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THE BATTLE AGAINST ANTIMICROBIAL DRUG RESISTANCE: ANALYZING RECENT DEVELOPMENTS AND THE NECESSITY FOR MAJOR AGRICULTURAL REFORMS

NIKKI SANFORD*

INTRODUCTION

Antimicrobial drug resistance is currently a major public health, environmental, and economic concern. When the effectiveness of current drugs diminishes, the ability to treat diseases and contain outbreaks is greatly reduced and healthcare costs rapidly increase.¹

Over the past decade, several legislative proposals unsuccessfully attempted to address the issue, and public interest groups continue to pressure the government to take action.² Most recently, the Second Circuit's July 2014 ruling in *Natural Resources Defense Council v. FDA* reversed the District Court's decision that the Food & Drug Administration ("FDA") is obligated to hold hearings to withdraw approval on certain drugs found to promote antibiotic-resistant bacteria through its current usage.³ In September 2014, President Obama signed an Executive Order establishing the National Strategy on Combating Antibiotic-Resistant Bacteria, and created a Task Force and Presidential Advisory Council on the matter.⁴

This Note will argue that the Second Circuit erred in its decision in *NRDC v. FDA*, and that while President Obama's directive is a crucial,

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¹ *Antimicrobial resistance*, WHO, available at <http://www.who.int/mediacentre/factsheets/fs194/en/> [https://perma.cc/TLY7-RRYF] (last updated Apr. 2014).

² See *infra* Part I.C.

³ *Natural Res. Def. Council v. FDA*, 760 F.3d 151 (2d Cir. 2014) [hereinafter *NRDC II*].

⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL STRATEGY FOR COMBATING ANTI-BIOTIC-RESISTANT BACTERIA, (Sept. 2014), available at http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf [https://perma.cc/RPP6-JTM2].

productive step in addressing antimicrobial drug resistance, the main strategy must focus on reforming current agricultural practices. To accomplish this, there are three main areas that must be addressed. First, scientific research must be increased to find efficient, alternative methods to current feed practices. Second, the United States should look to international strategies and efforts for policy guidance. Third, public awareness and knowledge must be raised to promote action.

I. BACKGROUND

A. *Current Agricultural Overuse of Antibiotics*

1. Historical Background of Antibiotic Use in Livestock

In the 1950s, scientists investigating dietary supplements for poultry found that the fermentation byproducts of a new antibiotic, chlorotetracycline, increased the weight gain of chickens.⁵ Commercially, this discovery became widely favored, since livestock could be brought to market weight with less feed.⁶ Similar studies on swine and cattle were conducted soon after and also found that those antibiotics accelerated weight gain.⁷ Producers immediately began to realize significant economic benefits.⁸

In addition to these commercial benefits, the overall health of livestock seemed to benefit as well.⁹ The prevalence of common cattle and poultry diseases decreased since entire herds could be treated in an efficient manner.¹⁰

2. Current Usage

Recently, antibiotic usage has been increasing despite the growing issue of drug resistance in humans.¹¹ Antibiotic sales for livestock raised

⁵ R.H. Gustafson & R.E. Bowen, *Antibiotic use in animal agriculture*, 83 J. APPLIED MICROBIOLOGY 531, 531–32 (1997).

⁶ *Id.*

⁷ *Id.*

⁸ *Id.* at 531.

⁹ *Id.*

¹⁰ *Id.* at 531–32.

¹¹ Sabrina Tavernise, *Antibiotics in Livestock: F.D.A. Finds Use Is Rising*, N.Y. TIMES (Oct. 2, 2014), <http://www.nytimes.com/2014/10/03/science/antibiotics-in-livestock-fda-finds-use-is-rising.html> [<https://perma.cc/TM4R-F8DA>].

for consumption rose 16% between 2009 and 2012.¹² The FDA enacted stricter usage regulations for cephalosporins, which are a type of drug used in livestock, yet sales still increased by 37% between 2009 and 2012.¹³ The FDA's 2012 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals states that overall, animal feed additives account for 70% of all medically important antibiotics sold, and drinking water additives account for 24%.¹⁴

Fluoroquinolone usage provides a clear example of the dangers of resistance due to agricultural practice.¹⁵ Similarly, after campylobacter strains became introduced in poultry feed, resistance developed at rates correlated to their agricultural use.¹⁶ There had been no previous resistance issues in individuals unless they had taken the drug or been to countries where the drug was permitted in agricultural feed.¹⁷ Although the FDA banned fluoroquinolone usage in 2005, this is a clear example of threats posed by agricultural uses of antibiotics.¹⁸

B. Public Health & Environmental Impacts

1. Public Health Impacts

Antibiotic resistance severely affects public health,¹⁹ and is recognized by the World Health Organization ("WHO") as a top global health issue.²⁰ Resistance occurs when bacteria evolve and adapt to their environment.²¹ Antibiotics kill their targeted microorganisms, and bacterial

¹² *Id.*

¹³ *Id.*

¹⁴ Summary Report, FDA, ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 16 (2014).

¹⁵ *Prescription for Trouble: Using Antibiotics to Fatten Livestock*, UNION OF CONCERNED SCIENTISTS, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/prescription-for-trouble.html#.VMrYF3DF990 [https://perma.cc/5DAW-69N7] (last visited Mar. 20, 2016).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ WORLD HEALTH ORG., ANTIMICROBIAL RESISTANCE: GLOBAL REPORT ON SURVEILLANCE 3 (2014), available at <http://www.who.int/drugresistance/documents/surveillance-report/en/> [https://perma.cc/D772-LCC5].

²⁰ AM. SOC'Y OF AGRONOMY, *Antibiotic resistance in agricultural environments: A call to action*, SCIENCE DAILY (Sept. 26, 2013), <http://www.sciencedaily.com/releases/2013/09/130926142926.htm> [https://perma.cc/GFA5-5NUP].

