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Recommended Citation

Note, Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria, 27 J.L. & Health 259 (2014)

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SQUASHING THE SUPERBUGS: A PROPOSED MULTIFACETED APPROACH TO COMBATTING ANTIBIOTIC-RESISTANT BACTERIA

LAUREN ORRICO*

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I. INTRODUCTION

In 1977, disco flairs were all the rage, quarterback Tom Brady was only just born, and investors had the option to buy stock in a new company called Apple,

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which was incorporated in January of that year.¹ Economic and spending considerations were also at play in the 1970's as President Jimmy Carter attempted to fight unemployment by allowing the federal deficit to swell and establishing job programs.² Finally, 1977 saw the Food and Drug Administration (FDA) issue notices announcing its intent to withdraw approval of the use of certain growth-promoting antibiotics in animals raised for food (commonly referred to as "food animals").³ The FDA found that broad use of these antibiotics led to the development of antibiotic-resistant bacteria.⁴ These bacteria were deemed detrimental to human health because they caused antibiotic-resistant infections, which were difficult to treat.⁵ Thirty-five years later, few people would suggest giving those bell-bottoms another spin or debate the success of Apple, but the threat of antibiotic resistance is growing ever larger and costing Americans billions of dollars each year.⁶

Although government policies have evolved in the last thirty-five years, Americans still understand the importance of balancing costs and benefits, and of making sacrifices now to ensure a safe world for future generations. Antibiotic-resistant bacteria threaten the health of current and future generations if their effects are not curbed soon.⁷ According to the Infectious Diseases Society of America (IDSA), just one antibiotic-resistant organism, Methicillin Resistant Staphylococcus Aureus (MRSA),⁸ kills more Americans every year than emphysema, HIV/AIDS,

¹ See *Frequently Asked Questions, Apple Corporate Information*, APPLE, <http://investor.apple.com/faq.cfm?FaqsSetID=6> (last visited Mar. 8, 2014) (for information regarding Apple); see also Tom Brady, ESPN, http://espn.go.com/nfl/player/_/id/2330/tom-brady (last visited Mar. 8, 2014) (for information on Tom Brady).

² Ann Mari May, *Fiscal Policy, Monetary Policy and The Carter Presidency*, 23 *Presidential Studies Quarterly* 699 (1993), available at <http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1033&context=econfacpub>.

³ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 11 CIV. 3562 THK, 2012 WL 983544 (S.D.N.Y. Mar. 22, 2012).

⁴ *Id.* at ¶¶ 1–2. For clarity, the reader should note that an antibiotic is a type of antimicrobial drug. While antimicrobial resistance is also a concern, this Note uses the term "antibiotic" since animal feed largely contains antibiotics as opposed to other types of antimicrobials. For the purposes of this Note, the two terms can be used interchangeably. The reader should also note that the terms "antibiotic-resistant bacteria" and "antibiotic-resistant infections" are related, but not completely synonymous. Antibiotic-resistant bacteria are the organisms that cause antibiotic-resistant infections, which in turn make humans ill. See *infra* Part II(B).

⁵ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 11 CIV. 3562 THK, 2012 WL 983544 (S.D.N.Y. Mar. 22, 2012).

⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, *ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES* (2013), available at <http://www.cdc.gov/media/releases/2013/p0916-untreatable.html>.

⁷ U.S. DEP'T OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMIN., *GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS* (2012), available at http://www.FDA.gov/downloads/animal_veterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf [hereinafter *GUIDANCE #209*].

