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## Note

### Slowing Antibiotic Resistance by Decreasing Antibiotic Use in Animals

Jennifer Nomura\*

While antibiotics were originally developed for human use, veterinarians eventually began using them in animals, hoping the drugs would perform in animals the same way they did in humans.<sup>1</sup> Approximately sixty percent of the diseases that humans get originate from animals,<sup>2</sup> so veterinarians hoped that by giving animals antibiotics, the spread of disease would lessen.<sup>3</sup> Today, antibiotics are mainly used in farm animals for both health reasons and animal growth purposes.<sup>4</sup> Antibiotics

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1. See, e.g., Barbara O'Brien, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 422 (1996) (noting that use of antibiotics in animals "began after veterinarians experimented with administering antibiotics to sick animals to determine if the miracle drugs that save so many human lives could also help livestock").

2. COLO. DEPT OF AGRIC., ZONOTIC DISEASE ADDENDUM 1 (2011), available at <http://www.colorado.gov/cs/Satellite?blobcol=urldata&blobheader=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251690810562&ssbinary=true>.

3. See *Animal Antibiotics and Food Safety: What You Should Know*, FOOD INSIGHT (July 18, 2012), [http://www.foodinsight.org/Resources/Detail.aspx?topic=Animal\\_Antibiotics\\_and\\_Food\\_Safety\\_What\\_you\\_Should\\_Know](http://www.foodinsight.org/Resources/Detail.aspx?topic=Animal_Antibiotics_and_Food_Safety_What_you_Should_Know); see also *Browse by Disease*, CENTERS FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/healthypets/browse\\_by\\_diseases.htm](http://www.cdc.gov/healthypets/browse_by_diseases.htm) (last updated Sept. 28, 2012) (listing the diseases that are known to pass from animals to humans).

4. See, e.g., KENNETH H. MATHEWS, JR., U.S. DEPT OF AGRIC., ANTIMICROBIAL DRUG USE AND VETERINARY COSTS IN U.S. LIVESTOCK PRODUCTION 3 (2001), available at [http://www.ers.usda.gov/media/480677/aib766\\_1\\_.pdf](http://www.ers.usda.gov/media/480677/aib766_1_.pdf); Herbert S. Goldberg, *Veterinary Medical and Nonmedical Uses*

are typically given to animals either through their feed<sup>5</sup> or water supply.<sup>6</sup> The use of antibiotics in farm animals occurs most often in pork and poultry.<sup>7</sup> Because farmers have been feeding antibiotics to animals for so many years, animals are becoming resistant to the effects of these drugs.<sup>8</sup> Farmers want to continue to profit from the effects of antibiotics and have increased the amount of antibiotics given to animals to counter the effect of resistance.<sup>9</sup> Today, animal consumption of antibiotics accounts for almost half of total antibiotic use in the United States.<sup>10</sup>

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of *Antibiotics*, 22 FOOD DRUG COSM. L.J. 33, 34 (1967) (listing some of the benefits of antibiotics being used in animals, which includes animal survival and growth rate); Vanessa K.S. Briceño, Note, *Superbug Me: The FDA's Role in the Fight Against Antibiotic Resistance*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 521, 523 (2005) (discussing how antibiotics are used in animals to promote growth and prevent disease); Steve Mirsky, *Animal Production Practices Create Antibiotic Resistance*, SCI. AM. (Oct. 20, 2011), <http://www.scientificamerican.com/podcast/episode.cfm?id=animal-production-practices-create-11-10-20>; *Is Your Meat Safe? Antibiotic Debate Overview*, PBS, <http://www.pbs.org/wgbh/pages/frontline/shows/meat/safe/overview.html> (last visited Sept. 5, 2013); see also Goldberg, *supra*, at 34 (discussing how antibiotics are helpful for weak and runt animals); O'Brien, *supra* note 1, at 422 (discussing how antibiotics are mainly used to promote an animal's growth rate).

5. See, e.g., Arielle Lessing, *Killing Us Softly: How Sub-therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 470 (2010) (“[A]ntibiotics are administered preemptively to all confined animals in drug-laced feed . . .”); O'Brien, *supra* note 1, at 422 (discussing how farmers feed their animals antibiotic-laced feed).

6. Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 50 (2000).

7. Terence J. Centner, *Regulating the Use of Non-Therapeutic Antibiotics in Food Animals*, 21 GEO. INT'L ENVTL. L. REV. 1, 19 (2008) (“In the United States, the greatest quantities of non-therapeutic antibiotics are used for swine and poultry production.”).

8. See O'Brien, *supra* note 1, at 423; cf. Goforth & Goforth, *supra* note 6, at 51 (“[T]here is a general consensus among scientists that subtherapeutic doses of antibiotics used in animal feed favors the selection of antibiotic-resistant bacteria.”).

9. See, e.g., Goforth & Goforth, *supra* note 6, at 46–47; O'Brien, *supra* note 1, at 423 (“Over time, farmers have had to increase gradually the amounts of antibiotics fed to the animals to maintain the same rate of growth per pound of laced feed.”).

10. See Lessing, *supra* note 5, at 469 (estimating seventy percent of all antibiotics in the United States are used in animals); Briceño, *supra* note 4, at 524 (estimating that the antibiotic use in animals accounts for thirty-five to eighty-five percent of all antibiotic use); Edwin Dobb, *Growing Resistance*, MOTHER JONES, <http://www.motherjones.com/politics/2000/11/growing->

Antibiotic resistance in humans is a major health concern.<sup>11</sup> Antibiotic resistant bacteria can pass from animals to humans.<sup>12</sup> As humans become resistant to antibiotics, health care for treatable diseases becomes more costly.<sup>13</sup> Antibiotic resistance can lead to hospitalization, longer-term care, and potentially even death.<sup>14</sup> However, the cause of antibiotic resistance in humans is difficult to determine.<sup>15</sup> Some studies have found a causal link between antibiotic use in animals and antibiotic resistance in humans.<sup>16</sup> However, antibiotics are given to animals in such low doses that antibiotic resistance may be the consequence of over-use of antibiotics among humans.<sup>17</sup> While there is some evidence of a linkage between

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resistance (last visited Sept. 5, 2013) (estimating approximately forty percent of all antibiotics are used in animals).

11. See, e.g., Lessing, *supra* note 5, at 476; Briceño, *supra* note 4, at 521.

12. See Centner, *supra* note 7, at 26–27 (“Resistant bacteria in animals are passed to humans through the consumption of contaminated meat, [and] the handling of food products . . . .”); Lessing, *supra* note 5, at 474 (“There are three main ways in which antibiotic use—and therefore antibiotic resistance—in animals is transferred to humans: via food, via human contact with livestock, and via the environment.”); O’Brien, *supra* note 1, at 426 (“[C]onsumers pick . . . up [resistant strains of bacteria] by eating contaminated foods.”).

13. Centner, *supra* note 7, at 13; Richard S. Saver, *In Tepid Defense of Population Health: Physicians and Antibiotic Resistance*, 34 AM. J.L. & MED. 431, 441 (2008); *Antibiotic/Antimicrobial Resistance*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugresistance/index.html> (last updated Sept. 19, 2012); see Goforth & Goforth, *supra* note 6, at 67.

14. See Centner, *supra* note 7, at 13 (discussing how antibiotic resistance has led to more human suffering and death); Saver, *supra* note 13, at 441 (discussing how antibiotic resistance has a mortality risk, along with longer hospital stays, more follow-up care, and a greater risk of complications); Briceño, *supra* note 4, at 521 (discussing how antibiotic resistance can lead to hospitalization and severe side effects).

15. See, e.g., Robert R. Nelson, *Antibiotics in Animal Feeds: Short-Term Economics v. Long-Term Health*, 31 S.D. L. REV. 416, 421 (1986) (discussing the difficulty in determining where someone’s antibiotic resistance came from); Goforth & Goforth, *supra* note 6, at 51 (questioning whether antibiotic use in farm animals has actually contributed to the growing amount of antibiotic resistant bacteria).

16. See Goforth & Goforth, *supra* note 6, at 48–49, 53; Briceño, *supra* note 4, at 525.

17. See O’Brien, *supra* note 1, at 424 (discussing how human overuse of antibiotics likely contributes to antibiotic resistance).

antibiotic use in animals and antibiotic resistance in humans, no direct connection has been established.<sup>18</sup>

Three governmental agencies, the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA), all play a role in the regulation of antibiotics—in both animals and people.<sup>19</sup> Each of these agencies has an interest in regulations developed to control and slow the spread of antibiotic resistance.<sup>20</sup> These agencies have formed the National Antimicrobial Resistance Monitoring System (NARMS), to monitor the spread of antibiotic resistance among people.<sup>21</sup> The FDA is the agency with primary rulemaking authority for regulating antibiotic use in animals.<sup>22</sup> So far, the FDA has not banned many classes of antibiotics from animal use.<sup>23</sup> Because the FDA has taken little action, there is limited case law governing the use of antibiotics in animals.<sup>24</sup> The FDA has issued a guidance document discussing the recommended proper use of antibiotics in animals.<sup>25</sup> This guidance document provides a framework to eliminate the unnecessary and inappropriate use of antibiotics in food-producing animals.<sup>26</sup>

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18. See Lessing, *supra* note 4, at 474 (discussing how there is circumstantial evidence linking antibiotic use in animals to the increase in antibiotic resistance in people); see also Goforth & Goforth, *supra* note 6, at 64 (discussing how there is an “ideal situation” created by the high amount of antibiotics used in animal feed for the growth of antibiotic-resistant bacteria).