²¹ *Antibiotic Use in Food-Producing Animals*, CDC, <http://www.cdc.gov/narms/animals.html> [https://perma.cc/AR8G-9DEY] (last updated Sept. 4, 2014).

strains that are genetically resistant will survive and reproduce.²² The population of these resistant bacterial strains can increase and infect humans and animals.²³ Those infected with resistant bacteria cannot be treated by common antibiotics, and may be sick for a longer period of time.²⁴ The Center for Disease Control (“CDC”) estimates that antibiotic resistant diseases infect over two million people each year, and kill at least 23,000.²⁵ The WHO states that resistance to certain strains of common bacteria has spread to all regions of the world.²⁶ This issue is a current threat, which must be addressed before common infections become untreatable.²⁷

According to the CDC, the bacteria that pose the greatest threat (categorized as “urgent”) are *Clostridium difficile*, Carbapenem-resistant *Enterobacteriaceae* (“CRE”), and drug-resistant *Neisseria gonorrhoeae*.²⁸ These three bacteria alone are estimated to cause over 500,000 cases of human infections annually.²⁹ Among the groups most at risk when antibiotics become resistant are cancer chemotherapy patients, patients undergoing surgery, individuals with rheumatoid arthritis, end-stage renal disease dialysis patients, and organ and bone marrow transplant recipients.³⁰

2. Environmental Impacts

Antibiotics fed to livestock have a widespread impact that affects crops, soil, water quality, and other living organisms.³¹ Treated livestock

²² Teshome H. Regassa et al., *Antibiotic Use in Animal Production: Environmental Concerns*, HEARTLAND REG'L WATER COORDINATION INITIATIVE 5, available at <http://extensionpublications.unl.edu/assets/pdf/rp196.pdf> [<https://perma.cc/5XX9-E9R4>] (last visited Mar. 20, 2016).

²³ *Id.*

²⁴ *Id.*

²⁵ *Antibiotic Resistance Threats in the US*, CDC, <http://www.cdc.gov/features/AntibioticResistanceThreats/index.html> [<https://perma.cc/WF3D-5AWQ>] (last updated Sept. 16, 2013).

²⁶ *Antimicrobial resistance*, *supra* note 1.

²⁷ *Id.*

²⁸ CTNS. FOR DISEASE CONTROL & PREVENTION, *ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES* 7 (2013), available at <http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf> [<https://perma.cc/5FMK-TG7K>].

²⁹ *Id.* at 15–16.

³⁰ *Id.* at 27.

³¹ See Regassa, *supra* note 22; Matthew Cimitile, *Crops absorb livestock antibiotics, science shows*, ENVTL. HEALTH NEWS (Jan. 6, 2009), <http://www.environmentalhealthnews.org/ehs/news/antibiotics-in-crops> [<https://perma.cc/E7EZ-H48D>]; R. Pulicharla et al.,

excrete 90% of administered drugs in their urine and manure.³² Manure is used as a fertilizer on over nine million hectares of U.S. land, and plants readily absorb and accumulate the antibiotics in that soil.³³ The specific health implications of these reabsorbed antibiotics are not certain, although plants “in direct contact with the soil,” (such as tubers and root crops) may absorb antibiotics more easily, and crops that are not processed before consumption (like cabbage and lettuce) will have greater quantities of antibiotics.³⁴ A peer-reviewed scientific report from the University of Nebraska states that the antibiotic toxicity risk to humans from manure-grown crops is very low, yet the effects on microorganisms in the manure and soil require additional research.³⁵

Effects on native animals are another environmental concern. All animals that graze fields with manure from antibiotic-fed livestock are potential vectors for resistant bacteria.³⁶ Resistance could then be transferred from those animals to other organisms and spread to other ecosystems.³⁷

Wastewater treatment plants are another source that often introduces antibiotics into the environment.³⁸ Sewage from both livestock and antibiotic-tainted soil can spread antibiotic resistant bacteria through runoff, spills, and soil leeching.³⁹ Scientific data recognizing potential contamination and waterborne bacterial pathogens due to runoff in recycled water irrigation systems supports the concern for antibiotic resistance in humans, resulting from these treatment plants and irrigation systems.⁴⁰

C. *Recent Legislative Attempts Addressing Antimicrobial Resistance*

In light of these known consequences of drug resistance, several legislative attempts have occurred in recent years to address the issue.

A persistent antibiotic partitioning and co-relation with metals in wastewater treatment plant—Chlortetracycline, 2 J. ENVTL. CHEM. ENG'G 1596, 1596–97 (2014).

³² Cimitile, *supra* note 31.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ Pulicharla et al., *supra* note 31, at 1596.

³⁹ Nicole Fahrenfeld et al., *Reclaimed Waters as a reservoir of antibiotic resistance genes: distribution system and irrigation implications*, 4 FRONTIERS IN MICROBIOLOGY 1, 8 (2013), <http://journal.frontiersin.org/Journal/10.3389/fmicb.2013.00130/full> [<https://perma.cc/C64C-9LZ5>].

⁴⁰ *Id.*

In March 2013, Congresswoman Louise Slaughter (New York) introduced H.R. 1150: Preservation of Antibiotics for Medical Treatment Act ("PAMTA") to the House Committee on Energy and Commerce.⁴¹ The related Senate bill, S. 1256: Preventing Antibiotic Resistance Act of 2013 ("PARA"), was introduced to the Senate Health, Education, Labor, and Pensions Committee by Senator Dianne Feinstein (CA) in June 2013.⁴²

PAMTA and PARA address several issues concerning animal drugs and propose to (1) require new animal drugs applications to show with reasonable certainty that no human harm will result due to any nontherapeutic use of the drug; (2) prohibit the nontherapeutic use of medically important antimicrobials in food-producing animals, unless the reasonable certainty standard for no human harm is met; and (3) prohibit using antimicrobials on food-producing animals for non-routine disease control, unless certain standards are met.⁴³

However, neither of these bills have made it past their initial introductions and committee referrals.⁴⁴ Public interest groups and city councils across the nation continue to urge Congress to act on PAMTA and PARA.⁴⁵ Petitions launched by Food Policy Action and Dr. Mark Hyman in support of PAMTA and PARA have gathered over 130,000 signatures as of August 2013.⁴⁶ Food & Water Watch has assisted in local efforts, and fourteen city councils have passed resolutions to prompt Congress to pass the legislation.⁴⁷

Another bill, H.R. 2285: Strategies to Address Antimicrobial Resistance Act, was introduced to the House Energy and Commerce Committee by Congressman Jim Matheson (Utah) in June 2013.⁴⁸ The related Senate Bill with the same title was introduced by Senator Sherrod Brown (Ohio) in April 2014.⁴⁹ This legislation would enhance efforts to address

⁴¹ H.R. 1150, 113th Cong., 1st Sess. (2013); *Antibiotic Resistance*, Congresswoman Louise M. Slaughter, <https://louise.house.gov/issues/antibiotic-resistance> [<https://perma.cc/KKZ8-KD94>] (last visited Mar. 20, 2016) (discussing the rationale behind the Preservation of Antibiotics for Medical Treatment Act).

