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### **PUBLIC HEALTH LAW—REMEDYING AND REGULATING THE UNINTENDED CONSEQUENCES OF SUBTHERAPEUTIC DOSING OF LIVESTOCK WITH ANTIBIOTICS: CAN THE EPA’S IMPLEMENTATION OF THE CLEAN WATER ACT REIGN IN THE PROBLEM?**

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PUBLIC HEALTH LAW—REMEDYING AND REGULATING THE  
UNINTENDED CONSEQUENCES OF SUBTHERAPEUTIC DOSING OF  
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PROBLEM?

*Chris Erchull & Laura Fisher\**

*The way in which the United States has come to practice agriculture has changed drastically over the past century. As urban populations have grown and rural populations dwindled, research focused on raising production levels and decreasing costs led to the increasingly common practice of low-dose and long-term application of antibiotics to animals being raised for slaughter. Such use of antibiotics continues to have far-reaching consequences impacting human, animal, and environmental health and wellness. This article examines the fractured federal oversight of the use of antibiotics in industrial agriculture and proposes an interpretation of provisions of the Clean Water Act as a mechanism for mitigation.*

INTRODUCTION

As so often happens, solutions to societal problems are formulated piecemeal, usually without sufficient substantive reflection, study, or inquiry. Technological and scientific developments are lauded; however, their unforeseen, unintended consequences arrive later and frequently pose more dire circumstances than the initial problems. Generally, the miracle cure of one era causes the biggest headache for the next generation. The use of antibiotics in animal husbandry in the United States tracks this familiar theme.

This Article introduces the development of the historically

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common practice of continuously feeding large herds and flocks of farm animals low doses of antibiotics, examines the consequences of this practice, and proposes a potential solution based on an existing regulatory scheme. Antibiotic-resistant bacteria are now a very real concern, and the practice of antibiotic overuse negatively impacts our environment and collective health.

An examination of existing regulatory frameworks illustrates the diluted nature of federal oversight of agricultural activities.<sup>1</sup> Many agencies have some existing regulatory structure that oversees some portion of our nation's agricultural sector and processes.<sup>2</sup> This Article discusses each potential regulatory solution and concludes that the Clean Water Act is a viable and fitting means by which the effects of agricultural antibiotics could be halted and reversed.<sup>3</sup> In light of *Massachusetts v. EPA*,<sup>4</sup> we suggest that the impact of agricultural antibiotics on the nation's waterways are significant enough to warrant what would in effect be a downstream regulation with upstream consequences.<sup>5</sup>

In turn, this Article will discuss the history of the now often-maligned practice, examine various potential statutory and regulatory frameworks that could be utilized to control the burgeoning problems, and ultimately conclude that the Clean Water Act is best poised to remedy the environmental implications of the practice.

## I. THE USE OF ANTIBIOTICS IN AGRICULTURE: A BRIEF HISTORY

This section will discuss the historical and scientific development as well as the early justifications for the use of antibiotics in agricultural settings. To fully appreciate and understand the current usage trends, it is necessary to examine historical societal trends and trace the scientific development.

### A. *Urbanization and the Changing Landscape*

As historian Maureen Ogle describes in her entry on the

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1. See generally 21 U.S.C. 822(g) (2014); 21 U.S.C. 828(b)(3) (2014); 33 U.S.C. § 1251, et seq. (1972); 33 U.S.C. §§ 1253–54 (2014); 33 U.S.C. § 1313 (2014); 33 U.S.C. § 1342(c) (2014); 33 U.S.C. § 1362 (2014); 33 U.S.C. § 1370 (2014); 42 U.S.C. §§ 6901–6992k (1976).

2. See generally 40 C.F.R. § 131.6 (2015).

3. 33 U.S.C. § 1251, et seq. (1972).

4. *Massachusetts v. EPA*, 549 U.S. 497 (2007).

5. See generally *id.*

*Scientific American Blog*,<sup>6</sup> farmers were a minority during the early 1900s, often operating on a small scale.<sup>7</sup> The massive agricultural operations now seen in the United States simply did not exist.<sup>8</sup> Ogle's post follows the progression and integration of antibiotics in the production of America's domestic food sources as urban populations grew and became almost entirely reliant on the food producing capabilities of rural populations for their nourishment.<sup>9</sup> Simply put, the new city-dwelling, urban populations were generally not engaged in agriculture on a meaningful scale.<sup>10</sup> As urban populations grew, rural populations shrank, and food prices rose as demand outpaced supply.<sup>11</sup> Meat in particular became very expensive and consumers became frustrated and angry.<sup>12</sup> Notably, in 1910, Americans engaged in a nationwide meat boycott in protest of the high prices.<sup>13</sup> Seven years later, protesters picketed and vandalized butcher shops.<sup>14</sup> Consumers and policymakers alike yearned for a solution that would provide affordable and dependable sustenance to the country's growing and changing population.<sup>15</sup>

Pressure was placed on the United States Department of Agriculture (USDA) to develop and implement solutions. There would be no simple, blanket cure-all to the issue; on one hand, single-stomach animals like pigs and chickens posed one problem, while ruminant animals, like cattle and sheep, might require a different solution.<sup>16</sup> At first, research focused on the single-stomach animals.<sup>17</sup> Ogle states that this research was focused on raising production levels and decreasing costs.<sup>18</sup> Farmers had

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6. Maureen Ogle, *Riots, Rage, and Resistance: A Brief History of How Antibiotics Arrived on the Farm*, SCIENTIFIC AMERICAN (Sept. 3, 2013), <http://blogs.scientificamerican.com/guest-blog/riots-rage-and-resistance-a-brief-history-of-how-antibiotics-arrived-on-the-farm/> [<https://perma.cc/79GW-JC2Z>].

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

13. *Meat Boycott Spreads Over United States*, 107 S.F. CALL 53, 9–10 (1910), <http://cdnc.ucr.edu/cgi-bin/cdnc?a=d&d=SFC19100122.2.2> (providing a compilation of news clippings from around the nation discussing the various strikes spread across the United States).

14. Ogle, *supra* note 6.

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

previously used animal-based proteins like cod liver oil and fishmeal in their feed for single-stomach animals because these additions helped the animals gain weight rapidly and remain healthier.<sup>19</sup> These supplements were expensive and it was believed that lower-cost alternatives would help to remedy the high price of meat.<sup>20</sup> Thus, research focused on alternatives that would boost animal health and create a higher output for the market.<sup>21</sup>

### B. *Wartime Solutions and a Serendipitous Discovery*

During World War II, food production became a central tenet of patriotism as Americans scrambled to produce meat despite the lack of availability of the aforementioned animal proteins.<sup>22</sup> Animals were largely provided plant-based feed (instead of the much richer animal protein feed) and as a result the animals being raised simply did not put on weight as rapidly.<sup>23</sup> Ogle suggests that this was the catalyst that caused scientists and lawmakers to search for a solution that would boost outputs.<sup>24</sup>

In a strange and almost accidental manner, scientists discovered that low doses of antibiotics seemed to accelerate growth in the animals. In one study, farm animals were given doses of vitamin B12; however, these vitamins were laced with a low-level dose of the antibiotic Aureomycin.<sup>25</sup> Such low doses of antibiotics were inexpensive and promoted rapid growth and weight gain in pork and poultry—and the discovery was lauded as a fairly comprehensive solution to the issue.<sup>26</sup>

Around this same time, the structure of production of livestock was changing to a more industrialized output-based system. Historically, disease could eliminate an entire herd or flock and numbers were usually therefore limited. With the discovery of penicillin, antibiotics found human applications that grew during the 1930s.<sup>27</sup> Developments in veterinary medicine developed vis-à-

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19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. See Claudia Reinhardt & Bill Ganzel, *Farming in the 1940s: Antibiotics & Feed Additives*, WESSELS LIVING HISTORY FARM, [http://www.livinghistoryfarm.org/farminginthe40s/crops\\_09.html](http://www.livinghistoryfarm.org/farminginthe40s/crops_09.html) [https://perma.cc/5CBF-3QTS] (last visited May 10, 2016).

vis the research and development of human antibiotics. In 1943, the microbiologist Selman Waksman discovered Streptomycin, which was used in both human and veterinary application.<sup>28</sup> The use of Streptomycin helped to eliminate bovine tuberculosis and mastitis, the diseases that increased the costs associated with maintaining larger herds.<sup>29</sup> With the use of antibiotics, there arose fewer possibilities for entire herds to be fatally infected. The demand for low-cost meat and the development of antibiotics allowed farmers who previously had smaller herds and flocks to keep larger groups of animals.

Eventually, antibiotics at low doses were generally just added to animal feed. Farmers and scientists noted that such low doses seemed to prevent disease and promote rapid growth. After World War II, the population of the country continued to grow and cities expanded outward into developing suburbs.<sup>30</sup> Further strain was put on producers to supply an ever-growing demand for sustenance.