19. See Nancy E. Halpern, *Antibiotics in Food Animals: The Convergence of Animal and Public Health, Science, Policy, Politics and the Law*, 14 DRAKE J. AGRIC. L. 401, 423 (2009) (discussing the roles of the FDA, CDC, and USDA in the regulation of antibiotic use).

20. See *id.*

21. See, e.g., *FDA Announces Availability of the NARMS Strategic Plan 2012–2016*, FOOD & DRUG ADMIN. (May 25, 2012), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm305710.htm>.

22. See, e.g., Halpern, *supra* note 19, at 423; Briceño, *supra* note 4, at 530.

23. See *Cephalosporin Order of Prohibition Questions and Answers*, FDA, <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm054434.htm> (last updated July 22, 2013).

24. See *infra* Part I.A.2.

25. CTR. FOR VETERINARY MED., FDA, GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 4 (2012) [hereinafter GUIDANCE #209], available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216216.pdf>.

26. *Id.* (describing how the guidance document provides strategies promulgated by the FDA to limit the amount of use of antibiotics that are important to human health).

Conflicts could develop between the governmental agencies, since they all have an interest in how antibiotic use in animals is regulated.<sup>27</sup> Once one main governmental authority is designated by Congress to have complete regulatory control, the question becomes: what actions should that agency take? There is pressure from some consumers to increase regulations,<sup>28</sup> while the farming industry wants the current regulations to remain.<sup>29</sup>

This Note makes recommendations for which government agency should be in complete control over the issue of antibiotic use in animals and what action that agency should take. Part I will describe the current regulation of antibiotic use in animals. Part II will analyze which government agency is best suited to have primary rulemaking authority and weigh the options for what steps should be taken next. Finally, this Note will conclude that the FDA is the agency that should be given primary regulatory control, and it should begin banning the use of antibiotics in animals.

## I. BACKGROUND: ANTIBIOTICS, ANTIBIOTIC RESISTANCE, CURRENT REGULATIONS, AND REGULATORY BODIES

Antibiotics are a type of drug used to treat bacterial infections.<sup>30</sup> Antibiotics are not effective against viral infections such as influenza, most ear infections, and the common cold.<sup>31</sup> Antibiotics operate by killing off the bacteria in the human

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27. See, e.g., Centner, *supra* note 7, at 17 (discussing how there are problems with coordination because there are three agencies involved in the regulation of antibiotic use in animals).

28. See *id.* at 23 (discussing how some consumers are willing to pay a higher price for “antibiotic-free meat products”).

29. See *id.* at 24 (discussing how the farming industry wants to maintain its current production and management practices based on “economic, business, and social interests,” which it would not be able to do if antibiotic use in animals was banned).

30. E.g., U.S. Nat’l Library of Med. & Nat’l Insts. of Health, *Antibiotics*, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/antibiotics.html> (last updated Aug. 16, 2013) [hereinafter *Antibiotics*]; *Get Smart: Know When Antibiotics Work, Fast Facts*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html> (last updated Jan. 21, 2011) [hereinafter *Fast Facts*].

31. E.g., Mayo Clinic Staff, *Antibiotics: Misuse Puts You and Others at Risk*, MAYO CLINIC (Feb. 4, 2012), <http://www.mayoclinic.com/health/antibiotics/FL00075>.

body or by preventing the bacteria from multiplying.<sup>32</sup> A problem arises when the bacteria within the body develop a mutation thereby making the antibiotic ineffective in killing off the bacteria.<sup>33</sup> This mutation, commonly called antibiotic resistance, can develop from a variety of sources, such as overuse<sup>34</sup> and inappropriate use.<sup>35</sup>

Inappropriate use occurs when an antibiotic is used to treat a disease that it was not intended to treat.<sup>36</sup> One study has shown that pediatricians are more likely to prescribe an antibiotic when they perceive that the parent wants them to prescribe it, even if the antibiotic will likely be ineffective in treating the disease.<sup>37</sup> Inappropriate use can also occur when a patient does not follow the prescribed instructions, such as not taking the antibiotic for the entire length of prescribed time.<sup>38</sup> Overuse of antibiotics is also a leading cause of antibiotic

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32. See *Antibiotics*, *supra* note 30.

33. *About Antimicrobial Resistance: A Brief Overview*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/drugresistance/about.html> (last updated July 2, 2012) (“[T]he infectious organisms that antibiotics are designed to kill have adapted to them, making the drugs less effective.”).

34. See Mikaela Conley, *Overuse of Antibiotics May Cause Long-Term Harm*, ABC NEWS (Aug. 25, 2011), <http://abcnews.go.com/Health/antibiotics-bad-good-bacteria/story?id=14374547#.UKpD2YZtCS0> (discussing how the overuse of antibiotics adds to the increase of human disease).

35. See *Antimicrobial Resistance*, WORLD HEALTH ORG. (2011), available at <http://www.richmondinstitute.com/wp-content/uploads/2012/05/WHO-Fact-Sheet-on-Antimicrobial-Resistance-2011.pdf> (“Inappropriate and irrational use of antimicrobial medicines provides favourable [sic] conditions for resistant microorganisms to emerge, spread and persist.”); *Fast Facts*, *supra* note 30 (“Misuse of antibiotics jeopardizes the usefulness of essential drugs.”).

36. See *Antimicrobial Resistance*, *supra* note 35 (discussing some of the underlying factors that lead to antibiotic resistance, which include “inappropriate and irrational use of medicines”).

37. *Fast Facts*, *supra* note 30 (“For pediatric care, a study showed that doctors prescribe antibiotics 62% of the time if they perceive parents expect them and 7% of the time if they feel parents do not expect them.”).

38. Mayo Clinic Staff, *supra* note 31 (“Not taking antibiotics exactly as prescribed also leads to problems. For example, if you take an antibiotic for only a few days—instead of the full course—the antibiotic may wipe out some, but not all, of the bacteria.”).



resistance.<sup>39</sup> Overuse of antibiotics can occur in animals, which can lead to antibiotic resistance in humans.<sup>40</sup>

Antibiotic resistance is considered one of the world's most concerning health issues.<sup>41</sup> Some scientists argue that antibiotic resistance could put the world back to a pre-antibiotic time.<sup>42</sup> Bacterial infections that are now resistant to antibiotics are more difficult to treat.<sup>43</sup> When bacteria are resistant to the antibiotic developed to treat a condition, a second- or even third-choice drug will be used.<sup>44</sup> These second- or third-option drugs are usually not as effective at treating the infection.<sup>45</sup> As a result, patients can be hospitalized and have to undergo prolonged treatment.<sup>46</sup> In some cases, antibiotic resistance can lead to patient death.<sup>47</sup>

#### A. CURRENT FDA REGULATIONS FOR ANTIBIOTIC USE IN ANIMALS

Antibiotics used in animals are regulated when these drugs first come into the market under the rules regulating “new animal drugs.”<sup>48</sup> Before a new animal drug can be used, a

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39. See *Mission Critical: Preventing Antibiotic Resistance*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/features/antibioticresistance/> (last updated Nov. 7, 2012).

40. Cf. O'Brien, *supra* note 1, at 424 (“Human overuse [of antibiotics] certainly contributes to this problem, but the volume of antibiotics administered to animals vastly exceeds the amount taken by humans.”).

41. E.g., *Fast Facts*, *supra* note 30 (“Antibiotic resistance has been called one of the world's most pressing public health problems.”).

42. Cf. *Antimicrobial Resistance*, *supra* note 35 (“The achievements of modern medicine are put at risk by [antibiotic resistance].”).

43. See *About Antimicrobial Resistance: A Brief Overview*, *supra* note 33 (discussing how alternative treatments can be less effective).

44. See *Antimicrobial Resistance*, *supra* note 35 (“When infections become resistant to first-line medicines, more expensive therapies must be used.”).

45. E.g., *About Antimicrobial Resistance: A Brief Overview*, *supra* note 33 (“When the drug of choice for treating [the patient's] infection doesn't work, they require treatment with second- or third-choice drugs that may be less effective, more toxic, and more expensive.”).

