Abstract: This Note explores antibiotic-resistant bacterial strains in humans and their roots in American industrial livestock practices. Factory farms promote the growth of antibiotic-resistant bacteria—or “superbugs”—by giving animals subtherapeutic doses of antibiotics to prevent the diseases that result from confinement and unhygienic conditions. Although Congress has repeatedly attempted to pass legislation to curtail the use of subtherapeutic antibiotic dosing in livestock, those efforts have yielded little change for nearly a decade. Similarly, the Food and Drug Administration (FDA) has stood by while antibiotic-resistance in human bacteria has exploded into a critical public health issue. This Note advocates for citizen action under the Administrative Procedure Act to prompt the FDA to withdraw animal approval for antibiotics that are important to human health. A citizen petition has a greater chance of success today than in past years due to the newly available scientific data and international recognition of the dangers of the overuse of antibiotics in factory farming.

Introduction

For the latter part of the twentieth century, American farm policies and meat processing industries have sacrificed human health for the economic efficiency of industrialized livestock production.1 Doctors, scientists, and journalists have watched and protested as drug-resistant strains of bacteria, known sensationnally as “superbugs,” have become increasingly prominent in hospitals and areas surrounding livestock operations.2 These superbugs—such as dangerous antibiotic-resistant

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2 See Nicholas D. Kristof, Our Pigs, Our Food, Our Health, N.Y. Times, Mar. 12, 2009, at A29 (reporting on the increased rates of drug resistant bacterial infections in America and linking that increase to Midwest hog farms’ practice of feeding antibiotics to their livestock).
staphylococcus (staph) infections\(^3\) and vancomycin\(^4\)-resistant bacteria—are emerging, claiming the health and lives of Americans every year.\(^5\) In what Nicholas D. Kristof terms an “unconscionable” manner, Congress and the Food and Drug Administration (FDA) promote the growth of superbugs by permitting agribusiness to use sub-therapeutic levels of antibiotics in order to safely keep large numbers of food animals in confined, unsanitary conditions.\(^6\)

The precipitous rise in antibiotic-resistant strains of bacteria in the last few decades is due to the large amounts of sub-therapeutic doses of antibiotics being fed to livestock on industrial animal farms.\(^7\) The move from small, family-owned farms to large, industrial factory farms has resulted in farmers tightly packing their animals together in order to increase their profits.\(^8\) However, the competition among farmers to produce as much animal food product as possible necessitates the use of sub-therapeutic doses of antibiotics to keep livestock healthy and productive.\(^9\) In recent decades, studies have shown that the practice of administering sub-therapeutic doses of antibiotics to animals contributes to strains of antibiotic-resistant bacteria in humans.\(^10\) These antibiotic-resistant strains of bacteria cause humans to become more virulently ill for longer periods of time than their antibiotic-susceptible

\(^{3}\) ST398—a virulent strain of methicillin-resistant Staphylococcus aureus (MRSA). Id.

\(^{4}\) Vancomycin is an antibiotic used to treat staphylococcal infections that are resistant to other forms of antibiotics and to treat humans with penicillin allergies. Baxter Healthcare Corp., Fact Sheet on Vancomycin Hydrochloride Injection, Solution 5 (2009), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050671s014lbl.pdf.


\(^{7}\) Kristof, supra note 5; see U.S. GEN. ACCOUNTING OFFICE [GAO], FOOD SAFETY: THE AGRICULTURAL USE OF ANTIBIOTICS AND ITS IMPLICATIONS FOR HUMAN HEALTH 4 (1999).


\(^{9}\) See id.

\(^{10}\) See Michael Barza et al., Introduction to The Need to Improve Antimicrobial Use in Agriculture: Ecological and Human Health Consequences, at S74 (Michael Barza & Sherwood L. Gorbach eds., 2002).
When humans contract these more potent diseases, they are ill for a longer period of time; consequently, they suffer the physical and emotional burden of prolonged illness and death. They also put a larger financial burden on the public health system.\textsuperscript{12} Neither the legislature nor the FDA has been able to properly deal with the problem of sub-therapeutic livestock dosing and its creation of superbugs.\textsuperscript{13} This Note proposes citizen action through an FDA citizen petition as a viable solution to congressional and administrative inaction on the dangers that excessive antibiotic use in animals poses to public health.\textsuperscript{14} Such a petition, filed under the authority of the Administrative Procedure Act (APA), would ideally prompt the FDA to withdraw approval for certain antibiotics crucial to human health.\textsuperscript{15} Were the FDA to deny the petition, this Note further illustrates how a citizens’ group would successfully navigate an action for judicial review to compel the FDA to act.\textsuperscript{16}

Part I of this Note explores the history of factory farming in America and how the practice of sub-therapeutic dosing of food animals mitigates the inherent problems with industrial farming.\textsuperscript{17} Part II conveys how antibiotic resistance occurs and how antibiotic resistance moves from food animals to humans.\textsuperscript{18} Part III discusses proposed legislation and FDA action to curtail antibiotic use in livestock.\textsuperscript{19} Part IV addresses the process of FDA petitions and judicial review of agency inaction.\textsuperscript{20}

\textsuperscript{11} See id.

\textsuperscript{12} See id. It is estimated that the cost of treating patients with disease-resistant strains of antibiotics might be as high as $30 billion annually. Robyn Mallon, \textit{The Deplorable Standard of Living Faced by Farmed Animals in America’s Meat Industry and How to Improve Conditions by Eliminating the Corporate Farm}, 9 Mich. St. J. Med. & L. 389, 399 (2005).


\textsuperscript{14} See 21 C.F.R. § 10.30 (2009).


\textsuperscript{16} See \textit{infra} Part V.

\textsuperscript{17} See \textit{infra} Part I.

\textsuperscript{18} See \textit{infra} Part II.

\textsuperscript{19} See \textit{infra} Part III.

\textsuperscript{20} See \textit{infra} Part IV.
Finally, Part V analyzes how a citizens group might successfully challenge FDA inaction regarding animal antibiotic use under the APA. 21

I. THE GROWTH OF INDUSTRIAL ANIMAL HUSBANDRY

A. From Family Farm to Factory Farm

Before World War II, farming practices in the United States focused on small, family-owned farms, which produced multiple animal products from diverse livestock in amounts sufficient to subsist. 22 This practice allowed the animals and the land to work together so that farms continued producing food indefinitely without damage to the health of their ecosystems. 23 The symbiotic relationship between animal and land was effective because animals were fed by neighboring crops on the same farm while certain plots lay fallow. 24 Animal wastes were recycled back onto the fallow plots whose nutrients had been depleted by crops in previous seasons. 25 In addition to the improved land conditions from family farming, the animals themselves were given enough room to grow, exercise, and socially interact with other animals according to their behavioral needs. 26

The traditional style of farming began to change in the 1940s when farming practices shifted their focus to streamlined, assembly-line production of animal food products. 27 Farmers developed technology that allowed animals to live in specialized indoor environments in which animals’ dietary, physical, and social needs were largely ignored. 28 Animals’ natural needs became a liability to the farmer because they did not conform to the technological standards of the machines that, henceforth, would process the animals into food. 29 In addition to the new assembly-line style automation, farming in the United States became highly concentrated, resulting in fewer farms and greater amounts of

21 See infra Part V.
23 See id. at 43–44.
24 See id.
25 See id.
26 See id. at 43.
27 See id. at 44.
28 See Cheever, supra note 22, at 45; Jonny Frank, Note, Factory Farming: An Imminent Clash Between Animal Rights Activists and Agribusiness, 7 B.C. ENVTL. AFF. L. REV. 423, 427–30 (1979) (describing the changes that chickens and hogs undergo in order to modify the animals’ natural needs to the practices of the factory farm).
29 See Frank, supra note 28, at 424.
livestock.30 Today, factory farms are run more like industries than the mini-ecosystems of traditional family farms.31 At any given time, factory farms—which are known as animal feeding operations (AFOs)—raise hundreds, thousands, or even millions of animals in confinement.32