Meat production grew and changed alongside a growing, changing American citizenry. During the early 1900s, small family farms remained predominant. Rather rapidly, a sea change in animal husbandry came about when these scientific discoveries allowed for cheap production of rapidly-growing livestock in herds and flocks of greater numbers. As farming operations grew, the family farm model was largely replaced by industrial operations with corporate contracts.<sup>31</sup> The application of antibiotics in livestock was prevalent not only in treating disease, but also in encouraging rapid growth of animals and preventing disease by inclusion of antibiotics in animal feed.<sup>32</sup>

### C. *Early Concern and Later Confirmation*

Not everyone, however, was equally optimistic about subtherapeutic antibiotic dosing of livestock. Some scientists expressed concern about the long-term viability of a system reliant on antibiotics, noting the possibility of the application having the

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28. *See id.*

29. *See id.*

30. Ogle, *supra* note 6.

31. *See* CARRIE HRIBAR, NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 11 (Mark Schultz ed., 2010), [http://www.cdc.gov/nceh/ehs/docs/understanding\\_cafos\\_nalboh.pdf](http://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf) [<https://perma.cc/57D3-UTXL>].

32. Ogle, *supra* note 6.

unintended effect of creating antibiotic resistance.<sup>33</sup> In light of the seemingly economical solution, arguments about feed containing subtherapeutic levels of antibiotics did not gain much traction until the later half of the century.

Over the ensuing fifty years, “farming operations in the United States have gone from individualized production to mass production, commonly known as factory farming.”<sup>34</sup> Americans now consume approximately two hundred pounds of animal protein per year which is an “increase of 50 pounds per person from 50 years ago.”<sup>35</sup> Currently, the predominant source of meat in the United States is the Concentrated Animal Feeding Operation (CAFO).<sup>36</sup> The trend of utilizing subtherapeutic levels of antibiotics in animal feed has continued and become commonplace—now, over eighty percent of all antibiotics sold in the United States are used on livestock and poultry.<sup>37</sup> Animals raised in these CAFOs are often held in cramped quarters for extended periods of time and are therefore subject to disease—this is generally combatted by the supplementation of the livestock’s feed with antibiotics.<sup>38</sup>

Over time, public sentiment has begun to turn, with some viewing the use of subtherapeutic doses of antibiotics with

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33. See Julian Davies & Dorothy Davies, *Origins and Evolution of Antibiotic Resistance*, 74 MICROBIOL. MOL. BIOL. REV. 417, 419 (2010), <http://mmbr.asm.org/content/74/3/417.full.pdf+html> [<https://perma.cc/Y6UQ-GSHN>] (“The unexpected identification of genetically transferable antibiotic resistance in Japan in the mid-1950s [was] initially greeted with skepticism in the West.”).

34. R. Jason Richards & Erica L. Richards, *Cheap Meat: How Factory Farming is Harming Our Health, the Environment, and the Economy*, 4 KY. J. EQUINE, AGRIC. & NAT. RESOURCES L. 31, 31 (2012).

35. *Id.* (internal citation omitted).

36. See *Animal Feeding Operations*, U.S. DEP’T OF AGRIC. NAT. RES. CONSERVATION SERV., <http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/plantsanimals/livestock/afo/> [<https://perma.cc/QN4K-JDEC>] (last visited May 10, 2016)

A CAFO is an [animal feeding operation] with more than 1000 animal units (an animal unit is defined as an animal equivalent of 1000 pounds live weight and equates to 1000 head of beef cattle, 700 dairy cows, 2500 swine weighing more than 55 lbs, 125 thousand broiler chickens, or 82 thousand laying hens or pullets) confined on site for more than 45 days during the year.

37. *Food, Farm Animals and Drugs*, NAT. RES. DEF. COUNCIL, <http://www.nrdc.org/food/saving-antibiotics.asp> [<https://perma.cc/XEA7-RPS6>] (last visited May 10, 2016); see also Nicholas D. Kristof, *When Food Kills*, N.Y. TIMES (June 11, 2011), at WK10 on June 12, 2011, [http://www.nytimes.com/2011/06/12/opinion/12kristof.html?\\_r=0](http://www.nytimes.com/2011/06/12/opinion/12kristof.html?_r=0) (“North Carolina uses more antibiotics for livestock than the entire country uses for humans.”).

38. Richards & Richards, *supra* note 34.

skepticism and concern.<sup>39</sup> Worries range from the effects on the general welfare of the animals to the effects on human health posed by antibiotic-resistant bacteria to potential environmental consequences of these drugs.<sup>40</sup>

#### D. *The Threat of Antibiotic Resistance*

Scientists have expressed growing concern that the subtherapeutic dosing of livestock is promoting a perfect breeding ground for antibiotic-resistant bacteria.<sup>41</sup> Bacteria that are consistently exposed to low levels of antibiotics can then become resistant to the drugs.<sup>42</sup> This is not mere speculation; rather, this phenomenon is well-documented scientific fact.<sup>43</sup> In a 2013 report, *Antibiotic Resistance Threats in the United States*, the Centers for Disease Control and Prevention stated that “[u]p to half of antibiotic use in humans and much of antibiotic use in animals is unnecessary and inappropriate and makes everyone less safe.”<sup>44</sup> Although the resulting so-called “superbugs” can travel on the processed meat and reach an end-user consuming it,<sup>45</sup> these strains

39. *Food, Farm Animals and Drugs*, NAT. RES. DEF. COUNCIL, <http://www.nrdc.org/food/saving-antibiotics.asp> [<https://perma.cc/XEA7-RPS6>] (last visited May 10, 2016).

40. See CARRIE HRIBAR, NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 11 (Mark Schultz ed., 2010), [http://www.cdc.gov/nceh/ehs/docs/understanding\\_cafos\\_nalboh.pdf](http://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf) [<https://perma.cc/57D3-UTXL>]; see also *Food, Farm Animals and Drugs*, NAT. RES. DEF. COUNCIL, <http://www.nrdc.org/food/saving-antibiotics.asp> [<https://perma.cc/XEA7-RPS6>] (last visited May 10, 2016).

41. See, e.g., Rachel Fischer, *Antibiotic Use in Food Animals—How This Practice Affects Everyone*, UNIV. OF W. STATES (Apr. 20, 2015), <https://www.uws.edu/antibiotic-use-in-food-animals-how-this-practice-affects-everyone/>. Indeed, Alexander Fleming himself, the individual credited with discovering penicillin, stated at his Nobel Prize acceptance speech:

I would like to sound one note of warning . . . There may be a danger . . . in under dosage. It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body.

Sir Alexander Fleming, Nobel Lecture: Penicillin, 92–93 (Dec. 11, 1945), [http://www.nobelprize.org/nobel\\_prizes/medicine/laureates/1945/fleming-lecture.pdf](http://www.nobelprize.org/nobel_prizes/medicine/laureates/1945/fleming-lecture.pdf) [<https://perma.cc/U3LQ-CLUW>]; See Andrew Gunther, *supra* note 50.

42. See Richards & Richards, *supra* note 34, at 43.

43. CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013, 11 (2013), <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf> [<https://perma.cc/GD75-Z3V2>].

44. *Id.* at 31.

45. “Although as yet sparse, data show the flow of distinct salmonella clones from farm animals medicated with antibiotics in subtherapeutic concentrations,



can have devastating effects on the environment, animal health, and human health in other ways.

#### E. *Impact on Animal Health*

Although the scope of this Article largely centers on controlling the environmental effects of the administration of subtherapeutic doses of antibiotics, additional concerns about other harmful effects exist. Living conditions aside, animal welfare may well be implicated. Animals given subtherapeutic doses of antibiotics over time do indeed gain weight and grow more rapidly than they would otherwise.<sup>46</sup> The very administration of these antibiotics over a long period likely disrupts the animals' normal biological systems.<sup>47</sup>

CAFOs have been roundly criticized for their inhumane living conditions. These conditions are in large part facilitated by the administration of antibiotics, which are also used to prevent and treat disease. The result is often cramped quarters and mistreatment. Some argue that “[i]t would be unthinkable, not to mention illegal, under most states’ animal cruelty laws, for pet-owners to treat their pets with such disregard.”<sup>48</sup> Thus, antibiotics play a central role in the arguments levied by animal rights activists against large-scale commercial feeding operations.<sup>49</sup> Of course, as with humans, there are appropriate instances in which antibiotics are the correct course of action. Used sparingly and correctly for the treatment of disease, antibiotics are an important resource for doctors of veterinary medicine.<sup>50</sup>

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through food products, to humans, who thus acquire clinical salmonellosis.” INST. OF MED., DIV. OF HEALTH PROMOTION AND DISEASE PREVENTION, HUMAN HEALTH RISKS WITH THE SUBTHERAPEUTIC USE OF PENICILLIN OR TETRACYCLINES IN ANIMAL FEED 2 (1989).