⁸ MRSA is a "staph" germ that many of us carry around daily without falling ill. NAT'L CTR. FOR BIOTECHNOLOGY INFO., NAT'L LIBRARY OF MED., NAT'L INST. OF HEALTH, MRSA

Parkinson's disease, and homicide combined.⁹ The economic cost of antibiotic-resistant infections to the United States health care system is twenty-one billion to thirty-four billion dollars each year—along with an additional eight million hospital days for patients.¹⁰ These economic costs, along with the social costs of environmental degradation, animal cruelty, and adverse health effects, make cost-effective policy initiatives crucial for preserving the health and well-being of our society.¹¹

The spread of antibiotic-resistant infections is finally being widely recognized by medical professionals as a serious threat that can be slowed through proper policy.¹² Resistant bacteria multiply when antibiotics are overused.¹³ As around half of all antibiotics used in the United States are given to animals for various reasons, overuse in food animals is a major cause of this problem.¹⁴ Numerous studies have linked the wide-spread use of antibiotics in animal feed to the development of antibiotic resistance in humans.¹⁵ Antibiotic resistance has led to massive food recalls and a higher prevalence of drug-resistant infections, allergies, and autoimmune diseases in children.¹⁶ However, current legislation fails to address the problem, preferring instead to defer responsibility to the hesitant FDA¹⁷

The FDA, although recognizing the health concern as far back as 1977, has refused to ban the use of antibiotics for disease prevention and growth promotion in food animals.¹⁸ However, a recent U.S. District Court ruling brought subtherapeutic use back into the public spotlight when it ordered the FDA to follow through on proceedings initiated in 1977 to ban the subtherapeutic use of certain antibiotics in

(2012), available at <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004520/>. However, individuals who have weakened immune systems or other health issues are susceptible to the diseases effects, most notably: severe chest pain, fever and chills, wounds that do not heal, and death. As MRSA is commonly spread through skin-to-skin contact, and is now resistant to first-line antibiotics, the disease has become a serious problem in hospitals and long-term care facilities.

⁹ *Facts About Antibiotic Resistance*, INFECTIOUS DISEASES SOCIETY OF AM., http://www.idsociety.org/IDSA/Site_Map/Topics_of_Interest/Antimicrobial_Resistance/Public_Policy/Facts_about_Antibiotic_Resistance.aspx (last visited Mar. 3, 2013).

¹⁰ *Id.*

¹¹ *See infra* Part II(C)(2).

¹² *See* INFECTIOUS DISEASES SOCIETY OF AM., *supra* note 9.

¹³ STUART B. LEVY, *THE ANTIBIOTIC PARADOX: HOW MIRACLE DRUGS ARE DESTROYING THE MIRACLE* 141–42 (1992). While the overuse of antibiotics by humans themselves also contributes to the problem, such a discussion is beyond the scope of this Note.

¹⁴ *Id.* at 137–38.

¹⁵ *See* LEVY, *supra* note 13.

¹⁶ *See infra* Part II(B).

¹⁷ *See infra* Part III(A)–(B).

¹⁸ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 11 CIV. 3562 THK, 2012 WL 983544 (S.D.N.Y. Mar. 22, 2012).

livestock.¹⁹ The FDA has resisted, however, pointed out the detriment that an outright ban would have on our modern factory farming system and preferring to allow large farms to solve the problem themselves.²⁰ The FDA appealed the District Court's ruling, and the Second Circuit reversed the decision in July 2014.²¹ While this reversal may mean the FDA is not legally obligated to continue withdrawal proceedings, the case has brought an important health threat to the public's attention and has the potential to serve as a foundation for a reform movement.

New legislation is needed to reduce both the economic and social costs of subtherapeutic antibiotic use—taking into consideration the needs of farmers and the cost to the public of more expensive food. Even if the ruling had not been reversed, the ruling had several limitations. The ruling did not specify how the FDA must tackle the problem and only applied to a limited class of antibiotics.²² Accordingly, the economic and social costs of antibiotic resistance must be combated through congressionally mandated standards and requirements, mandatory FDA withdrawal of subtherapeutic antibiotic use in food animals, and procedural enforcement through the courts. These policies should be phased in and should consider costs to farmers and to the public.