Two main problems emerging from the density of AFOs are the enormous amounts of waste produced by the animals and the propensity of the animals to become diseased.33 Certain AFOs that contain an extremely large number of animals are known as concentrated animal feeding operations (CAFOs).34 For larger animals, such as cows, CAFOs contain at least 1000 animals while for smaller animals, such as chickens, CAFOs may house tens of thousands of animals.35 In addition to the density of animals within each individual CAFO, groups of CAFOs tend to be concentrated in certain parts of the country, exacerbating the environmental hazards that arise from these livestock factories.36 Because of the concentration of animals in each CAFO and the geographic concentration of the CAFOs themselves, farmers require even more technology to manage the problems that began to arise from the confinement of so many animals.37

B. The Legacy of Factory Farming: Waste and Disease

Animal waste imposes a negative environmental impact on the surrounding air and water.38 The total amount of waste produced by American factory farms is estimated to average 500 million tons of manure each year, or roughly three times the total human waste produced in the United States. These high levels of animal waste require special holding

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30 See Gurian-Sherman, supra note 1, at 2; Cheever, supra note 22, at 44.
31 Frank, supra note 28, at 424.
33 See Cheever, supra note 22, at 44–45.
34 Ctr. for Disease Control & Prevention, Animal Feeding Operations—Agricultural Water—Other Uses of Water—Healthy Water, http://www.cdc.gov/healthywater/other/agricultural/af0.html (last visited May 14, 2010). CAFOs are feed lots that house a large number of animals in a confined area for forty-five days or more over twelve consecutive months. Id.
35 Gurian-Sherman, supra note 1, at 2.
36 See id.
37 Cheever, supra note 22, at 44.
systems, such as the manure lagoons commonly found on swine farms.\(^{39}\) These manure lagoons contain the air pollutant ammonia, as well as water-soluble pollutants and pathogens that seep into nearby water supplies and are consequently regulated under the Clean Water Act.\(^{40}\)

The cramped quarters in which animals are kept and the stress of their unnatural lives on factory farms place them in greater danger of becoming diseased and behaving in aggressive and unnatural ways that promote injury and illness.\(^{41}\) Consequently, factory-farm animals are redesigned to minimize the dangers of infection and injury to the flock or herd.\(^{42}\) For example, battery chickens, hens raised for egg production, are confined in only forty-eight square inches of standing room per chicken and undergo a process called “forced molting.”\(^{43}\) Forced molting is a way to unnaturally increase a battery chicken’s egg production in the later stages of its life.\(^{44}\) First, the flock is denied food for two weeks.\(^{45}\) This starvation causes premature molting, which in turn, causes the hen to enter a second season of production instead of the natural waning of the egg cycle.\(^{46}\) Broiler chickens, raised for their meat, are de-beaked in order to prevent them from attacking one another as a...

\(^{39}\) See 40 C.F.R. § 122.23 (2009); see also Mallon, supra note 12, at 396 (citing a Sierra Club estimate that American CAFOs produce 2.7 trillion tons of waste per year).

\(^{40}\) See 33 U.S.C. § 1311 (2006); Revised National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitations Guidelines for Concentrated Animal Feeding Operations in Response to the Waterkeeper Decision, 73 Fed. Reg. 70,418, 70,419 (Nov. 20, 2008) (to be codified at 40 C.F.R. pts. 9, 122, 412); GAO, ANIMAL AGRICULTURE: INFORMATION ON WASTE MANAGEMENT AND WATER QUALITY ISSUES 11 (1995); Terence J. Centner, Establishing a Rational Basis for Regulating Animal Feeding Operations: A View of the Evidence, 27 Vt. L. Rev. 115, 118 (2002); Wilson, supra note 32, at 441. Water-soluble pollutants include an estimated 1.3 million tons of nitrogen and 700,000 tons of phosphorous from AFOs and CAFOs that pollute the nation’s rivers and streams each year. Centner, supra, at 118. These nutrients can over-stimulate algae growth in the tributaries, upsetting the natural ecological balance of a natural water source. See GAO, supra, at 11. While the extreme environmental impacts of modern factory farming are manifold, they require a separate analysis beyond the scope of this Note. See, e.g., Animal Feeding Operations Consent Agreement and Final Order, 70 Fed. Reg. 4958, 4958 (Jan. 31, 2005) (offering AFOs the chance to participate in a study of possible AFO liability under environmental statutes concerned with air quality, hazardous wastes, and toxic clean-up); National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs), 68 Fed. Reg. at 7176; Centner, supra, at 117–19; Wilson, supra note 32, at 439–42.

\(^{41}\) Mallon, supra note 12, at 396–97.

\(^{42}\) Cheever, supra note 22, at 45.

\(^{43}\) Id. Although the USDA discourages this practice, they do not prohibit it and some farmers still use it. See id. at 46.

\(^{44}\) Id. at 45.

\(^{45}\) Id.

\(^{46}\) See id.
reaction to their crowded confinement, poor ventilation, deficient diet, the presence of crippled birds in the pen. Veal calves endure an iron-deficient diet—consisting of antibiotics, vitamins, and powdered milk—that gives their meat the pale color that makes it marketable. Hogs also exhibit aggressive behavior in reaction to overcrowding, frequently biting each other’s tails; farmers deal with this problem by docking the tails of their pigs. As a result of overcrowding, pigs also suffer from “porcine stress syndrome,” a condition analogous to human shock, which can cause suffering so severe that pigs have been known to die from the stress.

The stress of modifications such as tail docking and de-beaking is compounded by the overcrowded conditions on CAFOs, making the animals perfect incubators for the growth and rapid spread of bacterial infections. Antibiotics are introduced into animal feed to combat disease and infection in order to maximize health and growth.

C. Sub-Therapeutic Doses of Antibiotics Mitigate the Stress of Factory Farm Life

Factory farm operations use antibiotics in feed animals for three main purposes: therapy for illness, to prevent disease, and to increase growth. Farmers administer antibiotics in sub-therapeutic doses when pursuing the latter two categories, disease prevention and growth. Sub-therapeutic doses are low levels of antibiotics that are insufficient to kill an invading bacterial infection, but are effective in preventing bacterial infection from occurring. About 70% of all antibiotics in the United States are administered to animals in sub-therapeutic doses.
resulting in the administration of 15 to 18 million pounds of antibiotics in sub-therapeutic doses annually.  

Sub-therapeutic antibiotics for disease prevention are typically used during high risk periods for the animal, such as after weaning. Animals in confinement are particularly susceptible to diseases such as pneumonia and diarrhea, the major causes of calf mortality, or necrotic enteritis, an intestinal infection in poultry. Today, antibiotics are administered preemptively to all confined animals in drug-laced feed instead of being prescribed by veterinarians to prevent these diseases. Though antibiotics are most often used during high risk periods to prevent diseases, the ability to mass medicate through feed enables farmers to continue administering antibiotics for growth enhancement over the course of the animals’ lives, contributing to the development of drug-resistant pathogens.

It appears that sub-therapeutic doses of antibiotics cause growth in livestock; however, the link between drug use and increased animal size is not well understood. While scientists do not fully understand how antibiotics improve growth, there are several possible explanations for the apparent relationship between weight gain and antibiotic use. One possibility is that the antibiotics mitigate the deleterious effects of diseases that drain animals’ nutrient reserves, but would not otherwise be severe enough to warrant medical treatment. Another possibility is that the antibiotics strengthen the animals’ immune systems, better enabling them to fight off the low-grade diseases resulting from overcrowding and trauma. Lastly, antibiotics in animal feed might alter the animals’ metabolic rate, resulting in weight gain. All three of these possibilities indirectly emphasize the notion that if animal hygiene was 2002), available at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=36410 [hereinafter KAW Press Release].