46. *Id.* at 199.

47. See Kai Kupferschmidt, *Do Antibiotics Make Us Fat?*, SCIENCE (Aug. 22, 2012, 2:07 PM), <http://www.sciencemag.org/news/2012/08/do-antibiotics-make-us-fat> [<https://perma.cc/T5K6-CU4R>]. Although scientific consensus is uncertain regarding the precise reasons that animals grow faster with low-level dosing, there are theories. One such theory is that the disruption of the normally present flora in the animal’s digestive system is skewed in such a way that more nutrients are absorbed from the food. *Id.*

48. See Richards & Richards, *supra* note 34, at 50.

49. See generally *id.*

50. See Andrew Gunther, *Is The Antibiotic Free Campaign Really “Antibiotic Free” Or Will It Just Create A Two Tier Food System?*, ANIMAL WELFARE APPROVED (Apr. 1, 2013), <http://animalwelfareapproved.org/2013/04/01/is-the-antibiotic-free-campaign-really-antibiotic-free-or-will-it-just-create-a-two-tier-food-system/> [<https://perma.cc/3DJ6-FPLA>].

## F. *Effects on Human Health*

There has been a growing global response to the connection between the overuse of agricultural antibiotics and so-called “superbugs.”<sup>51</sup> For European countries that have banned such overuse, there has been a decline in antibiotic resistance.<sup>52</sup> Antibiotic-resistant infections now kill more people each year in the United States than AIDS.<sup>53</sup> Consumer, scientific, and policymaking constituencies have vocalized concerns criticizing the costs as outpacing the benefits.<sup>54</sup>

Although some antibiotic resistance can be attributed to direct human overprescribing of antibiotics, there is growing consensus that the factory-farming model, with its long-term subtherapeutic application of antibiotics to livestock and poultry, has been largely to blame as well.<sup>55</sup>

The Centers for Disease Control and Prevention has expressed growing concern over the part that agriculture plays in the problem of antibiotic-resistant bacterial strains. The Center for Disease Control and Prevention noted in 2013 that “widespread use of antimicrobials in agriculture has resulted in an increase in resistant infections in humans.”<sup>56</sup>

There are multiple modes by which the antibiotic-resistant bacteria present in digestive tracts of factory farm animals reaches humans and poses a threat. Employees or workers who handle the animals, their excrement, or the meat may unwittingly make

51. Clint Rainey, *Superbugs Found in a Scary Percentage of Meat*, GRUB STREET (Nov. 19, 2015, 1:50 PM), <http://www.grubstreet.com/2015/11/superbugs-in-meat.html> [https://perma.cc/D5HK-NQXA].

52. See Richards & Richards, *supra* note 34, at 50 (Aug. 15, 2011) (detailing historical prohibitions against factory farming practices in European countries like, Switzerland, Sweden, Germany, Britain, and the 1998 European Union legislative protections for farmed animals).

53. See Kristof, *supra* note 37.

54. CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013 33 (2013), <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf> [https://perma.cc/GD75-Z3V2].

55. See *Antibiotic Debate Overview: Is Your Meat Safe?*, PBS FRONTLINE, <http://www.pbs.org/wgbh/pages/frontline/shows/meat/safe/overview.html> [https://perma.cc/BH5Z-MEH9] (last visited May 10, 2016); see also, Lydia Zuraw, *CDC Acknowledges Role of Farms in Antibiotic Resistance*, FOOD SAFETY NEWS (Sept. 17, 2013), <http://www.foodsafetynews.com/2013/09/drug-resistant-infections/#.VsXH2LQrJph> [https://perma.cc/LRN7-CYYY].

56. Lydia Zuraw, *CDC Acknowledges Role of Farms in Antibiotic Resistance*, FOOD SAFETY NEWS (Sept. 17, 2013), <http://www.foodsafetynews.com/2013/09/drug-resistant-infections/#.VsXH2LQrJph>.

contact with and transmit the bacteria off site.<sup>57</sup> Additionally, antibiotic-resistant bacterial strains have been found in cuts of meat sold for human consumption.<sup>58</sup> This bacteria is often antibiotic-resistant and is more prevalent in meat from animals treated with subtherapeutic doses of antibiotics.<sup>59</sup> Although scientific, medical, and consumer-based groups have become more vocal, the disastrous consequences of antibiotic-resistant bacterial strains have not been rectified.

### G. *Scope of Environmental Problem*

The treatment of livestock and poultry with ongoing subtherapeutic levels of antibiotics affects many facets of the environment in various and alarming ways. Not only do antibiotic-resistant strains of bacteria exist in the excrement of such animals, but most antibiotics also pass through the animal's digestive system and are released into the environment.<sup>60</sup>

Putting aside the issue of antibiotic-resistant bacteria that is also excreted, the antibiotics themselves can cause significant environmental problems in manure runoff and manure applications to vegetables and plants.<sup>61</sup>

While there are restrictions on use of raw manure in U.S. organic farming because of concern over bacteria, no such rules

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57. FOOD & WATER WATCH, ANTIBIOTIC RESISTANCE 101: HOW ANTIBIOTIC MISUSE ON FACTORY FARMS CAN MAKE YOU SICK 12 (Feb. 2015), <http://www.foodandwaterwatch.org/sites/default/files/Antibiotic%20Resistance%20101%20Report%20March%202015.pdf> [<https://perma.cc/LTX4-3TZL>].

58. See Clint Rainey, *Superbugs Found in a Scary Percentage of Meat*, GRUB STREET (Nov. 19, 2015, 1:50 PM), <http://www.grubstreet.com/2015/11/superbugs-in-meat.html> [<https://perma.cc/D5HK-NQXA>].

59. See Lena H. Sun, *Testers Find Twice as Many 'Superbugs' in Conventional Hamburger as Organic Ones*, WASH. POST (Aug. 25, 2015), <https://www.washingtonpost.com/news/to-your-health/wp/2015/08/25/you-just-cant-kill-the-bacteria-in-some-hamburger/> (“[B]eef from conventionally raised cows [is] more likely to have bacteria overall, as well as bacteria that are resistant to antibiotics, than beef from sustainably raised cows.”).

60. See 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/YU8V-KCSG>] (“Around 90 percent of these drugs that are administered to animals end up being excreted either as urine or manure . . . A vast majority of that manure is then used as an important input for 9.2 million hectares of (U.S.) agricultural land.”); see also Monica Eng, *Another concern: Drug residues in meat*, CHI. TRIB. (May 26, 2013), [http://articles.chicagotribune.com/2013-05-26/news/ct-met-antibiotics-residue-20130526\\_1\\_u-s-meat-the-fda-drug-violations](http://articles.chicagotribune.com/2013-05-26/news/ct-met-antibiotics-residue-20130526_1_u-s-meat-the-fda-drug-violations) [<https://perma.cc/Z6CX-MJ38>].

61. One study noted that excreted antibiotics were absorbed by crops that were treated with manure from factory farms. See Cimitile, *supra* note 60.

are in place regarding antibiotics or hormones. Not all organic growers use manure with antibiotics, but many do . . . Even if a product has the USDA organic label, it still might harbor traces of antibiotics.<sup>62</sup>

Additionally, antibiotics excreted by animals that enter the environment through runoff of any sort can disrupt the flora and biological makeup of ecosystems by potentially killing off microorganisms present in the environment.<sup>63</sup>

Beyond the presence of residual antibiotics moving through the digestive tracts of farm-raised animals, there is also the possibility that the excrement will contain so-called superbugs—the antibiotic-resistant strains of bacteria enabled by long-term low-dose antibiotic uses.<sup>64</sup> “Once farm-raised superbugs make it off the farm, they can exchange genetic material and give their resistance to other bacteria, even of other genera and species, that have never been anywhere near antibiotics. This can happen in lakes, in wild animals, and even in the human digestive tract.”<sup>65</sup> The potential for systemic disruption of ecosystems is inherent in the consequences of therapeutic antibiotic dosing of livestock and poultry.

#### H. *Effects on Water*

Animals at CAFOs produce large amounts of manure; generally, this manure is stored in aptly named waste lagoons and sprayed onto fields.<sup>66</sup> As discussed above, the components of this manure include both antibiotics and frequently contain antibiotic-resistant bacteria.<sup>67</sup> Although there is an effort to contain the manure, these waste lagoons frequently leak, overflow, and

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62. *See id.*

63. Preliminary studies of rivers in Virginia have shown that microorganisms in the ecosystem were sensitive to antibiotics potentially present in runoff. *See* Abstract by Jenefir Isbister, Thomas B. Huff, N.S. Simon, & Trinh Tu, *Ecological Effects of Antibiotics in Runoff From an Eastern Shore Tributary of the Chesapeake Bay*, <http://water.usgs.gov/owq/AFO/proceedings/afo/pdf/Isbister2.pdf> [<https://perma.cc/H58Q-VGFW>].