46. See Mayo Clinic Staff, *supra* note 31 (noting that antibiotic resistance can lead to “more doctor visits or extended hospital stays”).

47. E.g., *Antimicrobial Resistance*, *supra* note 35 (discussing how antibiotic resistance increases the risk of death); *About Antimicrobial Resistance: A Brief Overview*, *supra* note 33 (stating that a patient “may be more likely to die as a result of the infection”).

48. 21 U.S.C. § 321(v) (2012) (“The term ‘new animal drug’ means any drug intended for use for animals other than man, including any drug intended for use in animal feed . . .”).



new drug application must be filed.<sup>49</sup> The FDA is responsible for determining whether “the drug is safe and effective for its intended use and that any residue that may exist in animal-based food is safe with regard to human health.”<sup>50</sup> Unless and until a new animal drug application is approved, the drug is deemed unsafe for use.<sup>51</sup> In order to be approved, the drug must be shown to be safe, effective, a quality manufactured product, and must be properly labeled.<sup>52</sup> If the drug is intended to be used in food-producing animals, the FDA may require the development of a method to measure high drug residues in the food-product consumed by humans.<sup>53</sup> If the drug is approved, an allowable level for use in animal feed is established.<sup>54</sup> This maximum level is intended to prevent drug residues from ending up in the edible food product.<sup>55</sup> However, the FDA can only require a method to measure high levels of residues and a maximum level of residue if “there is a reasonable probability that a use of an animal drug . . . may present a risk to the public health . . . .”<sup>56</sup>

## 1. Withdrawal Procedure

Once a drug is approved for animal use, it can be difficult for approval to be withdrawn.<sup>57</sup> There is a specific procedure

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49. 21 U.S.C. § 360b(a)(1) (2012).

50. Halpern, *supra* note 19, at 424.

51. 21 U.S.C. § 360b(a)(1) (“A new animal drug shall . . . be deemed unsafe for purposes . . . of this title . . . unless [approved] . . . .”); *New Animal Drug Applications*, FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/NewAnimalDrugApplication/default.htm> (last updated Nov. 13, 2012) (discussing how a new animal drug may not be sold until its new animal drug application has been approved).

52. *Office of New Animal Drug Evaluation*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/WhatWeDo/ucm077923.htm> (last updated Nov. 13, 2012) (listing and describing the four requirements a new animal drug must meet in order to be approved).

53. 21 U.S.C. § 360b(a)(4)(B)(ii).

54. *Id.* § 360b(a)(4)(B); Halpern, *supra* note 19, at 424; LaVerne C. Harold, *What Level of Drugs Can Be Used in Feeds?*, 16 FOOD DRUG COSM. L.J. 239, 242 (1961).

55. *See, e.g.*, Halpern, *supra* note 19, at 424 (2009); LaVerne, *supra* note 54, at 242 (“The quantity and combination of drugs as permitted by the different paragraphs . . . of the antibiotic feed regulations must be kept at a level in a feed which will prevent drug residues in edible products.”).

56. 21 U.S.C. § 360b(a)(4)(B).

57. *See* Briceño, *supra* note 4, at 530 (“Courts have interpreted [withdrawal procedure from the FDCA] to mean that the FDA has the initial

that the FDA must follow in order to withdraw an animal drug from the market, which includes producing adequate evidence to show the potential dangers of the drug.<sup>58</sup> Once the FDA has obtained evidence that an animal drug is unsafe, they must provide notice to the drug's sponsor and allow the sponsor the opportunity for a hearing.<sup>59</sup> After the hearing the animal drug may be withdrawn, but only if the FDA finds one of the statutory scenarios to be true.<sup>60</sup> Because of the strict withdrawal procedure, the FDA has not withdrawn many antibiotics from use in animals.<sup>61</sup> However, on July 28, 2005 the FDA withdrew its approval of Baytril® "because it was contributing to the increase of antibiotic-resistant bacterial infections in humans."<sup>62</sup> Baytril® was a drug that was being used in farm animals,<sup>63</sup> and it had a similar chemical structure to a drug called Cipro.<sup>64</sup> Cipro was used in humans to treat food-borne illnesses, including salmonella.<sup>65</sup> The only other antibiotic to have its approval withdrawn is cephalosporin in early 2012.<sup>66</sup> Cephalosporins are a class of antibiotics that are

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burden, and must show that there are 'serious questions' as to a drug's safety." (footnotes omitted); GUIDANCE #209, *supra* note 25, at 18 ("Under [the withdrawal] provision, if FDA initiates a withdrawal action, it must produce evidence to show that there is a reasonable basis from which serious questions may be inferred about the ultimate safety of the drug and any substance that may be formed in or on food as a result of use of such drug under approved conditions.").

58. Briceño, *supra* note 4, at 530 (discussing the FDA's procedure for having a drug's approval withdrawn).

59. 21 U.S.C. § 360b(e)(1).

60. *See id.* The statute lists possible scenarios where a new animal drug's approval may be withdrawn. *Id.* This list includes: experimental data showing the drug is unsafe for the use it was approved for, new evidence not available at the time the application was submitted—examined together with the evidence available at the time of the application showing the drug is unsafe, or the application contained a false statement. *Id.*

61. The FDA has withdrawn approval of Baytril® and cephalosporins. *Infra* notes 62–68 and accompanying text.

62. Lessing, *supra* note 5, at 477.

63. *See* Briceño, *supra* note 4, at 524–25 ("[E]nrofloxacin . . . is the key ingredient in Baytril® and an antibiotic that combats the presence of *E. coli* and other bacteria found in poultry."); Lessing, *supra* note 5, at 477 (discussing how Baytril® was being used in poultry).

64. Lessing, *supra* note 5, at 477.

65. *Id.*

66. *See Cephalosporin Order*, *supra* note 23.

used in humans.<sup>67</sup> The ban on cephalosporins went into effect on April 6, 2012.<sup>68</sup>

## 2. Recent Case Law

A recent case brought by Natural Resources Defense Council, Inc. against the FDA dealt with the lack of regulation on antibiotic use in animals.<sup>69</sup> At issue was a 1977 FDA announcement declaring the Agency's intention to withdraw approval for multiple antibiotics that were being used in animals;<sup>70</sup> however, the FDA never took any action.<sup>71</sup> The three antibiotics at issue in this case were penicillin and two forms of tetracyclines.<sup>72</sup> In 1970, the FDA created a group of scientists to examine the risks of using these three antibiotics in animal feed.<sup>73</sup> In 1972, the group determined that meat consumed by humans contained antibiotic resistant bacteria.<sup>74</sup> The group also concluded that antibiotic resistance in humans was increasing.<sup>75</sup> The scientists recommended that the FDA withdraw approval of nontherapeutic uses of penicillin and the

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67. *Id.* ("The cephalosporin class of drugs is important in treating human diseases, such as pneumonia, skin and tissue infections, pelvic inflammatory disease, and other conditions.").

68. *Cephalosporin Order of Prohibition Goes into Effect*, FOOD & DRUG ADMIN. (Apr. 6, 2012), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm299054.htm>.

69. *See* Natural Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012).

70. *See id.* at 130.

71. *Id.* at 135 ("The Commissioner [of the FDA] never set a date for the hearings on the BVM's [Bureau of Veterinary Medicine, a subdivision of the FDA] proposal to withdraw approval of the use of penicillin and tetracyclines in animal feed.").

72. *Id.* at 132.

73. *Id.* ("[T]he agency convened a task force to study the risks associated with the use of antibiotics in animal feed. The task force was composed of scientists from the FDA, the National Institutes of Health, the U.S. Department of Agriculture, the Center for Disease Control, as well as representatives from universities and industry.").

74. *Id.* (describing the findings of the task force, including that "the use of antibiotics in animal feed, especially at doses lower than those necessary to prevent or treat disease, favors the development of antibiotic-resistant bacteria," that "animals receiving antibiotics in their feed may serve as a reservoir of antibiotic pathogens, which can produce human infections," and that "antibiotic-resistant bacteria had been found on meat and meat products").

75. *Id.* (describing the findings of the task force, including that "antibiotic resistant bacteria in humans had increased").

two forms of tetracyclines for animals.<sup>76</sup> Based on their recommendation, the FDA announced its intention to withdraw approval of all nontherapeutic uses of antibiotics in animals.<sup>77</sup> However, the FDA never scheduled the hearings required before withdrawal.<sup>78</sup> In 2011, almost twenty-five years after the FDA announced its proposed withdrawal of approval, the FDA rescinded it.<sup>79</sup> The Natural Resources Defense Council brought an action against the FDA alleging that the FDA violated 21 U.S.C. § 360b(e)(1) by not scheduling the hearings in the process of withdrawing approval.<sup>80</sup> The District Court concluded that the FDA was required to move forward with the steps to withdraw approval once the finding had been made that the drugs' use in animals presented a potential health risk for humans.<sup>81</sup>

In another case, *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, the Animal Legal Defense Fund Boston (ALDF) argued that Provimi, a producer of veal, should be required "to tell consumers that its veal . . . comes from calves that are fed antibiotics subtherapeutically."<sup>82</sup> The ALDF believed that the antibiotics placed in the calves' feed was a danger to human health<sup>83</sup> and that without providing this information to consumers, people were unknowingly putting themselves at risk.<sup>84</sup> The ALDF brought the claim against

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76. *Id.* at 132–33 ("The task force made several recommendations, including that (1) antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by the FDA, and (2) several specific drugs, including penicillin and tetracyclines, be reserved for therapeutic use unless they met safety criteria for non-therapeutic use.").