58 Id. at S93.
59 See id. at S95.
60 See Mallon, supra note 12, at 399.
61 See Gurian-Sherman, supra note 1, at 5.
63 McEwan & Fedorka-Cray, supra note 57, at S98. Reports of weight gain of 1% to 11% of an animal’s weight indicate that antibiotics are a valuable growth promoter for the livestock industry. See id.
64 See id.
65 See id.
66 See id.
II. THE RELATIONSHIP BETWEEN SUB-THERAPEUTIC ANTIBIOTIC DOSING AND HUMAN HEALTH

A. How Antibiotic Resistance Occurs

The conditions on factory farms and concentrated animal feeding operations (CAFOs) render them a dangerous source of antibiotic resistance. Sub-therapeutic doses of antibiotics administered over long periods of time to a large group of animals promote natural selection for drug-resistant bacterial strains. This natural selection occurs when an antibiotic used to treat an infection kills off the bacteria most susceptible to that antibiotic, leaving behind the most resistant bacteria to multiply and spread.

Antibiotics and the problem of antibiotic resistance are best understood in light of three broad principles. First, antibiotics are used to kill bacteria, but are not used to treat illnesses arising from other sources, such as viruses. Second, “antibiotic-resistant bacteria” are bacteria that can cause infection and are immune to the drug typically used to treat that infection. Third, antibiotic resistance in bacteria is a trait that can be spread from bacterium to bacterium without exposure to the antibiotic.

67 See id.
68 GAO, ANTIBIOTIC RESISTANCE: FEDERAL AGENCIES NEED TO BETTER FOCUS EFFORTS TO ADDRESS RISK TO HUMANS FROM ANTIBIOTIC USE IN ANIMALS 9 (2004).
69 See id.
70 See Stuart B. Levy, THE ANTIBIOTIC PARADOX: HOW MIRACLE DRUGS ARE DESTROYING THE MIRACLE 4–8 (1992). The term “antibiotic” traditionally refers to compounds made by microorganisms, whereas the term “antimicrobials” refers to synthetically derived compounds that perform the same function as antibiotics. Paul Ebner, CAFOs and Public Health: The Fate of Unabsorbed Antibiotics, PURDUE EXTENSION, Feb. 2007, at 1, 1, http://www.ces.purdue.edu/extmedia/ID/ID-348-W.pdf. Factory farms use both antibiotics and antimicrobials, and this Note will refer to them collectively as “antibiotics.”
72 See Levy, supra note 70, at 7.
73 See id. at 8; Thomas F. O’Brien, EMERGENCE, SPREAD, AND ENVIRONMENTAL EFFECT OF ANTIMICROBIAL RESISTANCE: HOW USE OF AN ANTIMICROBIAL ANYWHERE CAN INCREASE RESISTANCE TO ANY ANTIMICROBIAL ANYWHERE ELSE, in THE NEED TO IMPROVE ANTIMICROBIAL USE IN AGRICULTURE: ECOLOGICAL AND HUMAN CONSEQUENCES, supra note 10, at S78, S79.
Antibiotic resistance can occur in two different ways: it can happen spontaneously as the result of genetic mutation in bacteria’s genetic makeup or the resistance can be transmitted from bacterium to bacterium by genetic vectors such as plasmids, which are extra-chromosomal DNA molecules. A strain of bacteria that is not resistant to an antibiotic—a “susceptible strain”—differs from a strain that is resistant to an antibiotic—a “resistant strain”—because the latter exhibits a resistance gene. In Darwinian fashion, resistance genes tend to link with genes for virulence, resulting in a co-transfer of two genes that increases a disease’s level of contagiousness and harmfulness while simultaneously rendering the disease immune to certain antibiotics.

B. Animals to Humans: The Resistance Link

The Center for Disease Control and the American Medical Association have known about the link between antibiotic use in livestock and antibiotic resistance in humans at least since 1984 and 2001, respectively. According to the 2002 study by the Alliance for the Prudent Use of Antibiotics (APUA) and other medical scholars who have written on the subject, direct, temporal, and circumstantial evidence all definitively show that antibiotic use in livestock causes drug resistant infections in humans.

Primarily, scientists have discovered evidence directly tracing human infections back to specific livestock operations. One of the first indicators of this direct link between animal and human resistance was the 1976 study by Stuart Levy. This study showed the rise and fall of

74 O’Brien, supra note 73, at S79.

75 Id. A resistance gene can travel on the plasmid independently of the rest of the bacteria’s chromosomes, allowing the resistance gene to travel from one bacterial strain to another, creating an entire group of different bacteria which are all resistant to the same antibiotic. Id. at S79–80.

76 Michael Barza, Potential Mechanisms of Increased Disease in Humans from Antimicrobial Resistance in Food Animals, in The Need to Improve Antimicrobial Use in Agriculture, supra note 10, at S123, S124.

77 Mallon, supra note 12, at 400. The American Medical Association spoke out against sub-therapeutic antibiotic use in 2001 because of its belief that antibiotics in animals posed a threat to human health because of the increase in the number of drug-resistant pathogens. Id.


79 See Levy, supra note 70, at 145–47.

80 Levy, supra note 70.
tetracycline-resistant bacteria in members of a Massachusetts farm family whose animals were fed with tetracycline-resistant feed.\textsuperscript{81} Tetracycline-resistant E. coli bacteria began to appear in chickens within twenty-four to thirty-six hours after they were fed tetracycline-laced feed.\textsuperscript{82} Five to six months after the initial drug-laced feeding, tetracycline-resistant E. coli began appearing in the human family members working on the farm, even though the family members had not eaten any of the chickens and were not directly exposed to the tetracycline.\textsuperscript{83} A similar study showed the direct link between antibiotic resistant bacteria in farm animals and humans in a 1985 outbreak of salmonella in California.\textsuperscript{84} In that case, scientists traced a particular strain of multi-drug resistant salmonella back to a fast food restaurant, then to the meat processing plant, and ultimately back to the dairy farm that used an unapproved antibiotic in its feed.\textsuperscript{85}

A second type of evidence seeks to show the link between resistance in animals and humans by illustrating that human resistance usually follows animal resistance in a particular location.\textsuperscript{86} Perhaps the most notable example of animal drug resistance causing human drug resistance is the American experience with fluoroquinolone-resistant campylobacter.\textsuperscript{87} Two years after the FDA approved fluoroquinolone for animal use, the percentage of fluoroquinolone-resistant bacteria in chickens rose to 14\%.\textsuperscript{88} During the same time period, the amount of fluoroquinolone-resistant bacteria in humans rose from 1.3\% to 10.2\%.\textsuperscript{89} Similarly, in the Netherlands, fluoroquinolone-resistance rose in poultry from 0\% to

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{81} Id. Tetracycline is a family of antibiotics that is commonly used because of its low toxicity and broad spectrum of activity. Id. at 146. Additionally, its properties as a growth enhancer for livestock were discovered in 1947 when a farmer administered chlorotetracycline, the first member of the tetracycline family, to his chickens and noted an increased in their growth rate. Id. at 138–39.
  \item \textsuperscript{82} Id. at 145. Illustrating the ease with which resistance genes transfer between bacterial strains, the chickens showed E. coli resistance to other antibiotics that they had never been exposed to within three months of being started on tetracycline feed. Id.
  \item \textsuperscript{83} See id. at 145–47. Additionally, the humans on the farm exhibited the same multi-drug resistance as the chickens. Id. at 146–47.
  \item \textsuperscript{84} Morton N. Swartz, Human Diseases Caused by Foodborne Pathogens of Animal Origin, in THE NEED TO IMPROVE ANTIMICROBIAL USE IN AGRICULTURE: ECOLOGICAL AND HUMAN HEALTH CONSEQUENCES, supra note 10, at S111, S113.
  \item \textsuperscript{85} Id.
  \item \textsuperscript{86} See KAW Fact Sheet, supra note 78, at 1–2.
  \item \textsuperscript{87} See Swartz, supra note 84, at S114. Campylobacter is a food-borne illness found in cattle, hogs, and poultry whose symptoms typically include intestinal distress. See id. at S111.
  \item \textsuperscript{88} Id. at S114.
  \item \textsuperscript{89} Id.
\end{itemize}
\end{footnotesize}
14% within the same seven-year period and human infection rose from 0% to 11%. The close temporal link between animal resistance and human resistance illustrates that the former causes the latter.