⁴² S. 1256, 113th Cong., 1st Sess. (2013).

⁴³ H.R. 1150.

⁴⁴ See H.R. 1150; S. 1256.

⁴⁵ *Petitions Urge Congressional Action on Antibiotics Legislation*, FOOD SAFETY NEWS (Aug. 16, 2014), <http://www.foodsafetynews.com/2014/08/petitions-attempt-to-prompt-congressional-action-to-antibiotics-legislation#.VG0zY1XF9tI> [<https://perma.cc/5N8M-FHBY>].

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ H.R. 2285, 113th Cong., 1st Sess. (2013).

⁴⁹ S. 2236, 113th Cong., 2nd Sess. (2014).

antimicrobial resistance by amending the Public Health Service Act to require the Secretary of Health and Human Services to act in conjunction with the FDA and CDC to revise a program to combat antimicrobial resistance.⁵⁰ But like PARA and PAMTA, these bills have stagnated and have not gotten past their initial introductions to the Committee.⁵¹

D. *Food and Drug Administration Actions*

The FDA is making substantial efforts to take the lead and address antimicrobial resistance issues.⁵² The Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013 allows the FDA to gather information on the amounts and types of antimicrobial drugs sold and distributed for use in food-producing animals,⁵³ and to determine appropriate approval policies and fees for new animal drugs.⁵⁴ While this requirement gathers quantitative data about the amount of antimicrobial drugs in the market, the amount of drugs actually used is not known.⁵⁵

The FDA has also compiled a “Guidance for Industry” report (“GFI #213”), stating recommendations for the judicious use of animal drugs in feed and drinking water for food-producing animals.⁵⁶ Essentially, this report suggests that industry (1) eliminate antimicrobial drug use for enhancing animal growth or improving feed efficiency; (2) add “scientifically-supported disease treatment, control, or prevention uses”;

⁵⁰ H.R. 2285; S. 2236.

⁵¹ H.R. 2285; S. 2236.

⁵² See Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013, S. 622, 113th Cong. (2013); *FDA’s Strategy on Antimicrobial Resistance—Questions and Answers*, FDA, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm> [<https://perma.cc/E24Q-YAW6>] (last updated Mar. 28, 2014) (discussing current FDA strategies and rationales for addressing antimicrobial resistance).

⁵³ S. 622, 113th Cong. § 105 (2013).

⁵⁴ See generally S. 622.

⁵⁵ *Questions and Answers: Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, FDA, <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm236149.htm> [<https://perma.cc/6P59-UVW2>] (last updated Oct. 2, 2014).

⁵⁶ See generally *Guidance for Industry #213*, FDA, *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* (Dec. 2013), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> [<https://perma.cc/W833-MFAJ>].

and (3) increase veterinary oversight by changing the marketing status of drugs to either Veterinary Feed Directive (“VFD”) or prescription status.⁵⁷ However, FDA “Guidance for Industry” reports are merely recommendations and nonbinding.⁵⁸

E. CRDC v. FDA Lawsuit

1. Background

In 1972, an FDA Task Force studied the safety of subtherapeutic antibiotic use in animal feed.⁵⁹ The report stated that (1) subtherapeutic uses of antibiotics favored antibiotic-resistant bacteria; (2) such use could make treated animals hosts of resistant bacteria, and could transfer them to humans; (3) the prevalence of resistant bacteria increased; and (4) resistant bacteria had been found in meat products for human consumption.⁶⁰ The Task Force also recommended withdrawing approval for subtherapeutic uses of the drugs in animal feed, unless drug manufacturers could show evidence regarding a drug’s safety and effectiveness.⁶¹

Then in 1977, the FDA’s Bureau of Veterinary Medicine issued notice of opportunity hearings (“NOOH”) for two antibiotics commonly used subtherapeutically in animal feed: penicillin and tetracyclines.⁶² These hearings would address the “safety and effectiveness” of these two medicines on humans, since manufacturers had “failed to resolve the basic safety questions [concerning their] subtherapeutic use” in animal feed.⁶³

The formal withdrawal hearings to remove these antibiotics from livestock feed were delayed by a House Appropriations Committee report, which suggested that the National Academy of Sciences (“NAS”) should first complete their pending research on the matter.⁶⁴ The NAS studies ultimately found that the “subtherapeutic use of antimicrobials does increase

⁵⁷ See *FDA’s Strategy on Antimicrobial Resistance—Questions and Answers*, *supra* note 52; Guidance for Industry #213, *supra* note 56; Phasing Out Certain Antibiotic Use in Farm Animals, FDA, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378100.htm#voluntary> [<https://perma.cc/GNW9-WMHN>] (last updated Dec. 13, 2013) (detailing the plan and rationale behind the voluntary phase out of certain drugs used in animal feed).

⁵⁸ Guidance for Industry #213, *supra* note 56.

⁵⁹ *NRDC II*, 760 F.3d at 153.