64. JEAN HALLORAN, CONSUMERS UNION, *THE OVERUSE OF ANTIBIOTICS IN FOOD ANIMALS THREATENS PUBLIC HEALTH* 5 (Nov. 9, 2012), <http://consumersunion.org/research/the-overuse-of-antibiotics-in-food-animals-threatens-public-health/> [<https://perma.cc/DFB3-RX7F>].

65. *Id.* at 4.

66. *Pollution From Giant Livestock Farms Threatens Public Health*, NAT. RES. DEF. COUNCIL (last updated Feb. 21, 2013), <http://www.nrdc.org/water/pollution/nspills.asp>.

67. *See* Part I.G., *supra*.

otherwise spill, and manure runoff from field application is frequent.<sup>68</sup> These releases essentially allow the dangerous microbes, residual antibiotics, and other compounds into the environment; these constituent parts of the manure then find their way into the water table or water supply.<sup>69</sup>

## II. REGULATORY SCHEME

Federal agencies overlap in the areas they regulate, and the regulation of antibiotics in the environment is no exception.<sup>70</sup> The Food and Drug Administration (FDA), for example, has a direct role in the way that antibiotics are sold and administered.<sup>71</sup> The USDA, through its Food Safety Inspection Service (FSIS), makes and enforces rules about the medical treatments to which livestock may be subjected before being slaughtered and sold.<sup>72</sup> The Environmental Protection Agency (EPA) plays a role in regulating medical waste that would otherwise end up in our environment.<sup>73</sup> The regulation of medical waste, however, is generally managed at

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68. *Pollution From Giant Livestock Farms Threatens Public Health*, NAT. RES. DEF. COUNCIL (last updated Feb. 21, 2013), <http://www.nrdc.org/water/pollution/nspills.asp> [<https://perma.cc/ZB6J-6Q6M>] (last visited Apr. 25, 2016).

69. *Id.*

70. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-213, OVERSIGHT OF FOOD SAFETY ACTIVITIES: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES (Mar. 2005) <http://www.gao.gov/assets/250/245837.pdf> [<https://perma.cc/EPZ4-7MPA>] (analyzing overlap of regulation in food safety regulation). *See generally* Mark Warner, *Self-Replicating Regulation: How to Trim Government Overlap*, THE ATLANTIC (Mar. 12, 2012), <http://www.theatlantic.com/politics/archive/2012/03/self-replicating-regulation-how-to-trim-government-overlap/253898/> [<https://perma.cc/HB3P-8XW4>] (discussing proposed legislation to streamline regulation by federal agencies).

71. *See FDA's Strategy on Antimicrobial Resistance: Questions and Answers*, U.S. FOOD AND DRUG ADMIN. (last updated June 11, 2015), <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm>.

72. *See* U.S. DEP'T OF AGRIC. OFFICE OF THE INSPECTOR GEN., AUDIT REPORT 24601-08-KC, FSIS NATIONAL RESIDUE PROGRAM FOR CATTLE 1 (Mar. 2010), <http://www.usda.gov/oig/webdocs/24601-08-KC.pdf> [<https://perma.cc/D3S6-ASPX>] ("In order to safeguard the Nation's food supply from harmful residue, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) administers the national residue program.").

73. *See generally* *Management of Pharmaceutical Hazardous Waste*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste> [<https://perma.cc/68WE-NYMZ>] (last updated Aug. 31, 2015) (providing information about pharmaceutical waste management).

the state level.<sup>74</sup>

Federal agencies, in connection with state and local efforts, should work together<sup>75</sup> to accomplish the goals of eradicating the harm caused by the overuse of antibiotics in livestock production. As long as antibiotics are in use in the United States, some degree of residue will end up in our wastewater, drinking water, rivers, and lakes whether through storm drains, sewage, or runoff. As discussed herein, the Clean Water Act, as administered by the EPA,<sup>76</sup> should also play a central role in mitigating the problem of contamination by antibiotics in the national waterways. To understand how the Clean Water Act could play a role in the regulation of antibiotics, it is helpful to untangle the existing and potential regulatory schemes.

#### A. *The Food and Drug Administration*

The FDA has initiated a regulatory framework, known as the judicious use policy, to eliminate non-therapeutic uses of certain antibiotics from agriculture.<sup>77</sup> The strategy initially involved recommendations to companies that produce certain drugs—specifically those antibiotics used to treat humans as well as livestock—successfully seeking cooperation in removing non-therapeutic treatment from the approved uses for the drugs and eliminating over-the-counter sales; these changes are to be fully implemented by the end of 2016.<sup>78</sup> Another aspect of the strategy known as the Veterinary Feed Directive—the final rules for which went into effect in October of 2015—requires veterinary oversight of all administration of antibiotics to livestock in line with their

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74. See *Medical Waste: Who Regulates Medical Waste?*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/rcra/medical-waste> [<https://perma.cc/QT45-QREZ>] (last updated Apr. 29, 2015) (“Medical waste is primarily regulated by state environmental and health departments.”).

75. See Laura Fisher, *All (Food) Politics is Local: Cooperative Federalism, New England Small Farms, and the Food Safety Modernization Act*, 37 W. NEW ENG. L. REV. 337, 358–65 nn.120–71 (2015) (describing cooperative federalism in the United States).

76. The Clean Water Act is administered jointly on the federal level in some respects by the EPA and the Army Corps of Engineers. See *CWA Section 404 Enforcement Overview*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/cwa-404/cwa-section-404-enforcement-overview> [<https://perma.cc/LB9Z-U6TG>] (last updated Mar. 3, 2016).

77. See Michael R. Taylor, *Veterinary Feed Directive Will Protect Both People and Animals*, U.S. FOOD AND DRUG ADMIN: FDA VOICE (June 2, 2015), <http://blogs.fda.gov/fdavoce/index.php/2015/06/veterinary-feed-directive-will-protect-both-people-and-animals/> [<https://perma.cc/J2C9-SU3B>].

78. See *id.*

permitted therapeutic uses.<sup>79</sup>

A bill has been proposed by four United States senators<sup>80</sup> to force the FDA to close perceived loopholes in the regulatory scheme.<sup>81</sup> Some critics of the final rule claim that the regulations provide a loophole wherein a veterinarian may sign a directive that allows treatment to continue indefinitely.<sup>82</sup> Another perceived loophole allows for preventive treatment when a veterinarian believes that livestock may potentially become sick.<sup>83</sup>

The feed directive is perceived as having other shortcomings as well.<sup>84</sup> For example, some antibiotics not deemed “medically important” to human health by the FDA are not regulated under the final rule, despite evidence that the same antibiotics lead to cross-resistance to other medicines used in treating humans.<sup>85</sup> The issue of compliance, a concern under any regulatory structure, raises questions about whether the regulations will be effective in curbing the overuse of antibiotics on farms.<sup>86</sup>

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79. *See id.*

80. Preventing Antibiotic Resistance Act of 2015, S. 621, 114th Cong. (2015) (proposed by Diane Feinstein, Kirsten Gillibrand, Susan Collins, Elizabeth Warren).

81. *See* Ed Silverman, *Senators Introduce a Bill to Fight Overuse of Antibiotics in Livestock*, WALL ST. J.: PHARMALOT (Mar. 3, 2015, 9:09 AM), <http://blogs.wsj.com/pharmalot/2015/03/03/senators-introduce-a-bill-to-fight-overuse-of-antibiotics-in-livestock/> [<https://perma.cc/C9R7-77XF>].

82. *See* Chris Morran, *White House Acknowledges Health Risk of Antibiotics Overuse; Critics Say it Fails to Fully Address Problem*, CONSUMERIST (Mar. 27, 2015), <http://consumerist.com/2015/03/27/white-house-acknowledges-health-risk-of-antibiotics-overuse-critics-say-it-fails-to-fully-address-problem/> [<https://perma.cc/299K-WFSB>].

83. “[The veterinary feed directive] focus[es] on eliminating the use of antibiotics for growth promotion, but condone[s] the routine use of antibiotics to help animals survive crowded, stressful[,] and unsanitary confinement conditions.” Mae Wu, *More Action Needed in National Action Plan for Combating Antibiotic Resistant Bacteria*, NRDC EXPERT BLOG (Mar. 27, 2015), <https://www.nrdc.org/experts/mae-wu/more-action-needed-national-action-plan-combating-antibiotic-resistant-bacteria>.

84. *See NRDC Fact Sheet: FDA’s Efforts Fail to End Misuse of Livestock Antibiotics*, NAT. RES. DEF. COUNCIL (2015), <http://www.nrdc.org/food/subway/files/fda-guidance-213.pdf> [<https://perma.cc/HCE9-9J5T>].