There is also significant circumstantial evidence linking antibiotic resistance in humans to sub-therapeutic antibiotic dosing of food animals. Reports by the Union of Concerned Scientists show that 70% of all antibiotics produced in the United States are administered in sub-therapeutic doses to livestock. This 70% includes the 13.5 million pounds of antibiotics important to human medicine that American livestock producers administer. Antibiotics that are widely used in human medicine, such as tetracycline and penicillin, are also extensively used in livestock. The administration of antibiotics has contributed to the rise in drug resistant bacteria, notably among campylobacter, salmonella, and E. coli.

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. As demonstrated by the study of a Massachusetts farm family’s contraction of tetracycline-resistant E. coli, humans in close contact with food animals are likely to pick up resistant bacteria. In that study, two weeks after the tetracycline-laced feed was introduced to the livestock for the first time, farm hands and family members began to secrete tetracycline-resistant bacteria. Livestock workers can become infected with drug-resistant bacteria through handling animals themselves, animal feed, or animal manure. Once the drug-resistant bacterial strain infects a farm worker, it can be readily transferred to family, friends, and other members of the community.

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90 Id.
91 See id.
92 KAW Fact Sheet, supra note 78, at 1–2.
94 Mellon & Fodriest, supra note 93.
95 See id. Campylobacter, salmonella, and E. coli are all human food-borne illnesses, known colloquially as “food poisoning,” that generally cause intestinal distress. See Swartz, supra note 84, at S111.
97 Levy, supra note 70, at 145–47.
98 KAW Fact Sheet, supra note 78.
100 Id.
Another mode of animal to human transference is through the food products themselves.\textsuperscript{101} Over the course of an animal’s life on a factory farm, drug resistant bacteria build-up in its intestines; during slaughter and processing, those bacteria are released and spread to the processed and packaged meat.\textsuperscript{102} When someone consumes that processed and packaged meat, she also consumes drug-resistant bacterial strains, which then colonize in her intestines.\textsuperscript{103} The resistance gene will then thrive in the intestines where it can eventually cause harm by creating new resistant strains across different bacterial species.\textsuperscript{104} Reporting on this danger in 2002, Consumer Reports found that 42\% of supermarket broiler chickens were contaminated with campylobacter.\textsuperscript{105} Of that 42\% of infected broiler chickens, 20\% were infected with an antibiotic-resistant strain of the disease that can transfer to the human consumer.\textsuperscript{106}

A third method of human transference is through the environment, most notably through contaminated water.\textsuperscript{107} As mentioned above, the Union of Concerned Scientists estimated that 70\% of all antibiotics used in the United States are administered in sub-therapeutic doses to livestock that are not ill.\textsuperscript{108} In most instances, these antibiotics will pass through the animals’ intestines, which results in as much as 75\% of the antibiotics consumed being excreted in the animals’ manure.\textsuperscript{109} American CAFOs generate 2.7 trillion pounds of manure annually; manure that is stored in open manure lagoons and later spread as fertilizer on agricultural fields.\textsuperscript{110} This manure contains antibiotics and antibiotic-resistant bacteria from the animals’ intestines, and it frequently leaks from the lagoons into nearby groundwater.\textsuperscript{111} Furthermore, the animal excrement from lagoons themselves and the waste

\begin{thebibliography}{99}
\bibitem{101} Id.
\bibitem{102} Id.
\bibitem{103} KAW Fact Sheet, \textit{supra} note 78, at 2.
\bibitem{104} Id.
\bibitem{106} Consumers Union Press Release, \textit{supra} note 105.
\bibitem{107} Ohio Envtl. Council, \textit{supra} note 96.
\bibitem{108} KAW Press Release, \textit{supra} note 56.
\bibitem{109} Id.
\bibitem{110} Mallon, \textit{supra} note 12, at 396; see Wilson, \textit{supra} note 32, at 441.
\bibitem{111} See Ohio Envtl. Council, \textit{supra} note 96.
\end{thebibliography}
applied to fields mix with rainwater and irrigation that falls on the
fields, becoming runoff that enters lakes and streams, many of which
serve as water sources for human consumption.\footnote{112}{See Todd, supra note 38, at 481.}

According to Dr. Michael Barza, editor of the APUA Scientific Advi-
sory Panel, drug-resistant bacteria are a major threat to human health
because the bacterial strains make humans sicker than non-resistant
strains.\footnote{113}{See Barza, supra note 76, at S123–24 & tbl.1.} Humans are rendered sicker by at least three methods: (1)
patients taking an antibiotic are already weakened and their internal
bacteria are disturbed, leaving them vulnerable to resistant bacterial
strains;\footnote{114}{Id. at S124 & tbl.1. This first category of patients is particularly susceptible to dis-
eease resistant strains because those strains are the ones most likely to have survived the
initial antibiotic cycle. See id.} (2) patients suffer from the increased virulence of drug-
resistant bacterial strains due to the genetic linking of resistance genes
with virulence genes;\footnote{115}{Id.} and (3) patients become incubators of resistant
bacteria when their own intestinal bacteria acquire new resistance
genes.\footnote{116}{See id.}

Logically, the animal antibiotics most dangerous to human health
are those that are important to human therapy.\footnote{117}{See Preservation of Antibiotics for Medical Treatment Act of 2009, H.R. 1549, 111th
Cong. (2009) (stating its purpose to preserve the effectiveness of antibiotics important to
human therapy by targeting the agricultural use of those antibiotics).} For example, fluoro-
quinolones—an important human antibiotic used in treating campylo-
bacter and salmonella infections—have been compromised as a human
drug due to the resistance fostered by its use in poultry farming.\footnote{118}{GAO, supra note 68, at 6–7, 20.} The
resistant strain of bacteria caused more hospitalizations, longer ill-
nesses, and more expensive treatment for infected patients than a non-
resistant strain of the same bacteria.\footnote{119}{See id. at 24.}

III. Agency Driven Action and Antibiotic Bans

A. The Benefits of Antibiotic Bans

Legislative bans on the use of sub-therapeutic doses of antibiotics
in agriculture may mitigate drug resistant bacterial infections in hu-
mans because bans reduce the levels of antibiotic-resistant bacteria in
the environment.\textsuperscript{120} The European example is particularly telling.\textsuperscript{121} Legislation regulating antibiotic use in animals has been enacted since 1986, followed by bans in individual countries over the next several years.\textsuperscript{122} In 1998, the European Union Council Regulation 2821/98 withdrew approval for four animal feed additives.\textsuperscript{123} This baseline was augmented by individual countries that have passed more stringent standards since the initial ban.\textsuperscript{124} After these regulations were put into effect, studies in Europe showed a “significant decline” in the levels of resistant bacteria.\textsuperscript{125}

Although it is too soon for conclusive results, the object of the agency-driven fluoroquinolone ban in the United States was to lower the occurrence of fluoroquinolone-resistant bacteria in humans.\textsuperscript{126} In 2005, the Food and Drug Administration (FDA) banned the use of Baytril, a fluoroquinolone antibiotic, in poultry production.\textsuperscript{127} The FDA decided to withdraw approval for use of the drug because it was contributing to the increase of antibiotic-resistant bacterial infections in humans.\textsuperscript{128} Baytril is chemically similar to Cipro, a drug used in humans to fight off food-borne illnesses such as campylobacter and salmonella.\textsuperscript{129} Use of Baytril in animals caused more strains of fluoroquinolone-resistant food poisoning in humans than existed before Baytril’s approval for animal use, resulting in an estimated 8700 days of hospitalization per year.\textsuperscript{130} Because the continued use of Baytril in poultry production caused humans to contract Cipro-resistant infections, the FDA banned the drug in order to reverse the escalating number of Cipro-resistant strains of bacteria.\textsuperscript{131}