⁶⁰ *Id.* at 154.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ See *id.*; see also H.R. Rep. No. 95-1290, at 99 (1996).

the prevalence of resistance” among the several strands of bacteria observed, but more research on the matter should be conducted.⁶⁵

Over the next couple decades, studies by government agencies and independent organizations examined the connection between resistant bacteria from food animals to humans.⁶⁶ While evidence strongly indicated that the subtherapeutic and therapeutic uses of antimicrobials are a potential human health hazard, a “definitive direct link” had not been established.⁶⁷ Furthermore, the WHO recommended eliminating the animal use of any subtherapeutic antibiotics that are prescribed for human use.⁶⁸ Despite this body of information and multiple petitions from public-interest groups, the FDA continued to delay the hearings proposed in 1977, and they still have yet to be held.⁶⁹

2. District Court Ruling—“*NRDC I*” (2011)

The National Resources Defense Council (“NRDC”), Center for Science in the Public Interest (“CSPI”), Food Animal Concerns Trust (“FACT”), Public Citizen, and Union of Concerned Scientists (“UCS”) formed a coalition in 2011 attempting to compel hearing action regarding penicillin and tetracycline use in animal feed.⁷⁰ They brought the current suit under two separate claims.⁷¹

First, the plaintiffs claimed that the FDA is required under 21 U.S.C. § 360b(e)(1) to hold the proposed hearings from the 1977 NOOHs.⁷²

⁶⁵ *NRDC II*, 760 F.3d at 154–55.

⁶⁶ *Id.* at 155.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 155–56.

⁷⁰ Courtney Hamilton, *Superbug Suit: Groups Sue FDA Over Risky Use of Human Antibiotics in Animal Feed*, NATURAL RES. DEFENSE COUNCIL, <http://www.nrdc.org/media/2011/110525.asp> [<https://perma.cc/9LDR-FF8N>] (last visited Mar. 20, 2016).

⁷¹ *NRDC II*, 760 F.3d at 156.

⁷² *Id.*; see 21 U.S.C. § 360b(e)(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 under subsection (a)(4)(A) of this section;
- (B) that new evidence not contained in such application or not available to the Secretary until after such application was

Second, they claimed that the FDA unreasonably failed to respond to citizen petitions supporting the hearings.⁷³

The FDA responded by formally withdrawing the 1977 NOOHs, denying the citizen petitions, and stating that alternative strategies to combat negative consequences of subtherapeutic antibiotic use would be explored, instead of holding costly, lengthy withdrawal proceedings.⁷⁴ The plaintiffs then amended their complaint, claiming that the NOOH withdrawals were “arbitrary and capricious.”⁷⁵

The District Court granted summary judgment to the plaintiffs on both claims.⁷⁶ The court found that the 1977 NOOH showed that the drugs were not safe, and the FDA is required to institute withdrawal proceedings unless drug manufacturers could show the required safety and effectiveness for each drug.⁷⁷ The FDA subsequently appealed the District Court’s ruling, and the Second Circuit reviewed the decision *de novo*.⁷⁸

3. Second Circuit Ruling—“*NRDC II*” (2014)

In July 2014, the Second Circuit reversed the District Court’s decision, finding for the government on both claims.⁷⁹ As to the first claim, the court held that 21 U.S.C. § 360b(e)(1) should be interpreted that if, after a hearing, a drug is shown to be unsafe, then the FDA must withdraw the drug’s approval.⁸⁰ This contrasts with the NRDC’s view that after the agency’s internal finding that a drug is unsafe, it must hold a hearing,

approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (i) of paragraph (1) of subsection (d) of this section applies to such drug.

⁷³ *NRDC II*, 760 F.3d at 156.

⁷⁴ *Id.* at 156–57.

⁷⁵ *Id.* at 157. See 5 U.S.C. § 706(2) (2014) (indicating the “Scope of Review” for the arbitrary and capricious standard being contested).

⁷⁶ See *Natural Res. Def. Council v. FDA*, 884 F. Supp.2d 127 (S.D.N.Y. 2012) [hereinafter *NRDC I*].

⁷⁷ *NRDC II*, 760 F.3d at 157.

⁷⁸ *Id.*

⁷⁹ *Id.* at 153.

⁸⁰ *Id.* at 158.

report new findings from further investigation, and withdraw the order.⁸¹ Although the court admitted that the statutory language is ambiguous as to the sequential order of hearing, finding, and withdrawal process, the FDA's interpretation seems more plausible, since the statute does not explicitly state that two findings (before and after hearing notice) must be reported, or that the withdrawal process could be initiated prehearing.⁸²

Regarding the second claim, the court found that the denial of the citizens' petitions and withdrawal of the 1977 NOOHs were not "arbitrary and capricious."⁸³ The court reasoned that the decision to initiate or terminate hearings potentially leading to a drug's withdrawal "is a discretionary determination left to the prudent choice of the FDA."⁸⁴ The court also pointed out that the lack of direct scientific evidence that penicillin and tetracycline are "inherently dangerous" to humans,⁸⁵ and that these types of administrative decisions are typically deferred to the agency.⁸⁶ Furthermore, because the FDA has implemented a strategy to combat negative effects of subtherapeutic antibiotic use in animals, alternate regulatory mechanisms are in place to address the issue.⁸⁷

F. *Executive Order—Combating Antibiotic Resistant Bacteria*

In December 2013, President Obama issued a directive to the National Security Council ("NSC") and the Office of Science and Technology Policy ("OSTP") to investigate current trends of antibiotic resistance and to

⁸¹ *Id.* at 159.

⁸² *Id.* at 159–61.

⁸³ *NRDC II*, 760 F.3d at 153.

⁸⁴ *Id.* at 175.

⁸⁵ *Id.*

⁸⁶ *Id.* at 174–75 (quoting *New York Pub. Int. Research Group v. Whitman*, 321 F.3d 316, 331 (quoting 42 U.S.C. 7661a(i)(1))):

Rejecting the view that the EPA was required to issue a notice of deficiency whenever it found defects in a state permitting program, we noted that 'Congress could have fashioned a regime under which, for example, an interested party could initiate the process leading to a determination of whether "a permitting authority is adequately administering and enforcing a program,"' but that by referring to a "determination" on the part of the agency, Congress left it to the discretion of the EPA Administrator whether and when to initiate enforcement proceedings.