Section II of this Note will provide background on the practices of the United States farming system, which fosters the creation of antibiotic-resistant bacteria. This section will also provide background on the detrimental effects that antibiotic resistance has on human health and will briefly describe the legal history of food and drug regulations. After establishing an informational foundation, Part III will elaborate on current laws and describe the legal authority of key players, before pointing out the shortcomings in current animal feed policy and recommending the development of further regulation in this area. Additionally, Part III will propose new legislation to address social and economic costs, while also addressing the needs of farmers and meat consumers. This Note proposes a three-tiered approach for tackling the problem of antibiotic resistance based on congressional legislation, mandatory FDA standards, and proper court enforcement. Finally, this Note will conclude with a restatement of the essential issues and the way in which the proposed legislation will alleviate those problems.

¹⁹ *Id.* at ¶ 20.

²⁰ *Id.* at ¶¶ 11, 13. The opinion denying the FDA's request for a time extension provides that:

The Government contends that it will suffer irreparable injury if a stay is not granted because the significant resources the FDA will be required to expend in order to commence withdrawal proceedings will “compromise FDA's ability to pursue its goals with respect to antimicrobial resistance and animal drug licensing by diverting resources away from those programs... But the Government has not demonstrated that compliance would seriously threaten its mission or operations. Rather, it asserts that the diversion of resources will “compromise” the FDA's pursuit of goals relating to antimicrobial resistance.

Id.

²¹ *Natural Resources Defense Council, Inc. v. U.S. Food & Drug Admin.*, 2d Cir. No. 12-2106-CV L, 2014 WL 3636283 (July 24, 2014).

²² 11 CIV. 3562 THK, 2012 WL 983544 at ¶ 20.

II. BACKGROUND

Subtherapeutic antibiotic use²³ is necessary due to the existence of large factory farms, which keep profits high and meat prices low.²⁴ Factory farms pack a multitude of animals into small spaces where disease can spread quickly.²⁵ These close conditions make preventative disease treatment the only practical way to prevent mass epidemics.²⁶ Unfortunately, this practice has the adverse effect of creating antibiotic super bugs, which spread to other animals, the earth, and humans.²⁷ The federal government has attempted to ensure meat safety through legislation, the creation of executive agencies, and enforcement in the courts.²⁸ These efforts have fallen short.

A. *Factory Farming*

The vast majority of food animals are raised on factory farms.²⁹ Between 2002 and 2007, many small to medium sized farms gave way to massive factory farms,³⁰ largely due to a lack of antitrust and environmental regulations, as well as indirect subsidies to the farming industry.³¹ Factory farms enclose high concentrations of animals in small areas and unsanitary conditions in order to keep food production costs low and profits high.³² These cramped conditions are ripe for bacterial epidemics because disease can easily spread from animal to animal.³³ For these

²³ See *infra* Part II(B).

²⁴ Amy R. Sapkota et al., *What Do We Feed to Food-Production Animals? A Review of Animal Feed Ingredients and Their Potential Impacts on Human Health*, 115 ENVTL. HEALTH PERSP. 663, 663 (2007).

²⁵ *Id.*

²⁶ *Id.*

²⁷ See *infra* Part II(B).

²⁸ Robert Longley, *The U.S. Food Safety System – A Case of Shared Government Responsibilities*, USA TODAY (Sept. 20, 2013), http://usgovinfo.about.com/od/consumer_awareness/a/The-Us-Food-Safety-System.htm.

²⁹ See Sapkota, *supra* note 24.

³⁰ *Id.*

³¹ *Factory Farm Nation - How America Turned Its Livestock Farms into Factories*, FOOD & WATER WATCH (Nov. 2010), <http://www.factoryfarmmap.org/wp-content/uploads/2010/11/FactoryFarmNation-web.pdf>. Farm policy encouraged over-production of crops used in livestock feed, which artificially depressed the price of feed and indirectly subsidized factory farms. Additionally, unchecked mergers and acquisitions between the largest operations led to massive industry consolidation and made it more difficult for small or family farms to compete. Finally, the lack of environmental rules, the lack of animal rights legislation, and lax enforcement allowed farms to expand easily. *Id.*

³² *Factory Farm Definition*, Merriam Webster, <http://www.merriam-webster.com/dictionary/factory%20farm> (last visited Jan. 14, 2013).