The arguments against legislative bans on sub-therapeutic antibiotic doses usually focus on one issue: the cost to the agricultural indus-

\textsuperscript{120} See, e.g., Briceño, supra note 13, at 526–27; Centner, supra note 55, at 8.
\textsuperscript{121} See Briceño, supra note 13, at 528; Centner, supra note 55, at 8.
\textsuperscript{122} Briceño, supra note 13, at 528. Sweden, Switzerland, and Denmark were among the first countries to ban the use of certain antibiotics in animal husbandry practices. See id.
\textsuperscript{123} See Centner, supra note 55, at 16.
\textsuperscript{124} Id. The German Federal Veterinarians Association demonstrates this principle with their more stringent guidelines for antibiotic use. Id.
\textsuperscript{125} Id. at 6.
\textsuperscript{126} See id. at 7.
\textsuperscript{128} GAO, supra note 68, at 6.
\textsuperscript{129} See Baytril Press Release, supra note 127.
\textsuperscript{130} See GAO, supra note 68, at 24.
\textsuperscript{131} See Briceño, supra note 13, at 522; Baytril Press Release, supra note 127.
try of less robust animals.\textsuperscript{132} The additional costs associated with banning sub-therapeutic antibiotic use consist of the money spent on additional feed to make up for lost growth enhancement, and the increase in animal illness and mortality that can negatively affect yield.\textsuperscript{133} However, the validity of this argument is called into question by the European example, which shows that for certain producers, the additional cost of feed can be offset by the decrease in the cost of antibiotics.\textsuperscript{134}

There is disagreement between industry and research institutions on what effect a sub-therapeutic antibiotic ban would have in the United States.\textsuperscript{135} For example, one American study conducted by the agricultural industry projected that hog farmers would lose $0.79 per hog—a noticeable loss of profit—if antibiotics were no longer approved for use in feed.\textsuperscript{136} This study also predicted that the cost of a ban would increase during stressful times for the animal, such as weaning, and in farms with “questionable hygiene practices.”\textsuperscript{137} Another industry study, which focused on broiler chickens, predicted a 1.76\% rise in production costs per year if antibiotic use in feed was banned; however, a 2007 citizens’ group study refutes that estimate.\textsuperscript{138} Instead, the citizens’ study finds that banning growth enhancing antibiotics actually increases the value of the flock.\textsuperscript{139} A possible explanation for the positive industry results in Europe from reduced antibiotic use is different animal husbandry techniques and farm organization.\textsuperscript{140} Interestingly, in the American studies that found a similar benefit to the industry from reduced antibiotic dosing and improved hygienic practices, such as frequent litter changes, were directly related to lower mortality rates.\textsuperscript{141}

\begin{flushleft}
\textsuperscript{132} See Briceño, \textit{supra} note 13, at 527; Centner, \textit{supra} note 55, at 17–18.
\textsuperscript{133} See Centner, \textit{supra} note 55, at 18.
\textsuperscript{134} Henrik C. Wegener, \textit{Ending the Use of Antimicrobial Growth Promoters Is Making a Difference}, 69 \textit{ASM News} 443, 448 (2003). A Danish study where antibiotic use was cut by 50\% revealed that animal mortality rates did not increase. In fact they appeared to decline slightly, and the cost to the producer of raising the animals did not increase. \textit{Id.} at 446–48. Moreover, the study shows that when accompanied by changes in management practices that create a more hygienic environment for the animals, bans on antibiotic use are positive for the animals, the environment, and the farmers. \textit{See id.} at 448.
\textsuperscript{136} McBride et al., \textit{supra} note 135, at 4.
\textsuperscript{137} \textit{Id.} at 3–4.
\textsuperscript{138} Graham et al., \textit{supra} note 135, at 80 (discussing a National Research Council study using “unsubstantiated” industry estimates).
\textsuperscript{139} \textit{Id.} at 85.
\textsuperscript{140} \textit{Id.} at 86.
\textsuperscript{141} \textit{See id.}.
\end{flushleft}
B. A Study of Agency Driven Action: The Fluoroquinolone Example

In the case of Baytril, the FDA underwent a long and complicated process to ban its use in food animals.\textsuperscript{142} The FDA first proposed the Baytril ban in 2000, but the agricultural industry delayed the FDA’s action for five years while the Bayer Company appealed the decision through various levels of administrative review.\textsuperscript{143} Ultimately, the administrative law judge found that Bayer had not sufficiently demonstrated that Baytril was safe for use in poultry production.\textsuperscript{144} Additionally, the judge found that enrofloxacin use in poultry is a source of fluoroquinolone-resistant bacterial infections of campylobacter in humans that adversely affect human health.\textsuperscript{145} In 2005, the FDA successfully withdrew approval for Baytril; fluoroquinolones are no longer used in U.S. poultry production.\textsuperscript{146}

C. The Need for Citizen Driven Action

Though the FDA’s banning of Baytril through the Center for Veterinary Medicine (CVM)—the administrative branch that makes decisions regarding animal antibiotics\textsuperscript{147}—is encouraging, citizens’ groups cannot rely on the CVM to consistently ban from animal use the remaining seven antibiotics that are crucial to human health.\textsuperscript{148} The fluoroquinolone action, while ultimately successful, is the only withdrawal of any animal antibiotic that the FDA has ever undertaken.\textsuperscript{149} In fact, the only action that the FDA has taken since the decision to ban fluoroquinolone in poultry use is the issuance of Guidance #152, a set of

\begin{itemize}
\item[] 142 See Briceño, \textit{supra} note 13, at 529.
\item[] 144 Id. at 6.
\item[] 145 Id. at 5.
\item[] 146 See 21 C.F.R. §§ 520.813(d)(1)(iii), 556.228(b) (2005); FDA Baytril Ban, \textit{supra} note 143, at 121.
\item[] 148 See Briceño, \textit{supra} note 13, at 532–33 (noting that although favorable in its outcome, the FDA ruling on enrofloxacin took five years and is only the third agricultural drug withdrawal proceeding completed in FDA history) The seven essential antibiotics are: penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, and sulfonamide. \textit{See infra} note 154.
\item[] 149 See id. at 521.
\end{itemize}
guidelines for evaluating the safety of new animal antibiotics.\textsuperscript{150} Guidance \#152 recommends that pharmaceutical companies self-evaluate their drugs’ risk levels on the basis of release, exposure, and consequence—a recommendation that is likely to go unheeded given the industry’s concern that the banning of animal drugs will increase costs and adversely impact their bottom line.\textsuperscript{151} Moreover, the FDA’s fluoroquinolone ban is incomplete; it only applies to the use of the drug in poultry, allowing its continued use in swine.\textsuperscript{152}

Recognizing the need for uniformity and efficiency in the withdrawal of approval for animal antibiotics, both houses of Congress proposed bills to ban seven classes of antibiotics from animal use in 2003, 2005, 2007, and 2009.\textsuperscript{153} The bill, aptly titled the Preservation of Antibiotics for Medical Treatment Act (PAMTA), seeks to ban the subtherapeutic use in animals of seven antibiotics that are important in battling human diseases.\textsuperscript{154} If passed, the 2003, 2005, and 2007 bills would have circumvented the FDA withdrawal process altogether,\textsuperscript{155} yet given the history of the 2003, 2005, and 2007 bills, it is not surprising that the House has not passed the 2009 reincarnation of PAMTA.\textsuperscript{156}


\textsuperscript{151} See id. at 2, 6 fig.1 (showing that Guidance documents are non-binding); Centner, supra note 55, at 18.


\textsuperscript{154} See, \textit{e.g.}, H.R. 962 § 101(a)(2)(A) (proposing to ban penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, and sulfonamide).

\textsuperscript{155} See, \textit{e.g.}, H.R. 962 § 101(c).