⁸⁷ *Id.* at 193–94; Guidance for Industry #213, *supra* note 56 (stating the FDA's strategy of asking drug manufacturers for voluntary compliance in relabeling drugs to reduce and eliminate subtherapeutic uses in animals).

create a plan to combat resistance.⁸⁸ They established a policy committee comprised of representatives from multiple federal agencies, including: Department of Health and Human Services, Department of Agriculture, the Environmental Protection Agency, and Department of Defense to review recent efforts and goals.⁸⁹ Thus, these efforts led to the development of the *National Strategy for Combating Antibiotic-Resistant Bacteria*.⁹⁰

President Obama signed an Executive Order titled "Combating Antibiotic-Resistant Bacteria" on September 18, 2014.⁹¹ This established the *National Strategy for Combating Antibiotic-Resistant Bacteria*, a Task Force and Presidential Advisory Council, and plans to release a *National Action Plan* and its implementation plans.⁹² The President's Council of Advisers on Science and Technology also released their "Report to the President on Combating Antibiotic Resistance."⁹³

1. National Strategy for Combating Antibiotic-Resistant Bacteria

The five main goals of the National Strategy are to:

- a. Slow the development of resistant bacteria and prevent the spread of resistant infections.
- b. Strengthen national one-health surveillance efforts to combat resistance.
- c. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria.
- d. Accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines.

⁸⁸ NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4, at 6.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ See Exec. Order 13,676, 3 C.F.R. 13,676 (2014), available at <https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria> [<https://perma.cc/TJP3-RZ8H>].

⁹² *Id.*

⁹³ See PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT ON COMBATING ANTIBIOTIC RESISTANCE, (Sept. 2014), available at http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf [<https://perma.cc/9BNH-B9VR>].

- e. Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control, and antibiotic research and development.⁹⁴

These goals are informed by specific information on multiple strains of bacteria that are currently classified by the CDC as “Urgent,” “Serious,” or “Of Concern” in the United States.⁹⁵ By 2020, the National Strategy aims to drastically reduce the incidence of infection due to “Urgent” and “Serious” bacterial threats as well.⁹⁶

Furthermore, the Task Force established from the Executive Order was supposed to report the five-year *National Action Plan* by February 15, 2015.⁹⁷ This report will obtain input from the President’s Council of Advisors on Science and Technology (“PCAST”) and the Secretaries of Health and Human Services, Agriculture, and Defense to develop detailed steps and strategies to achieve National Targets.⁹⁸

2. PCAST Report to the President on Combating Antibiotic Resistance

Three main focus areas are identified in this report as necessary to combat the antibiotic-resistance threat:

1. Improving surveillance on the rise of antibiotic-resistant bacteria;
2. Increasing the longevity of current antibiotics; and
3. Increasing the rate at which new antibiotics as well as other inventions are discovered and developed.⁹⁹

Eight recommendations are then set forth as guidelines to accomplish goals in these focus areas:

1. Ensure strong federal leadership;
2. Implement effective surveillance and response for antibiotic resistance;

⁹⁴ NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4, at 5.

⁹⁵ *Id.* at 25–28.

⁹⁶ *Id.* at 33.

⁹⁷ Exec. Order 13,676, *supra* note 91, § 3(c).

⁹⁸ NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4, at 1, 24.

⁹⁹ PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., *supra* note 93, at 1–2.

3. Expand fundamental research to develop alternatives to antibiotics in agriculture;
4. Develop a new infrastructure and regulatory schemes to support clinical trials to develop new antibiotics;
5. Significantly increase government-supported economic incentives for developing urgently needed antibiotics;
6. Improve stewardship of existing antibiotics in health care;
7. Limit the use of antibiotics in animal agriculture; and
8. Ensure effective international coordination.¹⁰⁰

II. PROBLEMS AND/OR NEW DEVELOPMENTS

A. *Main Issues*

Both the *NRDC* decision and the National Strategy fail to take into account the driving force behind the development of antibiotic-resistant bacteria: agricultural practices. Over 70% of all the antibiotics used in the United States goes to healthy livestock.¹⁰¹ These drugs are not used for medicinal purposes, but to enhance these animals' size and weight and increase factory farm profits for companies in the agriculture industry.¹⁰² These practices have an alarming effect on not only the rate at which certain antibiotics are becoming ineffective, but on the environment as well. Water sources, native species, and public health are all being adversely affected,¹⁰³ and therefore, altering current industrial practices is the most direct way to counter these current effects.

III. PROBLEMS WITH THE *NRDC v. FDA* DECISION

The *NRDC v. FDA* decision gives the FDA great discretion in determining whether to hold proceedings concerning drugs used on animals, and whether to hold hearings over drugs with serious safety concerns.¹⁰⁴

¹⁰⁰ *Id.* at 5–7.

¹⁰¹ UNION OF CONCERNED SCIENTISTS, *supra* note 15.

¹⁰² *Id.*

¹⁰³ AM. SOC'Y OF AGRONOMY, *supra* note 20.

¹⁰⁴ Diana R.H. Winters, *Antibiotics in animal feed and thin statutory interpretation: NRDC v. EPA*, HARV. L. BILL OF HEALTH (July 25, 2014), <http://blogs.law.harvard.edu/bill>

This decision contradicts statutory mandates and is counterproductive in responding to scientific discoveries on the effects and implications of animal drug usage because “the decision lets the FDA ‘openly declare that a particular animal drug is unsafe, but then refuse to withdraw approval,’ and ‘effectively ignore’ challenges to that policy.”¹⁰⁵

A. *Statutory Interpretation*

One issue with the *NRDC v. FDA* decision lies with statutory interpretation—whether the FDA was required by 21 U.S.C. § 360b(e)(1) to hold the withdrawal hearings once it found that the two drugs’ usage was questionable.¹⁰⁶ Under the majority’s reading of the statute, the FDA’s discretion is so great that they may never be required to pursue formal withdrawal proceedings for a drug, despite compelling safety concerns.¹⁰⁷

Looking to other statutes of the Food, Drug, and Cosmetics Act, along with previous cases, the FDA should have been compelled to hold the withdrawal hearings.¹⁰⁸ For example, *United States v. Gypsum* holds that after the FDA’s preliminary finding of a drug to be unsafe, the drug’s sponsor must be given a hearing to rebut that finding.¹⁰⁹ In the current case, clearly no hearing was held.