³³ Henrik C. Wegener, *Antibiotics in Animal Feed and Their Role in Resistance Development*, 6 CURRENT OP. MICROBIOLOGY 439, 439 (2003).

reasons, the industry faces a fundamental problem: preventing the spread of disease among animals kept in close quarters.

During the 1950s, the food animal industry began experimenting with “nutritional factors” aimed at increasing animal growth and soon discovered that low doses of antibiotics increased growth.³⁴ As the full implications of broad antibiotic use remained unknown in the 1950s,³⁵ antibiotics were classified as “nutritional” and premixed into food without a prescription at low, subtherapeutic levels.³⁶ Subtherapeutic doses are generally about ten to one hundred times lower than therapeutic doses, are prescribed over a longer period of time, and are not directed against a particular microorganism.³⁷ Instead, subtherapeutic doses broadly protect against infection and promote growth so that animals can be slaughtered faster.³⁸

Today, in addition to antibiotics, premixed animal feed may contain hormones, animal waste products, and parts of animals not fit for human consumption.³⁹ The amount of antibiotics present in animal feed has steadily increased to almost therapeutic levels, as the food animals build up resistance to the lower doses.⁴⁰ Antibiotic resistance has been scientifically linked to across-the-board usage of subtherapeutic levels of antibiotics in food animals.⁴¹

³⁴ See LEVY, *supra* note 13, at 137–38. The reason antibiotics increase growth is unknown. Some believe that antibiotics have a hidden nutritional value, such as the ability to metabolize energy more efficiently; however, the nutritional value theory has been largely discredited. The most popular theory is that antibiotics either suppress the growth of certain bacteria that compete for needed nutrients, or that antibiotics inhibit production of proteins involved in adhesion and bacterial colonization of the intestinal tract. This allows animals to gain the full nutritional value of their feed but interferes with their normal processes which could have unknown adverse effects. *Id.*

³⁵ *Id.*

³⁶ See *id.* at 137.

³⁷ See *id.* at 137–38.

³⁸ *Id.*

³⁹ Nicholas D. Kristof, *Arsenic in Our Chicken?*, N.Y. TIMES (April 4, 2012), <http://www.nytimes.com/2012/04/05/opinion/kristof-arsenic-in-our-chicken.html?partner=rssnyt&emc=rss>. While testing for antibiotics in poultry raised on factory farms, researchers also found arsenic, caffeine, a banned class of antibiotics, the active antihistamine in Benadryl, the active ingredient in Tylenol, and an antidepressant, which is the active ingredient in Prozac. *Id.*

⁴⁰ See LEVY, *supra* note 13, at 142. In the 1950s, 5–10 parts per million of tetracycline were effective to increase growth and prevent infection. Today 50–200 parts per million are used to elicit the same effect. Additionally, multiple resistances can result from chronic use of one antibiotic. These trends seem to indicate that doses will eventually reach almost therapeutic levels, and soon higher doses or new antibiotics will be needed to treat animals who are actually sick. See *id.* at 142–43.

⁴¹ See GUIDANCE #209, *supra* note 7, at 13.

B. The Current Health Threat: Antibiotic Resistance

Subtherapeutic antibiotic use in food animals greatly increases the presence of antibiotic-resistant bacteria in those animals. Antibiotics are drugs used to treat infections caused by bacteria.⁴² Although antibiotics are a great asset for treating illnesses, overuse leads to a phenomenon known as antibiotic resistance.⁴³ Antibiotic resistance can develop in humans or animals; however, since the vast majority of antibiotics are given to food animals, their bodies are the main breeding ground for antibiotic-resistant bacteria.⁴⁴ Animals' bodies contain both bacteria that can be treated by antibiotics and bacteria that have, through random chance, genetically mutated so that antibiotics are ineffective against them.⁴⁵ The latter type is known as antibiotic-resistant bacteria.⁴⁶