\textsuperscript{156} The final action taken on the 2007 version of PAMTA introduced in the House of Representatives was one day after its introduction. THOMAS (Library of Congress), Bill Status, H.R. 962, \textit{http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR00962:@@@L& summ2=m&status (last visited May 14, 2010) (citing its referral to House subcommittee on Feb. 9, 2007 as the last major action taken on H.R. 962). The bill was introduced by Rep. Louise M. Slaughter (D-NY), and left to languish until the end of the term. See id. The version of PAMTA introduced in the Senate underwent similar treatment; the last action on the bill was the same day it was introduced by Sen. Tom Harkin (D-Iowa). See THOMAS (Library of Congress), Bill Status, S.1460, \textit{http://thomas.loc.gov/cgi-bin/bdquery/z?d110:SN01460:@@@
Perhaps recognizing that a bill as single-minded and straightforward as PAMTA has not been politically viable, a group of legislators introduced the Food Safety Modernization Act in the House of Representatives on February 4, 2009.157 This bill, if passed, seeks to establish a Food Safety Administration (FSA) and FSA Administrator who would oversee and improve food sanitation and “food safety practices.”158 Another of the Administrator’s duties would be to “analyze the incidence of antibiotic resistance as it pertains to the food supply and develop new methods to reduce the transfer of antibiotic resistance to humans.”159 While it is admirable that Congress is addressing the issue of antibiotic use in food animals, it has yet to successfully effect any significant changes in the agricultural regime that overuses antibiotics.160 Neither the FDA nor Congress has proven itself capable of effectively dealing with growing antibiotic resistance through sub-therapeutic animal dosing; it is time for a citizens’ group to petition the FDA to withdraw approval for animal use of important human drugs and, if necessary, accomplish the same outcome through an action for judicial review.161

IV. Citizen Petitions and Judicial Review of FDA (In)action

A. FDA Procedure for Approval Withdrawal

There are two junctures in an FDA decision to withdraw approval for an animal drug.162 First, the Center for Veterinary Medicine (CVM) must determine whether to commence formal withdrawal proceedings for the drug.163 Second, if the CVM does initiate formal withdrawal proceedings, it must follow the statutory requirements for such proceedings on a drug-by-drug basis, as set out in 21 U.S.C. § 360b and 21 C.F.R. § 514.115.164 Both provisions require that the CVM consider the

158 Id. § 303(a)(1).
159 Id. § 303(a)(11).
160 See, e.g. H.R. 962.
161 See, e.g., id. Despite all the scientific research, pleas from citizens groups, and the European example, the FDA has only completed withdrawal proceedings for one drug—fluoroquinoline—in one type of animal—poultry. See FDA BAYTRIL BAN, supra note 143, at 21; Briceño, supra note 13, at 521.
162 Sundlof Letter, supra note 147.
163 Id.
available scientific data to determine whether the drug is unsafe.\textsuperscript{165} If the CVM finds a drug to be unsafe—a phenomenon that has occurred only once in the history of the FDA\textsuperscript{166}—CVM must notify the drug’s sponsor and give the sponsor an opportunity for a formal administrative hearing.\textsuperscript{167} Such hearings are preceded by notice, and consist of formal evidentiary hearings that render a decision that can later be appealed to a U.S. Court of Appeals.\textsuperscript{168} Typically, formal withdrawal proceedings, like the one that occurred in the withdrawal of fluoroquinolone approval, are prolonged and expensive.\textsuperscript{169}

\textbf{B. Citizen Petitions}

Citizens can prompt the FDA to consider withdrawal of an animal drug by submitting a “citizen petition.”\textsuperscript{170} Agency action or inaction is subject to judicial review through the Administrative Procedure Act (APA), which provides that federal agencies must allow interested parties to petition for the repeal, modification, or creation of agency rules.\textsuperscript{171} To comply with the APA, the FDA has installed a process for judicial review through the “citizen petition,” a mechanism for petitioning the FDA to “issue, change or cancel a regulation, or to take other action.”\textsuperscript{172} The agency guidelines provide FDA staff a period of “several weeks to more than a year, depending on the issue’s complexity,” to evaluate a petition before deciding whether or not to grant it.\textsuperscript{173} However, some form of response must be furnished to the petitioner within 180 days of receipt of the petition.\textsuperscript{174} The citizen petition allows the FDA to apply its agency expertise in considering the petition request for action before allowing the courts to intervene.\textsuperscript{175} While this period of evaluation is vague and leaves open the possibility that citizen peti-

\textsuperscript{166} See Briceño, supra note 13, at 521.
\textsuperscript{167} 21 C.F.R. §§ 10.25, 514.115(b), 514.121, 514.200; Sundlof Letter, supra note 147.
\textsuperscript{168} 21 U.S.C. § 360b(h); 21 C.F.R. §§ 12.20–123, 12.80–99 (prescribing the hearing procedures), 314.235 (providing for judicial review in a U.S. Court of Appeals).
\textsuperscript{169} Sundlof Letter, supra note 147.
\textsuperscript{170} See 21 C.F.R. § 10.30.
\textsuperscript{173} U.S. Food & Drug Admin., supra note 172.
\textsuperscript{174} 21 C.F.R. § 10.30(e)(2). The response will approve the petition, deny it, or provide a “tentative response, indicating why the agency has been unable to reach a decision on the petition.” Id. § 10.30 (e)(2)(i)–(iii).
\textsuperscript{175} See 21 C.F.R. § 10.45.
tioners might be forced to wait longer than one year for a response, the citizen petition is the necessary first step for citizen action prompting the FDA to withdraw approval for certain animal antibiotics. When the FDA eventually does make a final decision on the citizen petition, that action is subject to judicial review pursuant to the APA.

C. Reviewability of Agency Action Under the APA

The APA denies reviewability to two categories of decisions: (1) decisions where the governing statute precludes review, and (2) decisions where the agency is given discretion by law. As to the first category, agency action is presumed to be reviewable under the APA except where “clear and convincing” evidence exists that Congress intended to prohibit judicial review. Arguably, agency inaction has no less a presumption of reviewability because the concerns behind the APA rules of reviewability—maintaining procedural standards and preventing careless enforcement of regulations—are equally pertinent to agency inaction. The second category of exclusion is a narrow one that precludes review only in “rare instances” where the governing statute is so broad that it does not establish standards to appraise the legality of an agency decision; in this case, the statute effectively provides “no law to apply.” However, this situation is uncommon, given that governing statutes usually set out sufficient guidelines to evaluate the legitimacy of agency actions.

D. Standing

The APA allows a plaintiff challenging reviewable agency action or inaction to sue under section 704. However, the Case or Controversy Clause in Article III of the United States Constitution, as interpreted by the Supreme Court, limits who can sue in federal court under section
It requires that a plaintiff have “standing” as evidenced by three characteristics: (1) the plaintiff has suffered injury-in-fact; (2) that injury is fairly traceable to the harm alleged; and (3) the injury will likely be relieved by a positive outcome.

The first requirement for standing is that the plaintiff has suffered an injury-in-fact. In *Lujan v. Defenders of Wildlife*, the Supreme Court held that a “generalized grievance” that is “undifferentiated and common to all members of the public” does not entitle a plaintiff to file suit under Article III. Rather, the plaintiff must show that “the action injures him in a concrete and personal way.” However, in *Friends of the Earth v. Laidlaw Environmental Services*, the court found sufficient standing for plaintiffs who suffered particular damage to “aesthetic and recreational values.” The court held that an environmental plaintiff could establish injury-in-fact by proving that they used a geographic area that was harmed by the defendant’s activity. The option of establishing injury-in-fact through proof that the plaintiff is geographically close to the harm suggests a broadening of the standing requirements for environmental plaintiffs.

The second requirement for standing is that the concrete and personal injury suffered by the plaintiff has been caused by the agency action that is the subject of the litigation. This requirement is straightforward, stipulating merely that the court must be able to follow a logical sequence of events from the agency action to the plaintiff’s harm. Lastly, the plaintiff must show that redress is possible through a

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185 Lujan 504 U.S. at 560–61.