In *NRDC*’s dissent, Judge Katzmann dispels the FDA’s argument that under *Heckler v. Chaney*, the FDA’s decision on the NOOHs is not judicially reviewable.¹¹⁰ Although courts typically defer to the discretion of agencies about administrative decisions, a practice supported by the holding in *Heckler*, here § 360b(e)(1)(B) requires the FDA to hold the hearings.¹¹¹ That decision is not up to the FDA’s discretion, since it requires the FDA “to commence withdrawal proceedings when the agency finds that a particular drug is not shown to be safe.”¹¹²

ofhealth/2014/07/25/antibiotics-in-animal-feed-and-thin-statutory-interpretation-nrdc-v-epa/ [https://perma.cc/J8TB-8BVX].

¹⁰⁵ Jonathan Stempel, *U.S. court upholds FDA animal feed policy despite health concern*, REUTERS, July 24, 2014, <http://uk.reuters.com/article/2014/07/24/us-usa-fda-animalfeed-decision-idUKKBN0FT2A220140724> [https://perma.cc/63MU-ZYCD].

¹⁰⁶ *NRDC II*, 760 F.3d at 174; see 21 U.S.C. § 360b(e)(1).

¹⁰⁷ *NRDC II*, 760 F.3d at 177.

¹⁰⁸ See 21 U.S.C. §§ 355, 360b(c)–(d) (2014).

¹⁰⁹ *U.S. v. Gypsum*, 438 U.S. 422 (1978).

¹¹⁰ *NRDC II*, 760 F.3d at 186.

¹¹¹ *Id.* at 187.

¹¹² *Id.*

B. *Arbitrary and Capricious Inaction*

Under *Massachusetts v. EPA*, “arbitrary and capricious” actions are done for reasons “divorced from the statutory text.”¹¹³ This situation is very similar to *Massachusetts v. EPA* in that both statutes in question require mandatory action following a discretionary finding, and the agency’s belief that action would require too much time and resources to be justified.¹¹⁴ But, while the Supreme Court rejected those arguments in *Massachusetts v. EPA*, the Second Circuit accepted them in *NRDC v. FDA*.¹¹⁵ Because the FDA recognized valid human health concerns about the drugs’ use in livestock, and failed to take the proper, statutorily mandated measures to address those concerns, the FDA’s decision should be considered arbitrary and capricious.¹¹⁶

IV. PROBLEMS WITH THE NATIONAL STRATEGY

The Five-Step National Strategy is a significant development and provides a solid starting point in addressing drug resistance,¹¹⁷ in contrast to failed legislative attempts.¹¹⁸ Promoting scientific research regarding improved diagnostic testing, pharmaceutical developments, prevention, and surveillance on antibiotic resistance are among the Strategy’s greatest assets.¹¹⁹

However, the main issue with the White House’s National Strategy report is that it does not directly address antibiotic usage in agriculture.¹²⁰ Although the fourth step of the Strategy (accelerating research and development) states that “alternatives to antibiotics are also needed in agriculture and veterinary medicine,” reducing current agricultural antibiotic usage is not mentioned.¹²¹

¹¹³ *Id.* at 190 (quoting *Mass. v. EPA*, 549 U.S. 497, 532–33 (2007)).

¹¹⁴ *Id.* at 191.

¹¹⁵ *Id.*

¹¹⁶ *NRDC II*, 760 F.3d at 191.

¹¹⁷ See NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4, at 1, 24.

¹¹⁸ See *infra* Part I.C.

¹¹⁹ *Id.*

¹²⁰ See generally NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4.

¹²¹ *Id.* at 2.

V. RECENT DEVELOPMENTS AND INCREASED FUNDING

In January 2015, the White House released a Fact Sheet that outlines the new federal efforts that will be taken to combat antibiotic resistance.¹²² The Fiscal Year 2016 budget allocates over \$1.2 billion in funding to improve risk assessment, surveillance, reporting capabilities, stewardship, and research innovation in the health and agricultural industries.¹²³ These goals nearly double the amount of federal funding in past years¹²⁴ and are a significant improvement to recent efforts.

The three proposed agricultural changes are (1) invest in basic life sciences research; (2) intensify research and development of new therapeutics and vaccines; and (3) develop alternatives to antibiotics in agriculture.¹²⁵

While these goals are likely to both reduce infection rates and resistance rates if successfully implemented in the agricultural sector, there is no certainty whether the industry will even adopt these potential alternatives. This Fact Sheet and its funding goals raise similar concerns to those that the National Strategy raises.¹²⁶ Improvements to the agricultural sectors are recognized,¹²⁷ but no proposals are announced that would substantively affect current practices and policies.

VI. AGRICULTURAL REFORMS AND SOLUTIONS

The most crucial step in developing an effective strategy to combat antimicrobial drug resistance is directly addressing its overuse in agriculture. Since livestock consumes the greatest quantities of antibiotics,¹²⁸ at a minimum, the usage of antibiotics in healthy livestock must be eliminated or greatly reduced.¹²⁹

¹²² *Fact Sheet: 2016 Budget Proposes Historic Investment to Combat Antibiotic-Resistant Bacteria to Protect Public Health*, THE WHITE HOUSE (Jan. 27, 2015), <http://www.whitehouse.gov/the-press-office/2015/01/27/fact-sheet-president-s-2016-budget-proposes-historic-investment-combat-a> [<https://perma.cc/2S6Z-TFJJ>].

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *See generally id.*

¹²⁷ *See generally id.*

¹²⁸ FDA, *supra* note 14.

¹²⁹ *See, e.g.*, Sharon Levy, *Reduced Antibiotic Use in Livestock: How Denmark Tackled Resistance*, ENVTL. HEALTH PERSPECTIVES, June 1, 2014, http://ehp.niehs.nih.gov/122-a160/?utm_source=rss&utm_medium=rss&utm_campaign=122-a160 [<https://perma.cc/SK9Z-GC7J>].

A. *Scientific Strategies*

Any plan to solve the growing issue of antibiotic drug resistance will require scientific research to study, analyze, and assess the current state of threats, as well as the effectiveness of potential strategies. Current proposals to combat resistance recognize this necessity¹³⁰ but do not do enough to lay out a concrete action plan.

Focusing on the agricultural industry, research into effective, healthy animal husbandry practices is an essential starting point.¹³¹ Optimizing livestock nutrition and maintaining lower animal densities are necessary to relieve some dependence on antibiotics.¹³² Developing cost-efficient vaccines to immunize farm animals and fish would help as well.¹³³ In Norway, for example, salmon vaccines reduced antimicrobial use by 99% between 1987–2007, and fish production increased from 350,000–850,000 tons.¹³⁴ Similar success may reasonably be expected in the United States if functional, economically efficient vaccines are developed.