There is a positive correlation between the production of antibiotic-resistant bacteria and antibiotic use.⁴⁷ When a food animal is given an antibiotic, the antibiotic kills off the non-resistant bacteria and the stronger, antibiotic-resistant bacteria remain.⁴⁸ Once their weaker competition has been eliminated, these resistant bacteria have a perfect breeding ground in which to multiply.⁴⁹ Bacteria's rapid multiplication and high mutation rates are heightened by a bacteria free area, leading to increases in the antibiotic-resistant presence.⁵⁰ Tetracyclines, one type of antibiotic most commonly used in animal feed, can affect a large variety of bacteria and select for resistance to themselves and other antibiotics.⁵¹ When food animals are

⁴² An antibiotic is a type of antimicrobial drug. According to the FDA:

Antimicrobial drugs are used to treat infections caused by microorganisms. The term "antimicrobial" refers broadly to drugs with activity against a variety of microorganisms, including bacteria, viruses, fungi, and parasites (such as malaria). The term "antibacterial" refers to drugs with activity against bacteria in particular. Another term commonly used to describe an antibacterial drug is "antibiotic." This term refers to a natural compound produced by a fungus or another microorganism that kills bacteria that cause disease in humans or animals. Some antibacterial drugs are synthetic compounds; i.e., they are not produced by microorganisms. Though these do not meet the technical definition of antibiotics, they are referred to as antibiotics in common usage.

Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 111th Cong. 33 (2010) (statement of Joshua M. Sharfstein, Principal Deputy Comm'r, Food & Drug Admin), <http://www.fda.gov/NewsEvents/Testimony/ucm219015.htm>.

⁴³ *Id.* at 34–35.

⁴⁴ *See* LEVY, *supra* note 13, at 140–41.

⁴⁵ *See id.*

⁴⁶ *See id.* at 141.

⁴⁷ *See id.* at 142.

⁴⁸ *See id.* at 140.

⁴⁹ *See id.*

⁵⁰ *See id.* at 140–41.

⁵¹ *See id.* at 143.

regularly given preventative doses of antibiotics, the opportunities for harmless bacteria to mutate into antibiotic-resistant bacteria are amplified.⁵²

Antibiotic-resistant bacteria are transferred from food animals to humans in several ways. The most obvious transfer occurs during human consumption of food animals containing antibiotic-resistant bacteria.⁵³ Past Salmonella and *E. coli* outbreaks provide evidence of animal to human transmission through consumption.⁵⁴ During these outbreaks, massive distributions of infected meat led to large food recalls, several deaths, and many more illnesses which were difficult to treat.⁵⁵ Salmonella is a common infection in animals that was largely treatable with antibiotics prior to 1970.⁵⁶ However, the Salmonella strains that are prevalent today are often incapable of being treated with the normal antibiotic treatment.⁵⁷ Salmonella is now largely resistant to two to five antibiotics, depending on the strain, and once the bacteria get into a human's bloodstream and multiply, the bacteria can cause high fevers, diarrhea, and death.⁵⁸ Bacteria such as Salmonella, when transferred to humans through the consumption of meat, can cause irreparable harm.⁵⁹

Antibiotic-resistant bacteria can also spread in more indirect ways. Several studies have shown a higher presence of human carriers of antibiotic-resistant bacteria in areas near farms that use growth promoters in their animals.⁶⁰ Stuart B. Levy, an expert in the field of antibiotic resistance, commissioned a study to test this

⁵² See *id.* at 142.

⁵³ See *id.* at 143.

⁵⁴ See *id.* at 148–150. In 2011, two separate Salmonella outbreaks led to massive food recalls, one of ground turkey originating from the Cargill Meat Solutions Corporation in Arkansas, and one of ground beef from a Maine based grocery store. The Salmonella strains present in ground turkey were resistant to three antibiotics including tetracycline and the ground beef strain was resistant to at least four different antibiotics. *Multistate Outbreak of Human Salmonella Heidelberg Infections Linked to Ground Turkey*, CTRS. FOR DISEASE CONTROL & PREVENTION ONLINE NEWSROOM, <http://www.cdc.gov/SALMONELLA/HEIDELBERG/111011/INDEX.HTML> (last visited Jun. 24, 2014); *Multistate Outbreak of Human Salmonella Typhimurium Infections Linked to Ground Ground Beef*, CTRS. FOR DISEASE CONTROL & PREVENTION ONLINE NEWSROOM, <http://www.cdc.gov/salmonella/typhimurium-groundbeef/122011/> (last visited Jun. 24, 2014).