186 Id. at 560.

187 Id. at 575 (quoting United States v. Richardson, 418 U.S. 166, 171, 176–77 (1974)).

188 Id. at 581. *But see* Fed. Election Comm’n v. Akins, 524 U.S. 11, 12 (1998) (holding that the fact that the harm was “widely shared does not deprive Congress of constitutional power to authorize its vindication in the federal courts where the harm is concrete”) (citing *Pub. Citizen v. Dep’t of Justice*, 491 U.S. 440, 449–50 (1989)).


191 See id. at 69.

192 See *Akins*, 524 U.S. at 12.

favorable decision of the courts. This requirement is likewise uncomplicated, requiring that a court-ordered cessation of defendant’s protested conduct will solve the plaintiff’s grievance.

V. BEYOND CITIZEN PETITIONS: THE NEXT STEP

A. EFFECTIVE STANDING FOR APA CHALLENGE

Standing is likely to be the biggest obstacle facing a plaintiff challenging an unfavorable decision on a Food and Drug Administration (FDA) citizen petition that requests withdrawal of approval for specified animal antibiotics. Difficulty showing standing will arise primarily from the difficulty in showing injury-in-fact. Standing is a particular burden for plaintiffs whose harm is intangible, or not yet realized, and is therefore less quantifiable for the courts. Despite the broadening of the injury-in-fact standard by Friends of the Earth v. Laidlaw Environmental Services—where damage to “aesthetic and recreational values” created sufficient standing—the standing requirement for a challenge to continued FDA approval for animal antibiotics is not easy to surmount.

The most problematic element to achieving standing is finding a plaintiff that has suffered particularized harm. However, following the slightly more relaxed approach to standing espoused in Laidlaw leaves room for a class of citizens that can identify a particular harm from an increased risk of contracting antibiotic-resistant strains of bacteria. For instance, any citizen with a compromised immune system would fit into a category of plaintiff with a particularized harm. Because antibiotic resistance and virulence tend to travel together, patients with acquired immune deficiency syndrome (AIDS), cancer patients undergoing chemotherapy, young children, the elderly, and any other person with a weakened immune system would likely be able to

194 Id. at 97.
195 See id.
197 See id.
199 See id. at 629.
200 See Lujan, 504 U.S. at 560 (holding that a plaintiff’s harm must be concrete and particularized).
prove a unique susceptibility to the alleged harm of contracting a drug-resistant bacterial infection.\textsuperscript{202}

Likewise, the dangers of contracting drug-resistant bacterial strains appear to be more prevalent the closer one lives to an animal feed lot.\textsuperscript{203} In \emph{Laidlaw}, the court found that citizens’ group located near the site of the challenged activity satisfied the injury-in-fact element of standing because that group’s proximity to the action caused them to suffer a particularized harm—loss of use of the land for recreational and aesthetic purposes.\textsuperscript{204} Similarly, a citizens group located near such an animal feeding operation (AFO) or concentrated animal feeding operation (CAFO) that uses antibiotic feed would suffer a particularized harm—a higher chance of contracting a drug-resistant bacteria strain from the proximity of the animals.\textsuperscript{205} By analogy, such a citizens group would have a strong argument for the particularized harm element of standing due to their close proximity to the source of the harm.\textsuperscript{206}

In a case against the FDA, the second and third requirements for valid standing—causation and redressability—should be easier to satisfy than the injury-in-fact requirement. In a case regarding harm from agricultural antibiotic use, the cause of the harm alleged is not a third party, rather the harm is directly traceable back to the FDA’s refusal to withdraw approval for animal use of antibiotics now shown to be dangerous to human health.\textsuperscript{207} The Union of Concerned Scientists’ 2002 study and the European example linking antibiotics in animal use to higher instances of drug-resistant bacteria together should satisfy Article III’s requirement of causation.\textsuperscript{208} Similarly, redressability is unambiguous in this instance because if the FDA were to withdraw approval for

\begin{thebibliography}{99}
\bibitem{202} See GAO, \textit{supra} note 7, at 4; Barza et al., \textit{supra} note 10, at S74; Leonardo Renna, Note, \textit{New York State’s Proposal to Unblind HIV Testing for Newborns: A Necessary Step in Addressing a Critical Problem}, 60 Brook. L. Rev. 407, 410 (1994) (describing the immune system’s reaction to HIV and subsequent susceptibility to infection).

\bibitem{203} See Levy, \textit{supra} note 70, at 145–47; see also Kristof, \textit{supra} note 2 (reporting that increased rates of MRSA—a drug resistant bacteria infection—are found in Indiana towns located near hog farms that dose their animals with antibiotics).

\bibitem{204} See \textit{Laidlaw}, 528 U.S. at 183–84.

\bibitem{205} See Levy, \textit{supra} note 70, at 145–47. Levy’s studies of the Massachusetts farm family show that proximity to the farm alone, even without direct contact with the animals, presents a higher risk of contracting a drug-resistant infection. \textit{See id.}

\bibitem{206} See \textit{Laidlaw}, 528 U.S. at 183–84; Levy, \textit{supra} note 70, at 145–47.

\bibitem{207} See Crossman, \textit{supra} note 198, at 629 (quoting \textit{Lujan v. Defenders of Wildlife}, 504 U.S. 555, 560 (1992)) (“[T]he injury has to be ‘fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court.’”).

\bibitem{208} See Barza et al., \textit{supra} note 10, at S71, S74; Centner, \textit{supra} note 55, at 8.
\end{thebibliography}
the seven classes of antibiotics specified, the science dictates that the amount of drug-resistant strains of bacteria would similarly diminish.\footnote{See Centner, supra note 55, at 8; Swartz, supra note 84, at S114.}

**B. A Citizen Petition to Withdraw Certain Animal Drug Approvals**

The first step for an interested citizen or citizens group with standing to petition the FDA is to complete the FDA citizen petition.\footnote{See 20 C.F.R. § 10.30 (2009).} In the petition, the citizens group must specify the action requested, the grounds for the request, an environmental and economic impact statement where warranted, and certification that all information contained in the petition is true.\footnote{Id. § 10.30(b).} In this case, the action requested is a withdrawal of approval for animal use of certain antibiotic classes, the grounds are a threat to human health, and an economic impact statement is not warranted.\footnote{See Citizen Petition Seeking Withdrawal of Approvals of Certain Herdwide/Flockwide Uses of Critically and Highly Important Antibiotics Pursuant to Guidance #152, FDA Docket No. 2005P-0139/CP 1 (Apr. 7, 2005), available at http://www.keepantibioticsworking.com/new/resources_library.cfm?refID=70402 [hereinafter Citizen Petition]; Letter from David Acheson et al., Assist. Prof. of Med., Dep’t of Infectious Disease, Tufts Univ., to Jane Henney, Comm’r, U.S. Food & Drug Admin. (March 9, 1999), available at http://www.cspinet.org/reports/letterhenney.htm [hereinafter Acheson Letter].} Though petitions have been filed in the past requesting the FDA to consider withdrawing approval for drugs important in human health, none has led to a direct withdrawal of approval.\footnote{See, e.g., Citizen Petition, supra note 212; Acheson Letter, supra note 212.} While the Center for Veterinary Medicine’s (CVM) decision to withdraw approval for fluoroquinolone was influenced by the citizen petitions it received regarding the dangers of animal antibiotic use, it did not cite those petitions as directly prompting their investigation.\footnote{Enroflaxin for Poultry; Opportunity for Hearing, 65 Fed. Reg. 64,954, 64,954–57 (Oct. 31, 2000).} The citizen petition process should be taken to the next stage: judicial review, as provided for in the APA should be used to force the FDA to reconsider the decision not to ban the classes of antibiotics most crucial to human health for use in animals.\footnote{5 U.S.C. §§ 704, 706 (2006).}