77. *Id.* at 133 (stating that the FDA "propose[d] to withdraw approval of all subtherapeutic uses of antibiotics in animal feed unless drug sponsors and other interested parties submitted data within the next two years" that demonstrated that these drugs did not have negative side effects for humans).

78. *Id.* at 135.

79. *Id.* at 136 ("On December 16, 2011, nearly twenty-five years after their initial publication and during the pendency of this [court] action, the FDA rescinded the 1977 NOOHs [notices of an opportunity for hearing].").

80. *Id.* at 137.

81. *See id.* at 148 (discussing the actions of the Commissioner of the FDA after the findings by the task force had been made, including agreeing that the drugs in question "had not been shown to be safe").

82. 626 F. Supp. 278, 279 (D. Mass. 1986).

83. *Id.* at 278.

84. *Id.* at 279 ("[T]he ALDF claim[s] that Provimi ought to tell consumers that its veal might be unhealthful because it comes from calves that are fed antibiotics subtherapeutically.").

Provimi under a Massachusetts consumer protection statute<sup>85</sup> and argued that not providing that information was a deceptive trade practice.<sup>86</sup> The District Court concluded that the claim brought by the ALDF was preempted under the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>87</sup> The court stated that the FDCA regulates the amount of antibiotics placed in animal feed, and therefore, the ALDF could not sue under state law.<sup>88</sup> Without state law, the ALDF had no cause of action because it could not bring a claim under the FDCA.<sup>89</sup> Ultimately, this case demonstrates that the solution to control antibiotic use in animals resides with regulatory agencies and not with the courts.<sup>90</sup>

#### B. ISSUE WITH MULTIPLE GOVERNMENTAL AGENCIES COMPETING FOR CONTROL

Within the United States government, there are three agencies and one group that all have a role in regulating antibiotic use in animals.<sup>91</sup> These different agencies must work together to slow the spread of antibiotic resistance stemming from meat and poultry consumption.<sup>92</sup> The United States is not the only country concerned with the spreading of antibiotic resistance. International organizations are also stepping forward to help reduce antimicrobial resistance.<sup>93</sup> In Europe,

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85. *Id.* at 278.

86. *See id.* at 281 (describing the ALDF's argument that by not telling Provimi's consumers, Provimi was engaging in a deceptive trade practice because Provimi was not complying with a Massachusetts public health statute or regulation).

87. *Id.* at 282.

88. *Id.* (discussing how the FDA has authority to determine whether a new animal drug is safe for humans).

89. *Id.* at 283.

90. *See, e.g., O'Brien, supra* note 1, at 437 ("*Provimi* demonstrates that the battle to restrict or abolish the use of subtherapeutic doses of antibiotics in animals might not be fought and won in the courtroom . . . . [The court in the *Provimi* case] did state, however, that the decision to allow the subtherapeutic use of antibiotics is in the hands of . . . governmental regulatory agencies.").

91. The three agencies are the FDA, the CDC, and the USDA. *See Halpern, supra* note 19, at 423. The group is NARMS, which is a collaboration of the three agencies. *See FDA Announces Availability of the NARMS Strategic Plan 2012–2016, supra* note 21.

92. *See Halpern, supra* note 19, at 423 (discussing how the three agencies collect data on antibiotic resistance in both humans and animals).

93. *See Briceño, supra* note 4, at 523 (discussing the World Health Organization); *id.* at 527 (discussing the European Union).

some countries have complete bans on non-therapeutic antibiotic use in animals.<sup>94</sup> But because there is no direct link between antibiotic use in animals and antibiotic resistance in humans, countries have taken different approaches.<sup>95</sup> When it comes to reducing the spread of antibiotic resistance, Europeans have generally acted more cautiously than the United States.<sup>96</sup>

### 1. FDA, CDC, USDA, and Collectively, NARMS

The FDA has the statutory authority to approve new animal drugs.<sup>97</sup> For drugs used in animals, the FDCA lists human health as a primary factor the FDA must consider when approving a new drug, “regardless of whether the drug is intended for human or animal[ ]” consumption.<sup>98</sup>

The federal authority governing antibiotic use in food animals falls largely upon the FDA which approves applications of new animal drugs for sale. The FDA also regulates the manufacture and distribution of antibiotics used in animals, as prescribed by veterinarians or through access to licensed feed mills that add specific antibiotics to animal feed in subtherapeutic dosages for growth promotion.<sup>99</sup>

If the FDA determines that a new animal drug may pose a threat to human health, the FDA can limit how much residue is allowed to be in meat products.<sup>100</sup> Little guidance is provided in the FDCA as to how the limit is to be determined.<sup>101</sup> The FDCA also contains permissive language, such as “may” instead of “must,” leaving the FDA discretion to make the final

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94. See Centner, *supra* note 7, at 15 (discussing how Sweden, Norway, Denmark, and Finland have all taken action to eliminate the use of antibiotics in animals).

95. *Id.* at 15 (“Given uncertainties accompanying purported risks, governments come to different conclusions when they make difficult rational decisions. The European Union and the United States have analyzed and evaluated uncertainties differently.” (footnote omitted)).

96. See *id.* at 15 (explaining that “Europeans have decided that the widespread uses of unnecessary feed additives . . . and antibiotics in animal production are not necessary and are exacerbating health problems,” and therefore, have enacted bans on these unnecessary uses of antibiotics).

97. Briceño, *supra* note 4, at 530 (discussing how FDA’s authority to regulate the use of antibiotics is based in the FDCA).

98. *Id.* at 530.

99. Halpern, *supra* note 19, at 423.

100. 21 U.S.C. § 360b(a)(4)(B) (2012).

101. See *id.*

decisions.<sup>102</sup> The FDA's decisions regarding new animal drugs can be influenced by a variety of other groups, including other agencies.<sup>103</sup>

Even though the FDA has statutory rulemaking authority when it comes to animal drugs, the CDC and the USDA also have an interest in regulating antibiotic use in animals.<sup>104</sup> The CDC approaches the issue from the perspective of human antibiotic resistance.<sup>105</sup> The USDA, on the other hand, is primarily concerned with the amount of drug residue that is present in meat eaten by consumers.<sup>106</sup> The FDA is working with the CDC and the USDA separately, but there is also a collective group formed by all three—the National Antimicrobial Resistance Monitoring System (NARMS).<sup>107</sup>

NARMS was formed in 1996 to begin monitoring changes in the reaction of salmonella to antibiotics in both humans and animals.<sup>108</sup> NARMS currently monitors the spread of antibiotic resistance in humans and then “provides [this] information to veterinarians and physicians . . . [and] aids in antimicrobial resistance research . . .”<sup>109</sup> NARMS is designed to focus on

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102. *See id.*

103. *See infra* Part II.B–C for a discussion about the USDA and the CDC.

104. *See Halpern, supra* note 19, at 423 (discussing how the CDC and USDA work with the FDA to collect data on antibiotic resistance occurring in both humans and animals).

105. *See* William M. Sage & David A. Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781, 828 (2010) (“The CDC is generally the lead agency on federal drug-resistance initiatives, including the interagency task force on the problem.”). The CDC has also recently “confirmed a link between routine use of antibiotics in livestock and growing bacterial resistance.” Carolyn Lockhead, *CDC Warns Against Overuse of Antibiotics*, NEWS TIMES (Sept. 16, 2013, 8:21 AM), <http://www.newstimes.com/local/article/CDC-warns-against-overuse-of-antibiotics-4819478.php>. The CDC believes there is enough evidence to show that antibiotic use in animals is leading to antibiotic resistance in humans. *See id.*

106. *See* Nelson, *supra* note 15, at 420–21 (discussing the USDA program that tests for drug residues in animal food products).

107. *See supra* note 91 and accompanying text.

108. *See, e.g.,* Marcia L. Headrick, *CVM Conducts Retail Meat Pilot Study*, FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm106078.htm> (last updated Apr. 16, 2013) (“NARMS was initiated in 1996 and initially monitored changes in antimicrobial susceptibilities of . . . Salmonella, isolated from human and animal clinical specimens, from carcasses of food-producing animals and animal products at processing, and from on-farm samples.”).