⁵⁵ See LEVY, *supra* note 13, at 150–53.

⁵⁶ See *id.* at 150.

⁵⁷ See *id.*

⁵⁸ See *id.* Salmonella outbreaks in four Midwestern states occurred when infected beef cattle were packed, sold, and consumed. A study by the Centers of Disease Control concluded that many people who ate infected meat were unaffected since the bacteria concentration was small. However, “[t]hose who were taking antibiotics to which the Salmonella were resistant . . . provided a perfect environment for the resistant strain to multiply, leading to over clinical disease.” See *id.* at 152.

⁵⁹ See *id.*

⁶⁰ See *id.* at 143–44.

phenomenon as far back as 1975.⁶¹ On a small family farm, Levy's research team fed some chickens antibiotic-laced feed and fed other chickens feed without antibiotics.⁶² Within forty-eight hours, the chickens given the antibiotic-laced feed began excreting tetracycline-resistant *E. coli*, and after three months the *E. coli* was also resistant to four other antibiotics.⁶³ Moreover, the farm family began displaying an "increasing number of fecal *E. coli* resistant to multiple antibiotics."⁶⁴ Levy found this evidence demonstrative of the way bacteria can spread from food animals to the environment and other humans through manure.⁶⁵ Bacteria in manure sink into the ground, and the ground water, and are transferred to humans through touch or consumption.⁶⁶ Bacteria may also be transferred to farm workers through the workers' mouth, nose, or throat when they come into contact with food animals.⁶⁷ These workers then spread the bacteria to other humans through day to day interactions.⁶⁸ Once antibiotic-resistant bacteria develop in animals, they can easily be spread around a farm and into the general population, thereby posing a serious threat to human health.⁶⁹

C. Costs of Factory Farms

1. Economic Costs

Antibiotic resistance costs the American public billions of dollars per year.⁷⁰ The spread of antibiotic-resistant bacteria seems inevitable when one considers the sheer amount of meat consumed by Americans. In 2007, the average American ate 273 pounds of meat.⁷¹ In order to satisfy the demand for meat, 10.378 billion U.S. land animals were slaughtered for food that year—roughly twenty-five percent of all animals killed for food in the world.⁷² Although this number has decreased slightly

⁶¹ *Hearing Before the Subcomm. on Health of the U.S. House Committee on Energy and Commerce*, 111th Cong. (2010) (statement of Dr. Stuart Levy, Distinguished Professor of Molecular Biology & Microbiology and of Medicine), available at <http://www.tufts.edu/med/apua/policy/7.14.10.pdf>.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Daily animal fecal excretions can be 5–400 times greater than humans. This greatly increases the transmission of antibiotic-resistant bacteria from animals to the environment and humans. Although some antibiotic resistance is caused by human overuse of antibiotics, subtherapeutic use in animals can have a much larger effect. *See* LEVY, *supra* note 13, at 143.

⁶⁶ *See id.*

⁶⁷ *See id.* at 144.

⁶⁸ *See id.* at 144–45.

⁶⁹ *See id.* at 147–48.

⁷⁰ Evelyn B. Pluhar, *Meat and Morality: Alternatives to Factory Farming*, 23 J. AGRIC. ENVTL. ETHICS 455, 456 (2010).

⁷¹ *Id.*

⁷² *Id.*

since 2007, in 2011 the average American consumed 185 pounds of chicken, turkey, pork and beef,⁷³ proving that the American appetite for meat is still substantial.⁷⁴ This massive appetite, combined with an increase in antibiotic resistance, has been costly for the American public.