To begin, a citizen group, such as the Center for Science in the Public Interest (CSPI), who filed petitions in 1999 and 2005, must submit a citizen petition requesting agency action to withdraw approval for the seven classes of antibiotics that have been identified as most crucial
to human health.\textsuperscript{216} The required “statement of grounds” section of the citizen petition should be modeled after the proposed Preservation of Antibiotics for Medical Treatment Act, which concisely lists congressional findings on the dangers of antibiotic use in animals.\textsuperscript{217} Because the FDA, in withdrawing approval, considers new scientific information not known at the time of the original decision,\textsuperscript{218} the citizen petition should include, along with the congressional findings, the conclusions of the GAO reports of 1999 and 2004, the Union of Concerned Scientists study of 2002 that appeared in \textit{Clinical Infectious Diseases}, and any other relevant and reliable scientific findings made since the approval of these seven antibiotics.\textsuperscript{219} The statement of grounds section is the most persuasive part of the petition, as it is the only part of the petition where petitioners have an opportunity to sway the agency to make a discretionary decision in their favor.\textsuperscript{220} Convincing presentation of the available science is crucial to the success of the petition.\textsuperscript{221}

Should the FDA refuse the request of the citizen petition to ban the seven classes of antibiotics, that refusal is subject to judicial review as provided for in the APA.\textsuperscript{222} The reviewing court will interpret the statute under which the FDA operates to determine if the agency action in denying the petition was arbitrary or capricious.\textsuperscript{223} This standard is meant to determine whether the FDA, among other factors, “failed to consider an important aspect of the problem, offered an explanation . . . that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view.”\textsuperscript{224}

Because of the plethora of available data on the impact of the use of animal antibiotics to human health—\textsuperscript{225} which will have been included in the grounds portion of the citizen petition—judicial review is

\textsuperscript{216} 21 C.F.R. § 10.30. Seven classes of antibiotic have been identified by the American Medical Association (AMA), the Infectious Diseases Society of America, and more than 350 health and environmental organizations as those most important to ban in the proposed Preservation of Antibiotics for Medical Treatment Act of 2007, H.R. 962, 110th Cong. (2007).

\textsuperscript{217} H.R. 962 § 2.

\textsuperscript{218} 21 C.F.R. § 514.115(b)(3)(ii).

\textsuperscript{219} GAO, \textit{supra} note 68; GAO, \textit{supra} note 7. \textit{See generally Alliance for the Prudent Use of Antibiotics, The Need to Improve Antimicrobial Use in Agriculture: Ecological and Human Health Consequences} (Michael Barza & Sherwood L. Gorbach eds., 2002).

\textsuperscript{220} \textit{See} 21 C.F.R. § 10.30(b)(B) (the other sections—action requested, environmental impact, economic impact, and certification—do not provide an opportunity to state the reasons for the petition).


\textsuperscript{223} \textit{Id.} § 706(2)(A).


\textsuperscript{225} \textit{See}, e.g., Barza et al., \textit{supra} note 10, at S71.
a particularly useful tool in the case of animal antibiotic bans.\textsuperscript{226} The available science that favors the plaintiffs is sound; the studies were conducted by reputable research institutions over a period of years, which gave the scientists ample opportunity to gather substantial data.\textsuperscript{227} This data convincingly categorizes the findings that sub-therapeutic dosing of food animals with antibiotics endangers human health.\textsuperscript{228} Furthermore, because the data is relatively new compared to the data available when these seven antibiotics were approved for animal use,\textsuperscript{229} a reviewing court would likely consider the studies “new evidence not contained in [the original] application or not available to the Secretary until after such application was approved”—a finding that would force the FDA to reconsider its original approval.\textsuperscript{230}

Although courts generally show considerable deference to agencies in judicial challenges to their actions,\textsuperscript{231} if a court finds the new information presented in the citizen petition to pertinently change the context in which the FDA made its initial decision, the court can force the FDA to institute rulemaking procedures to address the issue.\textsuperscript{232} Of course, the court cannot dictate the actual decision an agency makes, it can only ensure that the decision is made using all the available and applicable data.\textsuperscript{233} The goal of such judicial intervention would be to prompt the FDA to create rules that reflect the science, banning the sub-therapeutic use of seven classes of antibiotics identified as vital to human health.\textsuperscript{234}

**Conclusion**

It is no longer logical, as it once might have been, to deny the effect of sub-therapeutic antibiotic dosing on the rise of drug-resistant bacteria in America.\textsuperscript{235} Unhygienic conditions on American concen-

\textsuperscript{226} See Nidel, supra note 193, at 100.
\textsuperscript{227} See, e.g., GAO, supra note 68, at 3–5; Barza et al., supra note 10, at S71.
\textsuperscript{228} See, e.g., GAO, supra note 68, at 6.
\textsuperscript{232} See Nidel, supra note 193, at 100.
\textsuperscript{233} See id.
\textsuperscript{234} See id.
\textsuperscript{235} See Mallon, supra note 12, at 400 (listing the medical, scientific and governmental organizations that have conducted studies on the effects of the transferability of antibiotic-resistance from animals to humans).
trated animal feeding operations (CAFOs) lead farmers to administer sub-therapeutic doses of antibiotics to large groups of animals, encouraging a natural selection in favor of antibiotic-resistant bacteria. These resistant bacterial strains are then transferred to humans through the animal product, through human contact with livestock, and through environmental channels such as a contaminated water supply. As studies in the United States and Europe prove, drug-resistant strains of bacteria threaten human health more than non-resistant bacteria because the former type of infections make humans sicker for longer periods of time than the latter.

Although there is evidence that a legislative ban on the use of sub-therapeutic doses of antibiotics in agriculture would mitigate drug-resistant bacterial infections in the United States as it did in Europe, the American agricultural industry resists such bans because of the cost to the farmer. Accordingly, Congress has yet to pass a legislative ban on animal antibiotics, despite the introduction of four such bills in Congress. Another option to stop the increase of drug resistant bacteria is agency-driven withdrawal of approval for animal antibiotics. However, FDA-driven action has been limited to the 2005 fluoroquinolone ban and thus does not seem to be a reliable option for future regulation of animal antibiotics.

When Congress and the FDA refuse to act effectively, citizens can petition the FDA to consider withdrawing approval for animal drug use through the FDA petition process. If that petition is denied, the APA provides a mechanism for citizens to sue the FDA in order to force it to repeal, modify, or create agency rules. Plaintiffs must satisfy the Court’s prudential standing requirements. Of the three elements of standing—particularized harm, causation, and redressability—finding a plaintiff who has suffered particularized harm due to antibiotic use in

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236 See id. at 399.
237 See id. at 399.
238 See Ohio Envtl. Council, supra note 96.
239 See Barza et al., supra note 10, at S74.
240 See Barza et al., supra note 10, at S74.
241 See Centner, supra note 55, at 13, 18; Kristof, supra note 5.
242 See id. at 529.
243 See id. at 521.
244 See 21 C.F.R. § 10.30 (2009).
animal feed is likely to be the largest challenge. However, based on the expanded interpretation of standing in *Laidlaw*, two likely possibilities for successful plaintiffs are patients with compromised immune systems or those living near an animal feeding operation or CAFO.

A citizen petition under the APA has a significant chance of success because of the considerable amount of newly available data on the negative effects of antibiotic use. While judges generally show deference to agencies in petitions for judicial review, the new information on how FDA inaction affects human health by promoting drug-resistant bacteria is likely to prompt a court to force the FDA to reconsider its inaction. This reconsideration could lead the FDA to follow the examples of Europe and its own action on fluoroquinolone and pass stricter regulations on animal antibiotics to better protect Americans from the ravages of drug-resistant bacteria.

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246 See *id.* at 560 (finding that mere generalized harm to the public is not enough to create valid standing).
248 See *Nidel*, *supra* note 193, at 100.
250 See *Nidel*, *supra* note 193, at 100.