109. *Id.*



antibiotic resistance that originates in foodborne resistant bacteria.<sup>110</sup> NARMS has no rulemaking authority; it only monitors and collects data on the spread of antibiotic resistance.<sup>111</sup> Each year NARMS issues a report on all of its findings,<sup>112</sup> and the data collected is intended to help the FDA in issuing new regulations.<sup>113</sup>

However, it appears that the research done by NARMS has not been used to work towards any new regulations.<sup>114</sup> NARMS's most recent report showed patterns of increasing antibiotic resistance for some strains of salmonella and

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110. See *National Antimicrobial Resistance Monitoring System*, FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm> (last updated Apr. 22, 2013) ("NARMS monitors antimicrobial susceptibility among . . . bacteria from humans, retail meats, and food animals."); *National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS)*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/narms> (last updated Sept. 30, 2013); *NARMS—National Antimicrobial Resistance Monitoring System Animal Isolates*, U.S. DEPT AGRIC., <http://www.ars.usda.gov/Main/docs.htm?docid=6750> (last updated May 1, 2012).

111. See *National Antimicrobial Resistance Monitoring System*, *supra* note 110 (listing NARMS's objectives, which include monitoring resistance, conducting research on the spread of antibiotic resistant bacteria, and helping the FDA in making regulatory decisions); *National Antimicrobial Resistance Monitoring System (NARMS): Enteric Bacteria*, *supra* note 110; *NARMS—National Antimicrobial Resistance Monitoring System Animal Isolates*, *supra* note 110.

112. See, e.g., *National Antimicrobial Resistance Monitoring System: NARMS Annual Reports*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/narms/reports.html> (last updated Sept. 16, 2013) (listing all the past NARMS Annual Reports summarizing surveillance information on antimicrobial resistance).

113. See *FDA Announces Availability of the NARMS Strategic Plan 2012–2016*, *supra* note 21; *NARMS—National Antimicrobial Resistance Monitoring System Animal Isolates*, *supra* note 110; *National Antimicrobial Resistance Monitoring System*, *supra* note 110; *National Antimicrobial Resistance Monitoring System (NARMS): Enteric Bacteria*, *supra* note 110.

114. See Gretchen Goetz, *New Data on Antimicrobial Resistance a Mixed Bag: While Some Salmonella and Campylobacter Strains Grew in Resistance, Others Fell, Finds NARMS*, FOOD SAFETY NEWS (Aug. 1, 2012), <http://www.foodsafetynews.com/2012/08/new-data-on-antimicrobial-resistance-a-mixed-bag> (discussing how the FDA is requiring more information to determine which antibiotics are contributing to the resistance). While the NARMS data has not been used to form new regulations, it has been used in the past to withdraw approval for a poultry antibiotic. See, e.g., *id.*; see also *supra* Part I.A (discussing the withdrawal of approval of Baytril®).

campylobacter.<sup>115</sup> The FDA has stated that while the data may show a trend, it does not provide definitive evidence of antibiotic use in animals leading to antibiotic resistance in humans.<sup>116</sup> Without a more definite link between the two, the FDA has decided to wait to act.<sup>117</sup> In contrast, other countries have adopted a more cautious approach even without a direct link and have enacted bans or severely limited the use of antibiotics in animals.<sup>118</sup>

## 2. The World Health Organization and the European Union

Antibiotic use in animals is not just a concern within the United States, but worldwide.<sup>119</sup> The World Health Organization (WHO) has declared that “a main source of resistant bacteria is the overuse of antibiotics in animals.”<sup>120</sup> The WHO has published guidelines on the best ways to stop the spread of antibiotic resistance within food-producing animals.<sup>121</sup> The WHO has pushed for a ban of antibiotics that are used as growth promoters in animals, especially when those antibiotics are also used in human healthcare.<sup>122</sup> The

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115. NARMS, NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM: ENTERIC BACTERIA 2011, HUMAN ISOLATES FINAL REPORT, CENTERS FOR DISEASE CONTROL & PREVENTION 12–13 (2011), available at <http://www.cdc.gov/narms/pdf/2011-annual-report-narms-508c.pdf>; Goetz, *supra* note 114.

116. See, e.g., Goetz, *supra* note 114 (“[W]hile this data reflects some trends in resistance among strains, it does not provide definitive evidence of which drugs lead to resistance in human strains when used in animals.”).

117. See *id.* (discussing how without a direct link it is difficult for the FDA to decide what actions to take next and how the FDA is working to obtain a more direct correlation).

118. See Centner, *supra* note 7, at 15 (discussing how Sweden, Norway, Denmark, and Finland have all taken action to eliminate the use of antibiotics in animals).

119. See Briceño, *supra* note 4, at 523 (discussing the World Health Organization’s involvement and concern); *id.* at 527 (discussing the European Union’s involvement and concern).

120. *Id.* at 523.

121. See, e.g., *id.* (“[T]he WHO has issued global guidelines on how to contain antimicrobial resistance developing in animals raised for food.”).

122. See WHO GLOBAL STRATEGY FOR CONTAINMENT OF ANTIMICROBIAL RESISTANCE, WORLD HEALTH ORG. 5 (2001), available at [http://www.who.int/drugresistance/WHO\\_Global\\_Strategy\\_English.pdf](http://www.who.int/drugresistance/WHO_Global_Strategy_English.pdf) (recommending termination “or rapidly phase[ing] out the use of antimicrobials for growth promotion if they are also used for treatment of humans”).

WHO also has been an international leader in pushing for a complete ban on antibiotic use in animals.<sup>123</sup>

The European Union (EU) is also a proponent of eliminating the use of antibiotics in farm animals.<sup>124</sup> Within the EU, the European Commission (EC) proposes new legislation to the other branches of the EU and works with the member nations in implementing the EU laws.<sup>125</sup> In 2011, the EC developed an action plan to slow the spread of antibiotic resistance.<sup>126</sup> Part of the action plan includes strengthening the laws on medicated animal feed.<sup>127</sup> This action plan is a continuation of previous EU regulations banning certain drugs used in animal feed.<sup>128</sup> Some European nations' policies preceded the EU regulations by significantly cutting down on the use of antibiotics in animals.<sup>129</sup> Before these bans were implemented, European studies demonstrated how antibiotic use in animals could lead to antibiotic resistance in humans.<sup>130</sup> One study demonstrated that over time, pigs fed with medicated feed carried antibiotic-resistant bacteria, as did the farmers and other local community members.<sup>131</sup> Such studies

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123. See Centner, *supra* note 7, at 16 (“For ten years, the World Health Organization has recommended the elimination of growth promoters in animal production for antimicrobial agents that are used in human therapeutics or are known to select for cross-resistance to antimicrobials used in human medicine.”).

124. See, e.g., Briceño, *supra* note 4, at 527 (“The European Union has passed legislation banning all non-therapeutic antibiotics in livestock.”).

125. See *European Commission at Work*, EUR. COMM’N, [http://ec.europa.eu/atwork/index\\_en.htm](http://ec.europa.eu/atwork/index_en.htm) (last updated June 28, 2013).

126. See *Action Plan Against Antimicrobial Resistance: Commission Unveils 12 Concrete Actions for the Next 5 Years*, EUR. COMM’N (Nov. 17, 2011), [http://europa.eu/rapid/press-release\\_IP-11-1359\\_en.htm?locale=en](http://europa.eu/rapid/press-release_IP-11-1359_en.htm?locale=en) (setting out twelve concrete actions that the EC will work towards over the next few years).

127. *Id.*

128. See Lessing, *supra* note 5, at 477 (“Legislation regulating antibiotic use in animals has been enacted since 1986 . . . . In 1998, the European Union . . . withdrew approval for four animal feed additives.” (footnote omitted)).

129. See Centner, *supra* note 7, at 15–16 (discussing the actions different European countries have taken to prevent the spread of antibiotic resistance).

130. See Goforth & Goforth, *supra* note 6, at 53 (discussing a study performed in the former East Germany); *id.* at 53–54 (discussing some bacterial infection outbreaks and how some cases were traced back to infected animal products).

131. *Id.* at 53 (discussing a study from the former East Germany where a farmer fed his swine antibiotics, which caused the pigs, the farmer, and the

have led the EU to err on the side of caution and implement bans on unnecessary uses of antibiotics in animals.<sup>132</sup>

## II. POSSIBLE RESOLUTIONS TO THE LACK OF REGULATION

In order to reduce the spread of antibiotic resistance, the use of antibiotics has to be controlled.<sup>133</sup> There are conflicting ideas as to how the use of antibiotics in animals should be regulated.<sup>134</sup> Currently, the FDA is taking a wait-and-see approach—that is, waiting until it has hard evidence before taking any action.<sup>135</sup> But there are groups, such as the American Medical Association, the American Public Health Association, and the Humane Society of the United States, that are pushing for a complete ban on unnecessary use of antibiotics given to animals, even without conclusive evidence linking it to antibiotic resistance in humans.<sup>136</sup>

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locals to all develop antibiotic-resistant bacteria seven years later; even though only the pigs were given the antibiotic, humans still had the antibiotic-resistant bacteria in their bodies).