85. *See* Letter from Steven Roach, Public Health Program Director, Keep Antibiotics Working, to Division of Dockets Management, Food and Drug Admin., Docket No. FDA-2011-D-0889: Draft Guidance 213 Comments of Keep Antibiotics Working (July 11, 2012), [http://static1.squarespace.com/static/5519650ce4b01b71131cb5f9/t/552dcab0e4b06a8eecd0939d/1429064368341/KAW\\_Docket\\_on+Draft+GD+213.pdf](http://static1.squarespace.com/static/5519650ce4b01b71131cb5f9/t/552dcab0e4b06a8eecd0939d/1429064368341/KAW_Docket_on+Draft+GD+213.pdf) [<https://perma.cc/5K42-A39P>]. Tiamulin is not currently listed as medically important to human health, even though it has been shown that resistance to tiamulin is linked to resistance to other antibiotics used in the treatment of humans. *Id.* at § I.E.

86. A study found that fluoroquinolones, a category of antibiotics used to treat infections in humans and banned from agricultural use in 2005, are present in two

### B. *The Department of Agriculture*

The FSIS arm of the USDA plays a central role in preventing foods contaminated by antibiotics from reaching consumers.<sup>87</sup> According to USDA regulations, after an animal consumes antibiotics, a withdrawal period (varying depending on the animal, its weight, and the antibiotics administered) is required prior to slaughter to ensure that no residue remains in the meat when it is sold and consumed. The FSIS is responsible for inspecting meat to identify producers who do not act in conformity with these standards, but enforcement is imperfect.<sup>88</sup> An audit in 2010 showed that residue of antibiotics remained in our food supply.<sup>89</sup> In 2012, the USDA promulgated updated rules for organic meat products, with the intention of improving compliance by facilitating enforcement through increased testing requirements.<sup>90</sup>

### C. *Drug Enforcement Agency*

The Drug Enforcement Agency (DEA) is involved with the regulation of disposal of certain pharmaceuticals defined as “controlled substances” under the authority of the Controlled Substances Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.<sup>91</sup> The regulations, which were finalized in

thirds of samples of a poultry feed product. See D.C. Love, R.U. Halden, M.F. Davis, & K.E. Nachman, *Feather Meal: A Previously Unrecognized Route for Reentry into the Food Supply of Multiple Pharmaceuticals and Personal Care Products (PPCPs)*, 46 ENVTL. SCI. & TECH. 3795, 3797 (2012).

87. See Jeannine P. Schwehofer, *Antibiotic Residue Testing in Meat Results in Few Positive Samples*, MICH. STATE UNIV.: EXTENSION (Feb. 13, 2013), [http://msue.anr.msu.edu/news/antibiotic\\_residue\\_testing\\_in\\_meat\\_results\\_in\\_few\\_positive\\_samples](http://msue.anr.msu.edu/news/antibiotic_residue_testing_in_meat_results_in_few_positive_samples) [https://perma.cc/B52G-YGZY].

88. See Peter Eisler, ‘*Growing Concern*’ Over Marketing Tainted Beef, USA TODAY (Apr. 15, 2010, 11:57 AM), [http://usatoday30.usatoday.com/news/washington/2010-04-12-tainted-meat\\_N.htm](http://usatoday30.usatoday.com/news/washington/2010-04-12-tainted-meat_N.htm) [https://perma.cc/8BGY-5KJW]; see also Eileen O. van Ravenswaay & Sharon A. Bylenga, *Enforcing Food Safety Standards: A Case Study of Antibiotic and Sulfa Drug Residues in Veal*, J. AGRIBUSINESS 39, 40 (Spring 1991), <http://ageconsearch.umn.edu/bitstream/62298/2/JAB9one3.pdf> [https://perma.cc/AX4Q-Y4XA].

89. GIL H. HARDIN, U.S. DEP’T OF AGRIC., OFF. OF THE INSPECTOR GEN., AUDIT REPORT 24601-08-KC, FSIS NAT’L RESIDUE PROGRAM FOR CATTLE 1 (Mar. 2010), <http://www.usda.gov/oig/webdocs/24601-08-KC.pdf> [https://perma.cc/7A8Z-B6AE] (“Based on our review, we found that the national residue program is not accomplishing its mission of monitoring the food supply for harmful residues.”).

90. See William H. Kitchens, Arnall Golden Gregory LLP, *USDA issues final rule, draft guidance, and procedures on new periodic testing requirements for organic products*, LEXOLOGY (Nov. 27, 2012), <http://www.lexology.com/library/detail.aspx?g=a5d63278-dc66-4f1c-b8f3-338b51d1db93> [https://perma.cc/7CP6-PZK9].

91. See 21 U.S.C. §§ 822(g), 828(b)(3) (2014).



September of 2014,<sup>92</sup> expand the options available to users of controlled pharmaceuticals for disposing leftover drugs, including options to deliver the pharmaceuticals back to the manufacturer, to the distributor, or to a registered third-party reverse distributor tasked with properly disposing of the pharmaceuticals.<sup>93</sup> This flexibility is intended to reduce the possibility that pharmaceuticals will end up causing harm to drug abusers, who may have access to unused drugs that are disposed of in an unsafe manner, or to others, who may be exposed to drugs when disposal is accomplished by a method that may direct the pharmaceuticals into water ways (such as flushing leftover pills down a toilet).<sup>94</sup> Currently, antibiotics are not defined as controlled substances by the DEA.<sup>95</sup> While antibiotics may not be the type of pharmaceuticals that the DEA normally would regulate, the harm to human health caused by their presence in the environment may be a compelling reason to consider including antibiotics in the list of controlled substances subject to regulation.

#### D. *Medical Waste Regulations*

In September of 2015, the EPA proposed new rules banning the flushing of pharmaceutical waste by healthcare facilities.<sup>96</sup> These rules would mandate disposal procedures for pharmaceuticals under the Resource Conservation and Recovery Act (RCRA).<sup>97</sup> Previously, the EPA had failed to provide

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92. See Disposal of Controlled Substances, 79 Fed. Reg. 174 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, and 1317), [http://www.deadiversion.usdoj.gov/fed\\_regs/rules/2014/2014-20926.pdf](http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf) [<https://perma.cc/3SQR-3898>].

93. See Larry K. Houck & Andrew J. Hull, *DEA Issues Final Rule on Controlled Substance Disposal*, HYMAN, PHELPS & MCNAMARA, P.C.: FDA LAW BLOG (Sept. 14, 2014), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2014/09/dea-issues-final-rule-on-controlled-substance-disposal.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/09/dea-issues-final-rule-on-controlled-substance-disposal.html) [<https://perma.cc/T6U3-C44D>].

94. See *id.*

95. See CONTROLLED SUBSTANCES, U.S. DEP'T OF JUSTICE (Feb. 8, 2016), [http://www.deadiversion.usdoj.gov/schedules/orangebook/c\\_cs\\_alpha.pdf](http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf) [<https://perma.cc/927T-7FG7>]; see also WhiteCoat, *Antibiotics Need to Become Controlled Substances and Regulated*, KEVINMD.COM: MEDS (Nov. 29, 2010), <http://www.kevinmd.com/blog/2010/11/antibiotics-controlled-substances-regulated.html> [<https://perma.cc/NP9G-KMGL>] (calling for antibiotics to be listed as controlled substances).

96. *Proposed Rule: Management Standards for Hazardous Waste Pharmaceuticals*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals> [<https://perma.cc/N394-9UAV>] (last updated Mar. 28, 2016).

97. 42 U.S.C. §§ 6901–6992k (1976). RCRA is the statute that gives authority to the EPA to regulate the generation, transportation, treatment, storage, and disposal of

guidance on the disposal of pharmaceuticals at healthcare facilities, and control and enforcement were handled by state environmental agencies.<sup>98</sup> The proposed rules also clarify the role of reverse distributors in disposing of pharmaceuticals under RCRA.<sup>99</sup> In the absence of an established federal regulatory scheme, pharmaceutical waste has been approached in different ways at the state level over the past several years.<sup>100</sup> Pharmaceutical manufacturers, healthcare facilities, and reverse distributors, would benefit from comprehensive federal regulations that are consistent with rules in the individual states.

### E. *State-Level Agricultural Regulation*

Some state legislatures have attempted to control agricultural uses of antibiotics, but most efforts have been unsuccessful so far.<sup>101</sup> California is the only state to have enacted legislation that requires farmers to limit the antibiotics given to livestock.<sup>102</sup> California law goes further than the FDA judicious use guidelines by limiting preventive care, absent a showing of an elevated risk

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hazardous materials, from cradle to grave. See *Summary of the Resource Conservation and Recovery Act*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act> [https://perma.cc/FC7U-JPYY] (last updated Dec. 29, 2015).