Researching alternatives to antibiotics and the effects of currently used alternatives is another useful strategy that can be used to combat resistance. Certain metals like copper, zinc, and arsenic are often used as alternatives,¹³⁵ however, scientific studies have shown that these replacements may be exacerbating the problem, since manure can introduce these elements into water systems and soil.¹³⁶

¹³⁰ See generally NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA, *supra* note 4; *Fact Sheet: 2016 Budget Proposes Historic Investment to Combat Antibiotic-Resistant Bacteria to Protect Public Health*, *supra* note 122.

¹³¹ See *AVMA Strategy Regarding Antimicrobial-Resistant Bacteria*, AM. VETERINARY MED. ASS'N, <https://www.avma.org/KB/Policies/Pages/AVMA-Strategy-Regarding-Antimicrobial-Resistant-Bacteria.aspx> [<https://perma.cc/4YRW-PTLZ>] (last visited Mar. 20, 2016) (discussing the need for a science-based strategy to improve animal welfare, public health, and public education regarding antimicrobial resistance).

¹³² Carol Potera, *Germ Warfare? Strategies for Reducing the Spread of Antibiotic Resistance*, 121 ENVTL. HEALTH PERSPECTIVES 255 (Aug. 1, 2013), <http://ehp.niehs.nih.gov/121-a255/> [<https://perma.cc/R8BH-ZH97>].

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ Amy Pruden et al., *Management Options for Reducing the Release of Antibiotics and Antibiotic Resistance Genes to the Environment*, 121 ENVTL. HEALTH PERSPECTIVES 878, 879–80 (2013); see Nanthi Bolan et al., *Distribution and bioavailability of trace elements in livestock and poultry manure by-products*, 34 CRITICAL REV. IN ENVTL. SCI. & TECH. 291 (2004) (discussing the health and environmental effects of using trace elements in livestock feed).

¹³⁶ *Id.*

Thus, effective sanitation and waste management practices are crucial to reducing the environmental effects that antibiotics cause. Developing strategies to manage, contain, and treat antibiotic-resistance genes in manure will be the first step for improvement.¹³⁷ Research studies have found that composting waste can eliminate 50–70% of antibiotics,¹³⁸ and treatment of manure can reduce antibiotic-resistant genes up to one hundredfold, depending on the bacterial strain.¹³⁹ Scientific research needs to continue to develop ways to increase these kinds of beneficial findings, and efforts to implement efficient waste-management strategies must be increased.

B. *Adopt Strategies Used Internationally*

By looking internationally, especially at practices in Europe, the United States could acquire some guidance as to best practices and potential strategies. The European Commission's Action Plan against antimicrobial resistance proposes twelve specific steps, along with key actions to combat resistance.¹⁴⁰ Among these steps is the directive to "strengthen EU law on veterinary medicines and on medicated feed."¹⁴¹ Furthermore, the European Food Safety Authority works closely with the European Centre for Disease Prevention and Control ("ECDC") and the European Medicines Agency ("EMA").¹⁴² The United States should focus on increasing

¹³⁷ Pruden et al., *supra* note 135, at 880–81.

¹³⁸ *Id.* (citing Ranjana Sharma et al., *Selected antimicrobial resistance during composting of manure from cattle administered sub-therapeutic antimicrobials*, 38 J. ENVTL. QUALITY 567 (2009); Heather Storteboom et al., *Tracking antibiotic resistance genes in the South Platte River basin using molecular signatures of urban, agricultural, and pristine sources*, 44 ENVTL. SCI. & TECH. 7397 (2007); L. Wang et al., *Persistence of resistance to erythromycin and tetracycline in swine manure during simulated composting and lagoon treatments*, 63 MICROBIAL ECOLOGY 32 (2012); Wu et al., *Abundance and diversity of tetracycline resistance genes in soils adjacent to representative swine feedlots in China*, 44 ENVTL. SCI. & TECH. 6933 (2010)).

¹³⁹ Pruden et al., *supra* note 135, at 880–81 (citing Storteboom, 44 ENVTL. SCI. & TECH. 7397).

¹⁴⁰ Press Release, European Commission, Action Plan against antimicrobial resistance: Commission unveils 12 concrete actions for the next five years (Nov. 17, 2011), available at http://europa.eu/rapid/press-release_IP-11-1359_en.htm?locale=en [<https://perma.cc/DNG2-7CFP>]; see also *Antimicrobial Drug Resistance*, EUROPEAN COMMISSION, http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/index_en.html [<https://perma.cc/T43N-3FRC>] (highlighting the European Union's main research and policy goals to deal with antimicrobial drug resistance).

¹⁴¹ *Id.*

¹⁴² *Antimicrobial Resistance*, EUR. FOOD SAFETY AUTH., <http://www.efsa.europa.eu/en/topics/topic/amr.htm> [<https://perma.cc/XPC9-EBUN>] (last updated Jan. 30, 2015).

and improving collaboration between its federal food and public health agencies, as well as exploring legislative strategies to reduce unnecessary antibiotic use.

1. Denmark Case Study

To accomplish this, similar strategies to the ones successfully used in Denmark could be effective.¹⁴³ In 1995, Denmark became the first country in Europe to ban the use of avoparcin (a drug commonly used as a growth promoter for poultry), after studies demonstrated an increase in vancomycin-resistant enterococci (“VRE”) from its use in livestock.¹⁴⁴ Then in 1999, Denmark banned all nontherapeutic antibiotic use in pork.¹⁴⁵ Within two years, this policy resulted in a significant decline in VRE in the fecal flora of both humans and food animals.¹⁴⁶

Most notable, however, is that although antibiotic use in pigs declined over 50% between 1992–2008, the pork industry’s production of weaning pigs increased from 18.4 million to 27.1 million.¹⁴⁷ While there was a short term of increased pig mortality following the ban of avoparcin, those levels decreased back to rates seen in 1992.¹⁴⁸

A key factor in Denmark’s success is its monitoring of antibiotic sales and usage before implementing the usage ban.¹⁴⁹ By fostering cooperation and collaboration between the agricultural industry, scientists, and the government, the transition to eliminating avoparcin usage became practicable and more organized.¹⁵⁰ These same strategies could be applied in the United States, by targeting the drugs affecting bacterial strains that are the greatest threat to public health.

