uses when accounting for societal and environmental costs of antibiotic use. For example, the fact that antibiotic-resistant diseases are more prevalent in rural farming communities creates social equity concerns,¹⁹¹ and runoff from the land application of manure containing antibiotics can pollute streams and kill living organisms.¹⁹² When accounting for societal and environmental harm, industrial swine farming methods are unquestionably more expensive than alternative methods which do not use antibiotics for growth promotion.¹⁹³

Unfortunately, despite the fact that the research collected from the Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP), shows that the Danish ban has reduced human health risk without significantly harming animal health or farmers' incomes, representatives of organizations funded by industry forces have often criticized and misrepresented facts emerging from the Danish study.¹⁹⁴ Thus, the Danish success in using alternatives is often overlooked in the U.S. However, the evidence from Denmark and other countries across Europe has been convincing enough to inspire the entire European Union to ban the use of antibiotics as growth promoters in 2006.¹⁹⁵ Hopefully, as a trend emerges, the data will be harder to manipulate.

stay with their mothers for longer periods of time after birth, allowing them to naturally build their immune systems; Piglets that are separated from their mothers at early ages have been found to be more susceptible to infection. Levy, *supra* note 179, at A162.

190. THE PEW CHARITABLE TRUSTS, *supra* note 178, at 3–4. Researchers from John Hopkins University have found that the increased cost of feed containing antibiotics outweighs the costs associated with the increased amount of feed needed, plus slightly increased mortality, variability in weight gain, and increased condemnation rates (chickens with illness or disease). *Id.*

191. PCAST REPORT, *supra* note 1, at 51.

192. See Hannah M.M. Connor, *The Industrialization of Animal Agriculture: Connecting a Model With Its Impacts on the Environment*, in FOOD, AGRICULTURE, AND ENVIRONMENTAL LAW 65, 69 (Mary Jane Angelo, Jason J. Czarnecki, and William S. Eubanks II eds.) (2013). The USDA has estimated that confinement operations produce around 500 million tons of manure annually. *Id.* (citing U.S. EPA, National Pollution Discharge Elimination System Permit Regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations; Final Rule, 68 Fed. Reg. 7176, 7180 (Feb. 12, 2003)).

193. See THE PEW CHARITABLE TRUSTS, *supra* note 178, at 3.

194. Møller & Wegener Statement, *supra* note 175, at 1.

195. Levy, *supra* note 180, at A162–63.

E. Recommendations and Conclusion

First, the U.S. must continue to strengthen and improve NARMS surveillance systems to trace pathogens,¹⁹⁶ as well as establishing a surveillance system to monitor antibiotic sales and use.¹⁹⁷ Second, Congress must pass legislation that will initiate the process of withdrawal of approval of drugs that are considered medically important in human medicine in order to put the burden of proving the safety of the drug on the manufacturer.¹⁹⁸ Importantly, the legislation must properly distinguish between therapeutic and non-therapeutic use, the latter including both disease prevention and growth promotion, and provide clear language to eliminate the possibility of relabeling.¹⁹⁹ Third, information and advice on alternatives to antibiotic use must be collected and disseminated to help producers who are accustomed to the use of routine antibiotics.²⁰⁰ Federal and/or state grants to aid farmers in the transition into total elimination of subtherapeutic antibiotic use could also be of great importance.²⁰¹ Fourth, along with information to aid in compliance, the U.S. must create a system of monitoring and enforcement that mandates antibiotic reduction and imposes fines for non-compliance.²⁰² Finally, the U.S. must continue to work with other

196. NARMS is still working to establish universally acceptable, science-based testing methods, critical pathogen indicators, and surveillance tools to provide uniform data for analysis. Halpern, *supra* note 16, at 432–33.

197. Close monitoring of antibiotics sales and use has been an essential part of the Danish system to establish baseline data, to track the amount of antibiotics used in both animals and humans, and to monitor resistance in pathogens and indicator organisms. Levy, *supra* note 180, at A162 and A163. The DANMAP information system established in Denmark includes extensive monitoring systems that track drug resistance and antimicrobial use and services for research and data analysis. The information also served to identify farmers who continued to overuse antibiotics, and was used to convince the agricultural community that the ban had a positive effect on public health. *Id.*

198. For example, proposed legislation like PAMPTA and PARA propose to withdraw the use of 7 classes of antibiotics vitally important to human health from sub therapeutic use in food animal production. Krans, *supra* note 131.

199. See Levy, *supra* note 180, at A164.

200. To implement the Swedish ban, large efforts were dedicated to problem-solving and to providing services to farmers; Officials developed guidelines on appropriate feed, medicating, management, and hygiene practices to keep animals healthy and to prevent infection. Cogliani et al., *supra* note 7, at 276–77.

201. See Orrico, *supra* note 31, at 284.

202. For example, when the Dutch promulgated regulations to limit antibiotic use in animals without a plan to implement or enforce, antibiotics were still used extensively due to insufficient government control over antibiotic use and sales. The Netherlands have since imposed a mandate to reduce antibiotics in animals by 50% in the next three years, established a registration process for veterinary prescriptions, and have begun to impose fines for noncompliance. Cogliani et al., *supra* note 7, at 275–76.

countries to create international standards that restrict certain agricultural uses of antibiotics.²⁰³

The scientific community and organizations around the world have reached the consensus that antibiotic use in animals is dangerous to the public health, and there has already been success using alternatives to antibiotics to maintain animal health and production. Yet despite growing concerns, the agency charged with protecting the safety of the food supply has refused to enact binding regulations to fix the problem. Action must be taken immediately to reverse this trend. The U.S. should forgo any further delay or expenditures of time in the pure research stage and should begin implementing the withdrawal of non-therapeutic antibiotic use in animal production. In line with the recommendations above, government spending should be focused on helping farmers implement the bans and on disseminating and tracking information about antibiotic resistance generally. Any additional funds can be better directed toward preserving antibiotic effectiveness in human medicine. The bottom line is that antibiotics are a limited resource and must be conserved to help preserve their life-saving potential for the future; the more used today, the less availability and effectiveness in the future.²⁰⁴

203. Others have recommended the need for international standards. *See, e.g.*, PCAST REPORT, *supra* note 1, at 56. Recommendation 8 of the PCAST Report recommends that the federal government:

[V]igorously support development of the WHO Global Action Plan and continue to elevate the issue of antibiotic resistance to the level of a global priority by encouraging or requiring, as appropriate, coordination among countries for surveillance, reporting, research, antibiotic stewardship, and development of new and next-generation drug and diagnostics equipment.

Id. at 57.

204. CDC REPORT, *supra* note 2, at 41.