98. See Aaron S. Heisman, Jackson Kelly PLLC, *EPA Proposes New Rule Governing the Disposal of Hazardous Waste Pharmaceuticals at Healthcare Facilities*, JACKSON KELLY PLLC: HEALTH LAW MONITOR (Sept. 29, 2015), <http://healthlawmonitor.jacksonkelly.com/2015/09/epa-proposes-new-rule-governing-the-disposal-of-hazardous-waste-pharmaceuticals-at-healthcare-facilities.html> [https://perma.cc/E7NT-8NXC].

99. See Jean-Cyril Walker & Gregory A. Clark, Keller and Heckman LLP, *EPA Proposes RCRA Management Standards for Hazardous Waste Pharmaceuticals*, NAT'L L. REV. (Sept. 28, 2015), <http://www.natlawreview.com/article/epa-proposes-rcra-management-standards-hazardous-waste-pharmaceuticals> [https://perma.cc/5E3N-Z3E5].

100. See WATER SUPPLY DIV., TEXAS COMM'N ON ENVTL. QUALITY DIV., *STUDY OF THE METHODS FOR DISPOSING OF UNUSED PHARMACEUTICALS* 114–21 (SFR-098 Dec. 2010), [http://c.ybcdn.com/sites/www.productstewardship.us/resource/resmgr/imported/Study\\_of\\_Methods\\_for\\_Disposal.pdf](http://c.ybcdn.com/sites/www.productstewardship.us/resource/resmgr/imported/Study_of_Methods_for_Disposal.pdf) [https://perma.cc/3384-WF93].

101. See Alex Zielinski, *The States Trying To Regulate The Use Of Human Antibiotics In Livestock*, THINKPROGRESS: HEALTH (Oct. 22, 2015, 12:53 PM), <http://thinkprogress.org/health/2015/10/22/3715031/antibiotic-state-map/> [https://perma.cc/DBP8-NVFFV].

102. *Livestock: Use of Antimicrobial Drugs*, 2015 Cal. Stat. ch. 758; see John Tozzi, *California Enacts Strictest Animal Antibiotic Law in the U.S.*, BLOOMBERG (Oct. 11, 2015, 8:58 AM), <http://www.bloomberg.com/news/articles/2015-10-11/california-enacts-strictest-animal-antibiotic-law-in-the-u-s-> [https://perma.cc/35FG-2XU4].

requiring the use of antibiotics to prevent disease among a herd.<sup>103</sup> Nevertheless, the statute relies on the FDA's list of "medically important" antibiotics, possibly failing to account for some drugs that may aid the development of cross-resistance to medicine used to treat humans.<sup>104</sup> Oregon has also moved on legislating the issue.<sup>105</sup>

#### F. *Non-Governmental Efforts*

Various nonprofit organizations have worked to raise awareness and to lobby government and businesses to limit the use of antibiotics in agriculture.<sup>106</sup> The United States Public Interest Research Group ("U.S. PIRG") Education Fund, for example, has launched a campaign calling on restaurants to stop purchasing meat from farms that use antibiotics.<sup>107</sup> A group of four such organizations released a scorecard in September of 2015,<sup>108</sup> which assessed the efforts that individual restaurants have put forth to eliminate meat produced with antibiotics from their food. So far, a couple of companies have taken the lead, namely Chipotle Mexican Grill and Panera Bread,<sup>109</sup> both receiving an A according to the scorecard. Of other companies following Panera and Chipotle's

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103. Tozzi, *supra* note 102.

104. Keep Antibiotics Working, *supra* note 85 and accompanying text.

105. See S.B. 920 78th Leg., Reg. Sess. (Or. 2015); see also Lynne Terry, *Oregon's Senate Bill 920 targets antibiotic resistance*, OREGONIAN (May 26, 2015, 8:20 AM), [http://www.oregonlive.com/health/index.ssf/2015/05/oregons\\_senate\\_bill\\_920\\_target.html](http://www.oregonlive.com/health/index.ssf/2015/05/oregons_senate_bill_920_target.html) [<https://perma.cc/BW4T-7A7L>].

106. See Danielle Nierenberg, Sarah Small & Nicolas Giroux, *16 Organizations Working to Raise Antibiotic Resistance Awareness*, FOODTANK (May 28, 2014), <http://foodtank.com/news/2014/05/sixteen-organizations-working-to-raise-antibiotic-resistance-awareness> [<https://perma.cc/PH9A-Z7BQ>].

107. *Stop the Overuse of Antibiotics on Factory Farms*, U.S. PIRG EDUC. FUND, <http://www.uspirg.org/issues/usp/stop-overuse-antibiotics-factory-farms-0> [<https://perma.cc/N93X-AUFR>] (last visited Jan. 10, 2015).

108. KARI HAMERSCHLAG ET AL., NAT. RES. DEF. COUNCIL, CHAIN REACTION: HOW TOP RESTAURANTS RATE ON REDUCING USE OF ANTIBIOTICS IN THEIR MEAT SUPPLY 9 (Sept. 2015), <http://www.nrdc.org/food/files/restaurants-antibiotic-use-report.pdf> [<https://perma.cc/5SP3-ZRKH>]; see David Kesmodel, Jacob Bunge & Betsy McKay, *Meat Companies Go Antibiotics-Free as More Consumers Demand It*, WALL ST. J. (Nov. 3, 2014, 10:30 PM), <http://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802> [<https://perma.cc/2656-EFJ7>].

109. Aamer Madhani, *Most restaurant chains get failing on antibiotic use in new report*, USA TODAY (Sept. 15, 2015, 5:39 PM), <http://www.usatoday.com/story/news/2015/09/15/fast-food-scorecard-antibiotics-chipotle-mcdonalds-panera-starbucks-subway/72309072/> [<https://perma.cc/4QK7-6SFA>]; see Hamerschlag et al. *supra* note 108.

lead, Chick-fil-A, McDonalds, and Dunkin' Donuts are the only companies that managed to stay out of the F category on the scorecard.<sup>110</sup> Chick-fil-A has a policy in place eliminating the use of meat produced with antibiotics by 2019.<sup>111</sup> McDonald's anticipates the same result in two years.<sup>112</sup> Dunkin' Donuts has a similar policy with no timeline in place, however. While Tyson, the largest poultry producer in the United States,<sup>113</sup> was not evaluated on the scorecard (only restaurants were rated), the company has elected to eliminate human antibiotics from its chicken production by September of 2017.<sup>114</sup> An inherent problem with businesses amending practices under pressure from consumers and advocacy organizations, a self-regulatory approach, is that it appears to lack nuance and does not allow for the use of antibiotics to treat sick animals.<sup>115</sup> Ultimately, however, poor conditions on farms are often the source of the health problems facing livestock; if the conditions were improved, the need for treatment would be reduced.<sup>116</sup>

### III. ANTIBIOTICS AND THE CLEAN WATER ACT

#### A. *The Mechanics of the Clean Water Act*

The Clean Water Act<sup>117</sup> was enacted in 1972<sup>118</sup> to restore and maintain the “chemical, physical, and biological integrity of the

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110. *Id.*

111. *Id.*

112. *Id.*

113. See P.J. Huffstutter, *Tyson Foods to End use of human antibiotics in U.S. chickens by 2017*, REUTERS (Apr. 28, 2015, 12:22 PM), <http://www.reuters.com/article/us-tyson-foods-antibiotics-idUSKBN0NJ0TA20150428> [https://perma.cc/UNB7CHAU].

114. See *Antibiotic Use*, TYSON FOODS, <http://www.tysonfoods.com/Media/Position-Statements/Antibiotic-Use.aspx> (last visited Apr. 25, 2016).

115. See *Issues and Advocacy: Benefits of Antibiotics*, ANIMAL HEALTH INST., <http://www.ahi.org/issues-advocacy/animal-antibiotics/benefits-of-antibiotics> (last visited Apr. 25, 2016).

116. Robert S. Lawrence, *The FDA Did Not Do Enough to Restrict Antibiotics Use in Animals*, ATLANTIC (Apr. 16, 2012), <http://www.theatlantic.com/health/archive/2012/04/the-fda-did-not-do-enough-to-restrict-antibiotics-use-in-animals/255878/> [https://perma.cc/64TF-9HGH].

117. 33 U.S.C. § 1251 (2014).

118. *Id.* The predecessor to the Clean Water Act, the Federal Water Pollution Control Act, was enacted in 1948. *Digest of Federal Resources Laws of Interest to the U.S. Fish and Wildlife Service, Federal Water Pollution Control Act (Clean Water Act)*, FISH AND WILDLIFE SERV., <https://www.fws.gov/laws/lawsdigest/FWATRPO.HTML> [https://perma.cc/C4FY-S3RX] (last visited Apr. 25, 2016).