132. See Centner, *supra* note 7, at 14 (discussing the precautionary principle and how the EU has “decided to take precautionary action[s] by banning the use of antibiotics as animal growth promoters”).

133. See, e.g., *id.* at 29 (“Most scientists recognize that more prudent use of antibiotics in all areas is needed. While this may include banning some uses of non-therapeutic antibiotics, it also includes controlling the dissemination of antibiotics for therapy.” (footnotes omitted)); Jessica P. Schulman, Note, *Patent and Public Health: The Problems With Using Patent Law Proposals to Combat Antibiotic Resistance*, 59 DEPAUL L. REV. 221, 252 (2009) (“The best way to both slow the spread of antibiotic resistance and effectively use existing antibiotics involves . . . closely regulating antibiotic use . . .”).

134. E.g., Centner, *supra* note 7, at 15 (discussing how countries can disagree on the best way to handle the issue of antibiotic resistance); Halpern, *supra* note 19, at 422 (“The FDA’s failure to prohibit subtherapeutic antibiotic use has been criticized by some public health advocates, while the decision to withdraw approval of one poultry antibiotic has been denounced by animal health advocates joined by the pharmaceutical and animal agricultural industries.”).

135. See Halpern, *supra* note 19, at 426 (“The FDA required enhanced testing and reporting of antibiotic use, but declined to ban the use of sulfonamides in all animal feed without sufficient evidence of harm to humans to counterbalance the benefits.”).

136. See Centner, *supra* note 7, at 16; Briceño, *supra* note 4, at 527–28 (discussing how corporations such as McDonald’s and Bon Appétit are also putting pressure on the FDA to issue bans on nontherapeutic antibiotics).

### A. TWO POSSIBLE SOLUTIONS: WAIT-AND-SEE OR IMMEDIATE ACTION

Agencies and scientists agree that more evidence is needed in order to draw the conclusion that increases in antibiotic use in animals lead to the increase in antibiotic resistance among humans.<sup>137</sup> The FDA has begun requiring more testing and reporting of the use of antibiotics in animals in order to assist in deciding what, if any, action should be taken next.<sup>138</sup> Despite the push from some for the FDA to ban antibiotic use in animals,<sup>139</sup> the lack of any hard evidence linking it to antimicrobial resistance makes it a difficult decision for the FDA.<sup>140</sup> Industry groups are also weighing in, hoping to be able to continue using antibiotics in their animal feed.<sup>141</sup> Overall, the benefits of a complete ban are uncertain.<sup>142</sup>

The immediate action solution would qualify as the “precautionary principle.”<sup>143</sup> Instead of waiting until antibiotic resistance has spread to withdraw approval, this solution would prevent it from happening<sup>144</sup> (assuming there is a link between antibiotic use in animals and antibiotic resistance in

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137. See Halpern, *supra* note 19, at 422–23 (discussing how despite the disagreement over the strength of the current research data, all can agree that more data is needed).

138. See *id.* at 426; 21 C.F.R. § 558.15(b)–(c) (2013) (discussing how reports and updates must be submitted by “[a]ny person interested in developing data which will support retaining approval for such uses of . . . antibiotic[s]”).

139. See Briceño, *supra* note 4, at 527 (discussing how the EU and certain large-scale meat purchasers are pushing the FDA towards taking action).

140. See Centner, *supra* note 7, at 16–17 (“However, the absence of meaningful data on the amounts and use of non-therapeutic antibiotics in animal production in the United States makes it difficult to evaluate risks and justify a regulatory action that would withdraw their use.”); *id.* at 33 (“In the absence of sufficient data on antibiotic usage, it is impossible to accurately relate the use of non-therapeutic antibiotics to antibiotic-resistant human bacterial infections. This situation makes it difficult to alter the status quo whereby American law facilitates the widespread use of non-therapeutic antibiotics.” (footnote omitted)).

141. See *id.* at 32 (discussing how industry groups do not want antibiotics to be banned because if they were the industry groups would be required to adjust their production and management practices).

142. See *id.* at 15; Goforth & Goforth, *supra* note 6, at 66 (discussing the difficulty of quantifying the economic impact of regulating antibiotic usage).

143. Centner, *supra* note 7, at 13.

144. See *id.* at 14 (“Rather than adopting a reactive position whereby damages are awarded to injured persons, the precautionary principle seeks to prevent harm before it occurs.”).

humans). Animal activists are pushing for complete bans not just because of the possible benefits for human health, but also because of the likelihood of improvements in animal living situations.<sup>145</sup> Because of the crowded conditions that animals are kept in, disease spreads easily.<sup>146</sup> A ban of antibiotics would therefore likely lead to farmers changing the living conditions of the animals.<sup>147</sup> There are a variety of possible drawbacks from a complete ban of antibiotics, including food costs rising,<sup>148</sup> an increase in the risk of sick animals,<sup>149</sup> and the potential for drug companies to stop developing new antibiotics.<sup>150</sup>

#### B. TOO MANY AGENCIES CREATES CONTROL ISSUES

These potential solutions add to the conflict between the governmental agencies. Because the agencies approach the issue of antibiotic resistance from different perspectives, they could easily disagree on what the best solution is. Too many agencies with an interest in the regulation of antibiotic use in animals can create problems.<sup>151</sup> While the FDA has primary rulemaking authority, the CDC and the USDA have an interest

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145. See O'Brien, *supra* note 1, at 426 (discussing the dual benefit of improving conditions for animals and protecting human health).

146. MATHEWS, *supra* note 4, at 7 ("In situations where livestock are concentrated, especially in hog and poultry feeding operations, diseases can spread rapidly, and disease outbreaks can take a far heavier toll if low levels of antimicrobial drugs are not fed."); O'Brien, *supra* note 1, at 426 ("Overcrowded conditions on the farm contribute to the need for . . . antibiotic use. The closer the confinement, the greater the chance that an infectious disease will afflict the herd.").

147. O'Brien, *supra* note 1, at 426 ("[A ban] would ameliorate some of the overcrowded conditions in which farm animals live . . .").

148. Centner, *supra* note 7, at 17–18 (describing the concern that if antibiotics were banned feed costs would increase); Goforth & Goforth, *supra* note 6, at 64 ("[F]armers have attributed lower costs of meat, eggs, and milk to subtherapeutic doses of antimicrobials in animal feed."); O'Brien, *supra* note 1, at 438.

149. MATHEWS, *supra* note 4, at 7 ("Death losses and reduced production from diseases that had been prevented by feeding low levels of antimicrobial drugs could be costly.").

150. Briceño, *supra* note 4, at 526 ("[P]harmaceutical companies are unlikely to pursue the development of new antibiotics designed to respond to these 'superbugs' because economic factors, as well as scientific limitations, make their development of limited value."); Schulman, *supra* note 133, at 252 ("[C]losely regulating antibiotic use or cycling the use of antibiotics would decrease the financial incentive for pharmaceuticals to develop antibiotics.").

151. See *supra* Part I.B.1.

in how the issue is regulated, and they could influence the FDA's decision-making.<sup>152</sup> Each agency is approaching the issue from a different perspective and could disagree on the best way to regulate antibiotic use in animals.<sup>153</sup>

Another concern with multiple agencies interested in how antibiotics are regulated is the uncertainty regarding which agency will work with the international agencies to develop a solution to slow the global spread of antibiotic resistance.<sup>154</sup> The WHO and EU have pushed their member nations to adopt the cautious approach and enact bans on antibiotics.<sup>155</sup> The WHO and EU could begin putting pressure on the United States to follow their lead.<sup>156</sup> With all of these agencies and international organizations putting pressure on the United States, one agency should be selected to have primary regulatory control.

### C. THE FDA NEEDS COMPLETE RULE-MAKING CONTROL OVER ANTIBIOTIC USE IN ANIMALS

Because the CDC and the USDA approach the issue of antibiotic use in animals differently than the FDA,<sup>157</sup> it is likely that the agencies will disagree on what action to take. The FDA is best suited to take complete regulatory control because it has statutory rulemaking authority over antibiotic use in animals.<sup>158</sup> The FDA regulates animal drug use<sup>159</sup> and is

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152. See Halpern, *supra* note 19, at 423 (discussing the CDC's and the USDA's roles in assisting the FDA).

153. See Nelson, *supra* note 15, at 421 (discussing how the USDA tests for drug residues in animal food products); Sage & Hyman, *supra* note 105, at 828 (discussing how the CDC is the lead agency on "drug-resistance initiatives").

154. See WHO GLOBAL STRATEGY FOR CONTAINMENT OF ANTIMICROBIAL RESISTANCE, *supra* note 122, at 11 (discussing how combating the spread of antibiotic resistance needs global action).