Ultimately, a unified global effort is the most ideal way to best combat drug resistance most effectively. Doing so would require collective economic and legal mechanisms on behalf of each participating country.¹⁵¹ A WHO Bulletin addresses this idea, and points out that nations must

¹⁴³ Levy, *supra* note 129.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ Levy, *supra* note 129.

¹⁵⁰ *Id.*

¹⁵¹ Richard D. Smith & Joanna Coast, *Antimicrobial resistance: a global response*, 80 BULLETIN OF THE WHO 126, 126–27 (2002).

“perceive a net benefit, often in economic terms” if the practical, rational use of antimicrobials, is to occur.¹⁵²

VII. INCREASE PUBLIC AWARENESS

Raising awareness of the health and environmental concerns of antibiotic resistance could promote action and cooperation by government and private industry. While the CDC releases an annual report highlighting current threats,¹⁵³ more can and should be done. The FDA at least recognizes this, as shown through the creation of a task force to address resistance, and the actions of its members to raise public knowledge.¹⁵⁴

The Infectious Diseases Society of America (“IDSA”) has made a strong effort to raise awareness by working with Congress, the FDA, National Institutes of Health, and other agencies and industry leaders to consider research proposals and potential actions that the medical community can take.¹⁵⁵ Many groups, including the WHO, have noted that raising public awareness is crucial to tackling the many facets of antimicrobial resistance.¹⁵⁶ Efforts to do so must be continued in order to encourage political, scientific, and legal action in a timely manner.

CONCLUSION

Antimicrobial drug resistance is a growing concern that will continue to damage public health and the environment. The driving force behind the increased rates of drug resistance is the result of antibiotics’ extensive use in agricultural practices.¹⁵⁷ The majority of drugs used in livestock are not medically necessary, and questions about their negative health impacts in humans have been raised.¹⁵⁸

¹⁵² *Id.*

¹⁵³ See *Antibiotic Resistance Threats in the US*, *supra* note 25.

¹⁵⁴ *Antimicrobial Resistance*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm235649.htm> [<https://perma.cc/QJB3-E9ZP>] (last updated Sept. 26, 2012).

¹⁵⁵ HELEN W. BOUCHER ET AL., BAD BUGS, NO DRUGS: NO ESKAPE! AN UPDATE FROM THE INFECTIOUS DISEASES SOCIETY OF AMERICA 2 (2009), *available at* http://www.idsociety.org/uploadedfiles/idsa/policy_and_advocacy/current_topics_and_issues/advancing_product_research_and_development/antimicrobials/statements/76be6c147e7d4b6a891d7c2b860349fd3.pdf [<https://perma.cc/JXC4-3P35>].

¹⁵⁶ Maria Paula Brito, *Antibiotic Resistance Sparks New Health Policy*, THE CAMBODIA DAILY, Feb. 11, 2015, <https://www.cambodiadaily.com/news/antibiotic-resistance-sparks-new-health-policy-77730/> [<https://perma.cc/4W5F-V5GL>].

¹⁵⁷ Levy, *supra* note 129.

¹⁵⁸ *Id.*

The Second Circuit in *NRDC v. FDA* sought to address some of these health concerns after the safety of two antibiotics used subtherapeutically in livestock feed were found by the FDA to be questionable.¹⁵⁹ However, despite nearly four decades of inaction by the FDA and compelling arguments that FDA action is statutorily mandated, the Second Circuit chose to defer to the FDA's decision to refuse to investigate these concerns.¹⁶⁰ This decision allows the FDA to indefinitely refuse to address serious health concerns, and undermines attempts to reduce growing rates of antimicrobial drug resistance.¹⁶¹

Although several recent legislative attempts to curb the overuse of antibiotics have failed, President Obama issued an Executive Order that will hopefully spark increased efforts.¹⁶² The September 2014 National Strategy on Combating Antimicrobial Drug Resistance is a crucial step to prioritize the concern of antimicrobial drug resistance, strengthen surveillance and collaboration, and advance research and development regarding bacterial threats.¹⁶³

However, the National Strategy does not specifically address ways to deal with the agricultural overuse of antibiotics, which is where the majority of medically unnecessary drugs get introduced into organisms and the environment.¹⁶⁴

Effective management of resistance will require sweeping agricultural reforms and scientific research directed towards improving farming methods. A greater focus on scientific research to develop cost-effective vaccines for livestock, healthier nutrition plans to curb the necessity for drugs, and alternative feed additives are fundamental first steps towards enabling industry to reduce reliance on antibiotics in feed.

Furthermore, we should look towards Europe and other international strategies that have been used to deal with the threat of antibiotic resistance. Europe generally has stricter agricultural and antibiotic usage laws, and some countries have experimented with different policies.¹⁶⁵ The National Strategy should consider the European Commission's Action plan¹⁶⁶ for ways to improve from a regulatory and policymaking standpoint. The United States should also look towards Denmark and its

¹⁵⁹ Winters, *supra* note 104.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *See supra* Part IV.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ Levy, *supra* note 129.

¹⁶⁶ *Id.*

success in curbing the rates of several strains of resistant bacteria after implementing a ban on the use of avoparcin in pork.¹⁶⁷ Implementing a similar restriction or ban has the potential to also curb resistance without harming economic production and efficiency.

Addressing antibiotic resistance in the United States and raising public awareness is vital to protecting public health and our environment. While tackling this goal will inevitably require time and resources, it is necessary to prevent the more costly possibilities of widespread diseases, greater infections, and lack of effective medicines. Reforming the agricultural industry is feasible, realistic, and would have the greatest impact on reducing the rates of antimicrobial resistance. Policymakers, industry, and scientific research institutions must all develop strategies aimed at addressing agricultural practices. Only then will the threat of antimicrobial drug resistance be reduced to a manageable level.

¹⁶⁷ *Id.*