Nation's waters."<sup>119</sup> This legislation, however, is complicated and depends upon cooperation between the EPA and state environmental agencies to accomplish its mandates.<sup>120</sup> As contemplated by the Clean Water Act, the first step to controlling water contamination is to identify the level of pollution in each body of water<sup>121</sup> in each state.<sup>122</sup> The Clean Water Act accomplishes this task by requiring the EPA and cooperating state agencies to identify and study water bodies, designate the permissible uses of the water, and assess the pollution levels.<sup>123</sup> The EPA is charged with setting water quality criteria to support the particular designated beneficial uses.<sup>124</sup> This responsibility includes maintaining a list of regulated toxic pollutants and determining the maximum permissible levels of pollution that are acceptable for different designated uses.<sup>125</sup>

State agencies, or the EPA where states have chosen not to act,<sup>126</sup> are charged with setting water quality standards based on the federally determined criteria for the designated use of each body of water under the jurisdiction of the Clean Water Act.<sup>127</sup> This involves setting the maximum level of toxic pollutants that may continue to enter the body of water to keep the level of contamination within a safe range.<sup>128</sup> Total maximum daily loads

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119. 33 U.S.C. § 1251(a) (2014).

120. See 33 U.S.C. § 1253 (2014); *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992) (“The Clean Water Act anticipates a partnership between the States and the Federal Government, animated by a shared objective.”).

121. The jurisdictional question of which waters are covered by the Clean Water Act has continued to evolve since its enactment. See *Rapanos v. United States*, 547 U.S. 715 (2006).

122. See 33 U.S.C. § 1254(a) (2014).

123. *Id.*

124. Every five years, the EPA must review its water quality criteria and issue new or revised criteria to meet its legislative mandate; otherwise, federal courts may compel the EPA to release updated criteria. See *NRDC v. Johnson*, No. CV 06-4843PSGJTLX, 2007 WL 1121799, (C.D. Cal. Mar. 21, 2007).

125. See *WaterKeepers N. Cal. v. State Water Res. Control Bd.*, 102 Cal. App. 4th 1448, 1453 (2002) (“Section 307, subdivision (a)(1) of the Clean Water Act requires the EPA to compile a list of toxic pollutants that are to be subject to effluent limitations. (33 U.S.C. § 1317; 40 C.F.R. § 401.15 (2001).) The EPA has interpreted the list to include 126 priority pollutants. (40 C.F.R. § 423, appen. A (2001) . . . .”).

126. 33 U.S.C. §§ 1342(c), 1370 (2014).

127. 33 U.S.C. § 1313 (2014); 40 C.F.R. § 131.6 (2014).

128. U.S. ENVTL. PROT. AGENCY, WATERSHED ACADEMY WEB, DISTANCE LEARNING MODULES ON WATERSHED MANAGEMENT, INTRODUCTION TO THE CLEAN WATER ACT 7, <https://cfpub.epa.gov/watertrain/pdf/modules/introtocwa.pdf> [<https://perma.cc/VJT3-WL2J>]. Initially, upon implementation of the Clean Water Act, every body of water was to attain a safe level of pollution for its designated uses.

(TMDLs) of each listed pollutant represent the amount of discharge that a water body can tolerate while maintaining a safe level of pollution.<sup>129</sup>

Under the Clean Water Act permitting process, locations known as point sources<sup>130</sup> must secure permits under the National Pollution Discharge Elimination System (NPDES) program.<sup>131</sup> CAFOs are statutorily defined as de facto point sources.<sup>132</sup> All point sources must obtain permits that place restrictions on the quantity of pollutants discharged into adjacent water bodies based on technological and economical feasibility.<sup>133</sup> Due to a statutory exemption, most non-CAFO farms are not point sources,<sup>134</sup> and thus runoff from these farms is not regulated by the NPDES permitting process. The sum of pollution allowed under NPDES permits must be under the TMDLs for the particular body of water, and the marginal permissible pollution discharge is allocated to all other locations, known as nonpoint sources, by way of a supplemental regulatory process.<sup>135</sup> The regulatory process for nonpoint sources and the permitting process for point sources are the mechanisms by which the Clean Water Act controls water pollution from farms.<sup>136</sup> Typically, the regulation of discharge from farms has focused on nitrogen and phosphorous, the pollutants

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Thereafter, the Clean Water Act mandated that safe pollution levels be maintained.  
*Id.*

129. 33 U.S.C. § 1313(d) (2014).

130. Point sources are defined as “any discernible, confined[,] and discrete conveyance . . . from which pollutants are or may be discharged.” 33 U.S.C. § 1362(14) (2014).

131. The National Pollution Discharge Elimination System, commonly known as NPDES, is the regulatory structure under which point source polluters obtain permits to limit the discharge of toxic substances into the waters of the United States. NPDES also includes requirements for monitoring and reporting the discharge of pollutants. See *NPDES Frequent Questions*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/npdes/npdes-frequent-questions> [https://perma.cc/2QRY-7HRT] (last updated Nov. 16, 2015).

132. 33 U.S.C. § 1362(14) (2014).

133. 33 U.S.C. § 1311(b)(2)(A) (2014).

134. 33 U.S.C. § 1362(14) (2014); see *Nonpoint Source: Agriculture*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/polluted-runoff-nonpoint-source-pollution/nonpoint-source-agriculture> [https://perma.cc/K7KG-HP5D] (last updated Apr. 19, 2016). (“[A]gricultural nonpoint source (NPS) pollution is the leading source of water quality impacts on surveyed rivers and streams, the third largest source for lakes, the second largest source of impairments to wetlands, and a major contributor to contamination of surveyed estuaries and ground water.”).

135. See *Program Overview: Total Maximum Daily Loads (TMDL)*, U.S. ENVTL. PROT. AGENCY, <https://www.epa.gov/tmdl/program-overview-total-maximum-daily-loads-tmdl> [https://perma.cc/F9EH-N6H7] (last updated Dec. 1, 2015).

136. 33 U.S.C. § 1313(d) (2014).

most commonly associated with agricultural activity.<sup>137</sup>

B. *Massachusetts v. Environmental Protection Agency*<sup>138</sup>

*Massachusetts v. Environmental Protection Agency*<sup>139</sup> was a monumental case, not only because it resulted in the classification of greenhouse gases as pollutants under the Clean Air Act, but because of the limitations that it placed on the EPA's discretion to identify and classify pollutants. The litigation arose after several states petitioned the EPA to regulate motor vehicle emissions of greenhouse gases under the theory that, notwithstanding each state's autonomy to regulate within its own borders,<sup>140</sup> they were negatively impacted by the greenhouse gas emissions in other states.<sup>141</sup> In response to the petitions, the EPA researched the issue and determined that greenhouse gases were not appropriately within the statutory authority<sup>142</sup> of the EPA under the Clean Air Act. The EPA offered explanations for why it would decline to regulate even if it had the authority, which included the perceived uncertainty of the science surrounding climate change and the need for a comprehensive approach to greenhouse gas legislation.<sup>143</sup> Ultimately, the EPA concluded that Congress must take the initiative to enact legislation that specifically addresses climate change in order for the EPA to have the authority to regulate greenhouse gases, and that regulation under the Clean Air Act would be piecemeal and inadequate.<sup>144</sup>

Litigation ensued and, in a split decision, the DC Circuit ruled in favor of the EPA, reasoning that the EPA was entitled to weigh policy considerations in deciding whether to engage in rulemaking<sup>145</sup> and, according to a concurring judge who wrote

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137. See *The Sources and Solutions: Agriculture*, U.S. ENVTL. PROT.AGENCY, <https://www.epa.gov/nutrientpollution/sources-and-solutions-agriculture> [<https://perma.cc/5X3B-FQEU>] (last updated Mar. 1, 2016).

138. *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007).

139. *Id.*

140. Two federal district court cases upheld heightened state vehicle emissions standards that went beyond EPA standards. See *generally* *Central Valley Chrysler-Jeep, Inc. v. Goldstene*, 529 F. Supp. 2d 1151 (9th Cir. 2007); *Green Mountain Chrysler Plymouth Dodge Jeep v. Crombie*, 508 F. Supp. 2d 295 (2d Cir. 2007).

141. *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007).

142. *Id.* at 511.

143. *Id.* at 513.