155. See *supra* Part I.B.2.

156. See *Antimicrobial Resistance*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs194/en/> (last updated May 2013); *Combat Antimicrobial Resistance*, WORLD HEALTH ORG. (2011), [http://www.who.int/world-health-day/2011/WHD201\\_FS\\_EN.pdf](http://www.who.int/world-health-day/2011/WHD201_FS_EN.pdf) ("WHO will issue an international call for concerted action to halt the spread of antimicrobial resistance and recommends a six-point policy package for governments.").

157. *Supra* note 153 and accompanying text.

158. See Briceño, *supra* note 4, at 530 (describing how the FDA's authority to regulate antibiotic use in animals comes from the FDCA).

159. See *id.*



able to make animal antibiotic regulations without having to work with the CDC and the USDA. An easy way to ensure that the FDA has sole control of the issue is to have the agencies sign a Memorandum of Understanding (MOU).<sup>160</sup> Multiple agencies commonly sign an MOU when they all have an interest in regulating an issue.<sup>161</sup> An MOU can specify what each agency will be responsible for concerning the issue.<sup>162</sup> The FDA, CDC, and USDA can sign an MOU specifying that the FDA has primary rulemaking authority to decide how antibiotic use in animals is regulated, while NARMS remains in place for the CDC and the USDA to monitor the spread of antibiotic resistance. NARMS can continue to function as a way for all three agencies to work together to conduct research on how much antibiotics is used in animals and how rapidly antibiotic resistance is spreading among humans.<sup>163</sup>

The FDA is also best suited to work with international groups. The FDA has hosted discussions with the international community about other health concerns in the past, which shows the Agency's willingness to work across borders to develop solutions to pressing issues.<sup>164</sup> The WHO has emphasized that antibiotic resistance is a global issue and wants to work with rulemaking bodies worldwide in order to develop an international solution.<sup>165</sup> The WHO would likely want to work with the FDA, since the FDA is the agency with the rulemaking authority for antibiotic use in animals.<sup>166</sup> The FDA could form an international MOU with the EU and the

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160. See *FDA Memoranda of Understanding*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm> (last updated June 26, 2012).

161. See *id.* (describing the MOU as an agreement between the FDA and another governmental agency and constitutes an understanding between the parties).

162. See *MOU 225-78-1002*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116214.htm> (last visited Mar. 10, 2009).

163. See *supra* Part I.B.1.

164. *International Activities—FDA Hosts International BSE Discussions*, FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm093920.htm> (last updated Apr. 18, 2013).

165. See *Antibiotic Resistance*, *supra* note 35 (“WHO calls on all key stakeholders, including policy-makers and planners... to act and take responsibility for combating antimicrobial resistance.”).

166. See *supra* Part I.B.1 (discussing the FDA's statutory rulemaking authority on this issue).

WHO in order to clarify how these different organizations will work together to combat antibiotic resistance.<sup>167</sup>

#### D. PROBLEMS WITH POSSIBLE REGULATION SOLUTIONS

The United States lags behind Europe when it comes to regulating antibiotic use in animals.<sup>168</sup> European countries have adopted a more cautious approach by implementing bans on antibiotic use in animals.<sup>169</sup> Instead of following the lead of the WHO or the EU, the FDA has adopted a wait-and-see approach.<sup>170</sup> The FDA is currently performing research to see if there is a link between antibiotic use in animals and antibiotic resistance in humans,<sup>171</sup> while allowing all approved antibiotics to remain in use.<sup>172</sup> A direct link between antibiotic use in animals and antibiotic resistance in humans might never be found.<sup>173</sup> But there is circumstantial evidence linking the two,<sup>174</sup> and that should be enough for the FDA to take action,

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167. See *Memoranda of Understanding and Other Cooperative Arrangements*, FOOD & DRUG ADMIN., <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm> (last updated Dec. 13, 2012) (listing all of the FDA's international MOUs, one of which is between the FDA and the EU).

168. See Centner, *supra* note 7, at 14 (discussing the EU's precautionary ban on antibiotics as compared to the United States' approach); *supra* Part I.B.2.

169. Centner, *supra* note 7, at 15 (discussing how Sweden, Norway, Denmark, and Finland have all implemented bans).

170. See *supra* Part I.C.1.

171. NARMS is in place to monitor the spread of antibiotic resistance. See Headrick, *supra* note 108 ("NARMS also facilitates the identification of [antibiotic] resistance in humans and animals as it arises . . ."); see also *supra* Part I.B.1. (discussing the role of NARMS).

172. Halpern, *supra* note 19, at 426 (discussing how the FDA has reexamined antibiotic use in animals, but has continued to let antibiotics be used in animals); *supra* Part I.B.1.

173. See Nelson, *supra* note 15, at 421 ("[I]t is often difficult if not impossible to find the exact source of the residue contamination as well as the concrete link from antibiotics in animal feed directly to the injured human consumer of the food product.").

174. See *supra* Part I.B.2. (discussing the study performed in the former East Germany which showed that there was likely a link between antibiotic use in swine and humans); see also Lessing, *supra* note 4, at 473–74 (discussing how antibiotic use in animals may be linked to antibiotic resistance in humans). An example of circumstantial evidence is when chickens in the Netherlands became increasingly resistant to fluoroquinolone, human resistance to fluoroquinolone also increased. *Id.*

especially because antibiotic resistance poses a threat to human health.<sup>175</sup>

While the wait-and-see approach is not a good solution, neither is a complete ban of all antibiotic use in animals. An across-the-board ban on antibiotic use in animals would likely lead to high costs for both farmers and consumers.<sup>176</sup> Farmers would have to change the living conditions of their animals.<sup>177</sup> Currently, animals are kept in crowded conditions, which can lead to the spread of disease among the animals.<sup>178</sup> If all antibiotics were banned, farmers would have to implement major changes to their farms to decrease the spread of disease.<sup>179</sup> Even with different living conditions, there still is the possibility of animals contracting diseases.<sup>180</sup> A complete ban on antibiotics might lead to more animals getting sick because farmers would have nothing to use to treat their

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175. Centner, *supra* note 7, at 14 (“Due to evidence suggesting that antibiotics used in animal production contribute to antibiotic resistance, the response can be justified under the precautionary principle.”); Nelson, *supra* note 15, at 421 (“[T]he *possibility* that potential health hazards exist is *alone* sufficient for the FDA to propose and Congress to pass a ban.”).

176. Farmers would have to pay to change the living conditions of animals. See Centner, *supra* note 7, at 17–18 (discussing how a ban on antibiotics might lead to increased animal feed costs and change the animal production practices). Consumers would have to pay more for animal food products. *Id.* at 19 (discussing how pork prices would likely rise after an antibiotic ban).

177. See Centner, *supra* note 7, at 17–18 (discussing how farmers oppose antibiotic bans because of the possible costs and changes); O’Brien, *supra* note 1, at 426 (discussing how a ban on antibiotics would lead to the elimination of the overcrowded conditions found on farms); Briceño, *supra* note 4, at 527 (discussing how some animal producers consider antibiotic use a cheaper alternative than changing their animal facilities to provide healthier living conditions for the animals).

178. MATHEWS, *supra* note 4, at 7 (“[W]here livestock are concentrated, especially in hog and poultry feeding operations, diseases can spread rapidly, and disease outbreaks can take a far heavier toll if low levels of antimicrobial drugs are not fed.”); O’Brien, *supra* note 1, at 426 (“The closer the confinement [of the animals], the greater the chance that an infectious disease will afflict the herd.”).

179. See O’Brien, *supra* note 1, at 527.

180. See MATHEWS, *supra* note 4, at 7 (“Death losses and reduced production from diseases that had been prevented by feeding low levels of antimicrobial drugs could be costly.”); Centner, *supra* note 7, at 21 (discussing how there is concern that removal of antibiotics might lead to increased disease among animals).

animals.<sup>181</sup> Because of all the changes that would likely be implemented on farms, consumers would have to pay more for animal products.<sup>182</sup>

There also is concern that a complete ban on antibiotics would cause drug companies to cease developing new antibiotics.<sup>183</sup> Opponents of a complete ban are concerned that drug companies would lose the incentive to develop new antibiotics because of the high cost of drug development.<sup>184</sup> With drawbacks to both the FDA's current wait-and-see approach and a complete ban on antibiotics, the best solution is likely somewhere in the middle.

#### E. BAN SOME ANTIBIOTICS AND MONITOR THE USE OF THE REST

The FDA should pick a solution mid-way between their current wait-and-see approach and a complete ban on antibiotic use in animals. The United States should follow Europe's precautionary approach<sup>185</sup> and enact a ban on antibiotics that are also used in human health.<sup>186</sup> This mid-way approach would allow farmers to continue to use antibiotics not used by humans. This approach would likely still require farmers to

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181. See MATHEWS, *supra* note 4, at 7 (discussing how a complete ban on antibiotic use in animals could lead to increased risk of animals getting sick; this is primarily due to the large concentration these farm animals live in).