144. *Id.*

145. *Massachusetts v. EPA*, 415 F.3d 50, 53 (4th Cir. 2005) *rev'd*, 549 U.S. 497 (2007).

separately, the petitioners lacked standing to bring their claim.<sup>146</sup> The majority of the Supreme Court of the United States agreed with the dissenting opinion,<sup>147</sup> concluding the EPA has an obligation to regulate greenhouse gases.<sup>148</sup> The Court observed that the purpose of the Clean Air Act is to regulate all air pollutants that cause harm to humans.<sup>149</sup> As the EPA conceded, there is sufficient evidence to link greenhouse gases to consequences that are harmful to human health.<sup>150</sup> Therefore, greenhouse gases must be included within the definition of air pollutants.<sup>151</sup> The EPA, accordingly, has an obligation to regulate them.<sup>152</sup>

Unsurprisingly, the majority examined the text of the Clean Air Act to support its conclusions.<sup>153</sup> The preamble to the material section of the Clean Air Act states, unequivocally, that the EPA “shall” enact regulations to control “air pollution which may reasonably be anticipated to endanger public health or welfare . . . .”<sup>154</sup> Air pollutants are defined broadly in the statute as anything “emitted into or otherwise enter[ing] the ambient air.”<sup>155</sup> Greenhouse gases are air pollutants because motor vehicles emit them into the ambient air.<sup>156</sup> Moreover, greenhouse gases are air pollutants within the category of those that must be regulated by the EPA under the Clean Air Act because they contribute to climate change and, as the EPA conceded, they “may reasonably be anticipated to endanger public health or welfare.”<sup>157</sup> Therefore, according to the majority, the EPA must regulate motor vehicle emissions of greenhouse gases under the Clean Air Act.

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146. In his concurring opinion, Judge David Sentelle concluded that the alleged injuries impact humanity at large and are not sufficiently particularized to constitute an injury under which the plaintiffs may obtain relief. *Id.* at 59 (Sentelle, J., concurring in part).

147. *See id.* at 61 (Tatel, J., dissenting).

148. *Massachusetts v. EPA*, 549 U.S. at 534–35. Note that the Supreme Court determined that Massachusetts (in addition to the other appellant plaintiffs) had standing to bring this claim against the EPA. *Id.* at 521.

149. *Id.* at 529–30.

150. *Id.* at 521–22.

151. *Id.* at 528.

152. *Id.* at 530.

153. *Id.* at 528–30.

154. 42 U.S.C. § 7408(a)(1)(A) (2014).

155. 42 U.S.C. § 7602(g) (2014).

156. *Massachusetts v. EPA*, 549 U.S. at 529.

157. *Id.* at 514.



C. *Application of Massachusetts v. Environmental Protection Agency*

There is no doubt that antibiotics are causing harm to human health because of their overuse in agriculture. This is a fact that is not disputed within the scientific community.<sup>158</sup> In fact, along with the Centers for Disease Control and other federal agencies, the EPA has conceded that the overuse of antibiotics contributes to human health problems.<sup>159</sup>

The Clean Water Act was designed to limit the pollution of our waterways.<sup>160</sup> Antibiotics have not before now been included in the traditional list of agricultural pollutants causing water contamination. Just as the Clean Air Act defines the air pollutants to be regulated in a broad manner, the Clean Water Act defines toxic pollutants as discharged waste<sup>161</sup> that, “either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the [EPA], cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.”<sup>162</sup> The Clean Water Act also clearly states that “the discharge of toxic pollutants in toxic amounts be prohibited”<sup>163</sup> and charges the EPA with administering the statutory mandates.<sup>164</sup> Therefore, by definition, the EPA must regulate antibiotics under the Clean Water Act and parallel to the obligations under the Clean Air Act as determined by the Supreme Court in *Massachusetts v. Environmental Protection Agency*.

The Clean Water Act permitting provisions could provide a workable regulatory structure for antibiotics. If antibiotics were defined as pollutants, the EPA would then include antibiotics in the water quality criteria that are applied to each of the nation’s regulated bodies of water,<sup>165</sup> in turn compelling state

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158. CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013, 11 (2013), <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf> [<https://perma.cc/GD75-Z3V2>].

159. See *Science of Resistance: Antibiotics in Agriculture*, ALL. FOR THE PRUDENT USE OF ANTIBIOTICS (last visited Mar. 6, 2016), [http://www.tufts.edu/med/apua/about\\_issue/antibiotic\\_agri.shtml](http://www.tufts.edu/med/apua/about_issue/antibiotic_agri.shtml) [<https://perma.cc/F8LR-EA6S>].

160. 33 U.S.C. § 1251(a) (2014).

161. 33 U.S.C. § 1362(6) (2014).

162. 33 U.S.C. § 1362(13) (2014).

163. 33 U.S.C. § 1251(a)(3) (2014).

164. 33 U.S.C. § 1251(d) (2014).

165. See *supra* note 124 and accompanying text.

environmental agencies<sup>166</sup> to set limits on antibiotics in waterways.<sup>167</sup> Point sources, such as CAFOs, would be required to limit the discharge of antibiotics under the NPDES permitting system.<sup>168</sup> All other farms would be required to limit discharge based on the TMDLs for antibiotics set for each body of water.<sup>169</sup> This solution would allow for antibiotics to be used on farms to treat sick animals while preventing overuse by limiting the level of antibiotics discharged into the waters of the United States.

The issue of whether a federal agency may be compelled to regulate the use of antibiotics in agriculture has been litigated in the past.<sup>170</sup> In *National Resources Defense Counsel v. United States Food and Drug Administration*,<sup>171</sup> a federal appellate court ruled that the FDA could not be forced to mandate limitations on the use of antibiotics in agriculture.<sup>172</sup> The holding of this case, however, rested on the court's reading of the relevant statute,<sup>173</sup> with mandates that differ from those of the Clean Water Act. According to the majority, the FDA is not required to hold hearings on whether to withdraw approval of any drugs, regardless of whether scientific evidence shows that an approved use is no longer safe for human health.<sup>174</sup> This holding is specific to the statutory context in which the FDA grants and, more importantly, is entitled to withdraw approval for the uses of certain drugs.<sup>175</sup>

In another case, *Gulf Restoration Network v. McCarthy*,<sup>176</sup> the plaintiffs attempted to force the EPA to enact water quality standards to address the enormous "dead zone" in the Gulf of Mexico, a condition caused by agricultural runoff from the Mississippi River.<sup>177</sup> In that case, the EPA had already listed the pollutants at issue, specifically nitrogen and phosphorous, as toxic

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166. The EPA would be responsible for enforcement where state governments have chosen not to act. 33 U.S.C. §§ 1342(c), 1370 (2014).

167. See U.S. ENVTL. PROT. AGENCY, *supra* note 128 and accompanying text.

168. See *supra* Part III.A and accompanying text.

169. See *Program Overview: Total Maximum Daily Loads (TMDL)*, *supra* note 135 and accompanying text.

170. See *Nat. Res. Def. Counsel v. U.S. Food and Drug Admin.*, 760 F.3d 151 (2d Cir. 2014).

171. *Id.*

172. *Id.* at 175.

173. 21 U.S.C. § 1362(13) (2014).

174. 760 F.3d at 171–72.

175. *Id.*

176. 783 F.3d 227 (5th Cir. 2015).

177. *Id.* at 230.

pollutants.<sup>178</sup> The question for the federal appellate court was whether the EPA is required to develop water quality standards for the Gulf of Mexico where no state governments have acted to do so.<sup>179</sup> The EPA declined to take action and, in the ensuing litigation, the federal district court ruled that the EPA did not have discretion to act.<sup>180</sup> On appeal, the EPA prevailed in its argument that it maintained discretion with respect to the allocation of its resources, entitling the EPA to decline to regulate the levels of nitrogen and phosphorous in the Gulf of Mexico.<sup>181</sup> The Circuit Court agreed that the EPA maintained discretion and that the question for the district court was not whether the EPA must enact water quality standards, but rather whether its proffered explanation regarding resource allocation was sufficient.<sup>182</sup> This case does not address the issue at hand, whether the EPA may be compelled to regulate antibiotics under the Clean Water Act. The discretion the EPA has to determine how resources should be allocated with respect to implementing water quality standards is different from the question of whether to list harmful substances as toxic pollutants.

The purpose of the Clean Water Act is clear and the need for regulation of agricultural antibiotics cannot reasonably be disputed. The Clean Water Act provides a statutory mandate that demands all harmful substances that enter our waterways from industrial and agricultural activities to be regulated.<sup>183</sup> Farms should not be allowed to continue to pollute the waters of the United States without the protection promised by the Clean Water Act.

#### CONCLUSION

An agricultural system reliant on the use of antibiotics is unsustainable and unviable in the long run, as indicated by the significant repercussions to human, animal, and environmental health. Without one holistic federal agency addressing the entire scope of the problem presented by agricultural antibiotics, the response has been inadequate. The authors insist that the language

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178. *Id.* at 231.

179. *Id.* at 235.

180. *Id.* at 232.

181. *Id.*

182. *Id.* 243–44.

183. 33 U.S.C. § 1251(a) (2014).

and purpose of the Clean Water Act, especially in light of recent cases, tend to indicate that the Environmental Protection Agency maintains discretion to address the matter. In fact, we argue that the EPA is bound by a statutory mandate to identify such pollutants and control them through the permitting provisions of the Clean Water Act.