182. See, e.g., Bjorn Lomborg, *Food for the Wealthy, Not for the Poor*, N.Y. TIMES (Sept. 11, 2012, 9:55 AM), <http://www.nytimes.com/roomfordebate/2012/09/10/is-organic-food-worth-the-expense/organic-food-is-for-the-wealthy-not-the-poor> ("Finally, organic entails a huge price tag. For the U.S. alone, estimates . . . suggest a cost of at least \$100 billion annually.").

183. Centner, *supra* note 7, at 28 ("Some have expressed concern that regulations restricting the use of antibiotics in animal production may reduce the incentives for pharmaceutical companies to develop new antibiotic drugs."); Briceño, *supra* note 4, at 526 (discussing how drug companies are unlikely to develop new antibiotics if antibiotic resistance continues to be a problem).

184. Briceño, *supra* note 4, at 526.

185. See *supra* Part I.B.2.

186. It appears that this is the way the FDA is currently leaning. See Melinda Henneberger, *Report: Feeding Antibiotics to Livestock Is Bad for Humans, But Congress Won't Stop It*, WASH. POST, Oct. 22, 2013, [http://www.washingtonpost.com/politics/feeding-antibiotics-to-cows-is-bad-for-humans-but-congress-wont-stop-it-new-report-says/2013/10/22/eed2de08-3afd-11e3-a94f-b58017bfee6c\\_story.html](http://www.washingtonpost.com/politics/feeding-antibiotics-to-cows-is-bad-for-humans-but-congress-wont-stop-it-new-report-says/2013/10/22/eed2de08-3afd-11e3-a94f-b58017bfee6c_story.html) ("FDA guidelines in the pipeline . . . would require the industry to stop using antibiotics specifically to bulk up food animals but would continue to allow their use for disease control.").

change their animal housing practices,<sup>187</sup> and food costs would likely still rise,<sup>188</sup> but it can be justified by considerations of human health. There also is evidence that some of the concerns farmers have about a complete antibiotic ban may not be true.<sup>189</sup> In Finland, where nontherapeutic uses of antibiotics were banned, the rate of diseased pigs did not increase after the ban.<sup>190</sup> Denmark had a similar result among its poultry after nontherapeutic antibiotics were banned.<sup>191</sup> This mid-way resolution would also help decrease the pressure that the FDA is getting from both consumers and corporations.

Pressure from consumers can lead food producers to voluntarily change their animal care techniques. If consumers are concerned about what chemicals they consume, they may change their eating habits. A way for consumers to change these habits is by purchasing organic products. Organic food products are increasing in popularity.<sup>192</sup> To be a certified-organic food product, the animals cannot be given antibiotics in their feed.<sup>193</sup> The increasing popularity of organic food products demonstrates that people are concerned about what they are

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187. With farmers not being able to use all the currently-approved antibiotics, farmers would likely choose to lower the risk that their animals would get sick. *See supra* notes 176–78 (discussing how the crowded conditions that animals are kept in increases the risk that animals would get sick). If certain antibiotics were banned from animal use, however, farmers would not be without any option for treating their sick animals. *See Centner, supra* note 7, at 25 (“Changes in the ingredients in feed, amount of feed, disinfection, stocking density, and vaccines may improve herd health and prevent [disease].”).

188. *See, e.g., infra* notes 191–98 and accompanying text (discussing the use of organic food products).

189. *See Centner, supra* note 7, at 25.

190. *Id.* (“In Finland, data suggest that swine producers did not experience any significant negative consequences after the withdrawal of non-therapeutic antibiotics.”).

191. *Id.* (“For Danish poultry production, the elimination of non-therapeutic antibiotics has not negatively affected animal health . . .”). *But cf. id.* at 24–25 (discussing how the elimination of nontherapeutic antibiotics had negative effects on Denmark’s pigs).

192. Mayo Clinic Staff, *Organic Foods: Are They Safer? More Nutritious?*, MAYO CLINIC (Sept. 7, 2012), <http://www.mayoclinic.com/health/organic-food/NU00255> (“Once found only in health food stores, organic food is now a regular feature at most supermarkets.”).

193. *See id.* (listing the differences between conventional and organic foods).

consuming.<sup>194</sup> Companies like McDonald's, Tyson Foods,<sup>195</sup> and Bon Appétit<sup>196</sup> have reacted to the increasing popularity of organic food by changing their corporate policies. McDonald's has changed its poultry policy and will not use chicken that has been fed nontherapeutic antibiotics that are medically important to human health.<sup>197</sup> Tyson Foods only uses poultry that has been "raised without antibiotics."<sup>198</sup> And Bon Appétit, a catering company, does not allow any nontherapeutic antibiotics to be used in their poultry.<sup>199</sup> The FDA is also beginning to get pressure from the courts to follow through on its ban of certain antibiotics from animal use.<sup>200</sup> All the pressure the FDA is receiving is because of the growing national concern over antibiotic resistance.

Where human health is a concern, the FDA can take action to eliminate the risk.<sup>201</sup> The FDA is not allowed to consider benefits of an animal drug when there is a human health concern.<sup>202</sup> While the FDCA lists other factors that the FDA should consider when contemplating withdrawal of an animal

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194. *See id.* (listing reasons why some people choose organic food). Some people choose to buy organic food because the food additives that can be used in the food-producing animals are strictly regulated. *Id.*

195. Centner, *supra* note 7, at 23–24 (discussing actions that McDonald's and Tyson Foods have taken).

196. Briceño, *supra* note 4, at 527 (discussing McDonald's' and Bon Appétit's actions).

197. Centner, *supra* note 7, at 23; Briceño, *supra* note 4, at 527 ("McDonald's, one of the largest meat purchasers in the world, has implemented a purchasing policy by which it will only accept chicken that is raised without any medically-important antibiotics used for non-therapeutic purposes.").

198. Centner, *supra* note 7, at 23.

199. Briceño, *supra* note 4, at 527 ("Bon Appétit, has an even stronger restriction [than McDonald's]: they ban all use of non-therapeutic antibiotics in the poultry they purchase, not only medically important ones.").

200. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012). The district court is requiring the FDA to initiate the withdrawal proceedings for the antibiotics at issue in the lawsuit. *Id.*; *see also supra* Part I.A. (discussing the most recent lawsuit against the FDA over the FDA's inaction on withdrawing antibiotics from animal use).

201. *See Halpern, supra* note 19, at 425–26; Nelson, *supra* note 15, at 421 (discussing how the possibility of potential health hazards is enough for the FDA to propose a ban of the antibiotic); Briceño, *supra* note 4, at 530 ("[T]he [Federal Food, Drug and Cosmetic Act] cites human health as one of the primary factors for FDA decision making, regardless of whether the drug is intended for humans or animals.").

202. Briceño, *supra* note 4, at 531.

drug, the “overarching concern[ ]” is “human safety.”<sup>203</sup> Therefore, the FDA can withdraw approval of new animal drugs even without a direct link between antibiotic use in animals and antibiotic resistance in humans, as long as the FDA’s reason has to do with human health. The FDA can continue to monitor all the other antibiotics used in animal care that are not also used for human health. NARMS can remain in place to oversee the use of antibiotics and the spread of antibiotic resistance.<sup>204</sup>

### CONCLUSION

Antibiotic resistance in humans is a health concern; it can lead to long, expensive hospital stays and an increased risk of death. Antibiotic use in animals has increased over the years, and it is now commonplace in the United States for farm animals to be fed low doses of antibiotics on a daily basis. Because of the high use of antibiotics in animals, the animals can develop antibiotic-resistant bacteria. The antibiotic-resistant bacteria in farm animals can pass to humans through meat and poultry consumption, and therefore, antibiotic use in animals needs to be more stringently regulated. Currently, the FDA is working with the CDC and the USDA to monitor antibiotic use in animals and the spread of antibiotic resistance in humans. The FDA has decided to employ a wait-and-see approach and continues to perform research, through NARMS, to determine how big of a threat antibiotic use in animals actually is to humans. It seems the FDA is looking for a direct link before it acts.

Antibiotic resistance is a major health concern that needs to be prevented. Because antibiotic resistance poses such a large threat to human health, the better solution is to act now before antibiotic resistance spreads even more. The FDA should coordinate its regulation efforts with domestic agencies (the USDA and the CDC) and international groups (the WHO and the EU). Then, the FDA should enact a ban on all antibiotics that are used in human health care. Finally, the FDA can continue to monitor the remaining antibiotics used in animals in order to determine whether these drugs also pose a threat to human health.

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203. Halpern, *supra* note 19, at 425.

204. See *supra* Part I.B.1. (discussing the current role of NARMS).