Antibiotic resistance greatly increases healthcare costs due to longer hospital stays and the costs of alternative disease treatments.⁷⁵ In 1998, the National Academy of Sciences Institute of Medicine noted that antibiotic-resistant bacteria increased US health care costs by a minimum of four to five billion dollars annually,⁷⁶ while in 2009 the total health care cost of antibiotic-resistant infections was estimated to be over \$20 billion annually.⁷⁷ In contrast, eliminating antimicrobials would only cost each American five to ten dollars per year,⁷⁸ thereby saving a total of 1.3 to 3.7 billion dollars annually.⁷⁹ To further break down the cost, a 2005 analysis found that a hospital stay was \$6,000 to \$10,000 more expensive for a person infected with a resistant bacterium as opposed to an antibiotic-susceptible

⁷³ Allison Aubrey, *The Average American Ate (Literally) A Ton This Year*, THE SALT (Dec. 31, 2011, 7:39 AM), <http://www.npr.org/blogs/thesalt/2011/12/31/144478009/the-average-american-ate-literally-a-ton-this-year>.

⁷⁴ On average, each American consumes around 110 grams of protein a day, about twice the federal government's recommended allowance; of that, about 75 grams come from animal protein. The recommended level is itself considered by many dietary experts to be higher than necessary. It's likely that most of us would do well on around 30 grams of protein a day, virtually all of it from plant sources. See Mark Bittman, *Rethinking the Meat-Guzzler*, N.Y. TIMES (Jan. 27, 2008), http://www.nytimes.com/2008/01/27/weekinreview/27bittman.html?pagewanted=all&_r=0; see also *infra* Part III(C) (arguing that even if eliminating the root cause of antibiotic resistance means meat prices will rise, Americans can combat those costs and be healthier by eating less meat.).

⁷⁵ CTR. FOR DISEASE CONTROL AND PREVENTION, APPROPRIATE ANTIBIOTIC USE – SAVES LIVES, SAVES MONEY, MAKES SENSE (2010), available at <http://www.cdc.gov/getsmart/healthcare/resources/factsheets/pdf/antibiotic-use.pdf>.

⁷⁶ INFECTIOUS DISEASES SOC'Y OF AM., BAD BUGS, NO DRUGS: AS ANTIBIOTIC DISCOVERY STAGNATES A PUBLIC HEALTH CRISIS BREWS (2004), available at http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Antimicrobial_Resistance/10x20/Images/Bad%20Bugs%20no%20Drugs.pdf.

⁷⁷ ALLIANCE FOR THE PRUDENT USE OF ANTIBIOTICS, THE COST OF ANTIBIOTIC RESISTANCE TO U.S. FAMILIES AND THE HEALTH CARE SYSTEM (2010), available at http://www.tufts.edu/med/apua/consumers/personal_home_5_1451036133.pdf.

⁷⁸ THE PEW COMM'N ON INDUS. FARM ANIMAL PRODUCTION, PUTTING MEAT ON THE TABLE: INDUSTRIAL FARM ANIMAL PRODUCTION IN AMERICA 10 (2008), available at http://www.ncifap.org/_images/PCIFAPFin.pdf.

⁷⁹ The U.S. population in 1999 was 272,690,813 and the estimated cost per person of eliminating antimicrobials was \$5 to \$10 per person. *Id.*; POPULATION ESTIMATES PROGRAM, POPULATION DIVISION, U.S. CENSUS BUREAU, ST-99-1, STATE POPULATION ESTIMATES AND DEMOGRAPHIC COMPONENTS OF POPULATION CHANGE: JULY 1, 1998 TO JULY 1, 1999 (1999), <http://www.census.gov/population/estimates/state/st-99-1.txt>. Accordingly, the total cost of eliminating antimicrobials in 1999 was between \$1.3 and \$2.7 billion. This figure is \$1.3–\$3.7 billion less than the \$4–\$5 billion antimicrobials raise costs by.

infection.⁸⁰ Developing new antibiotics to replace those to which the new strands are resistant will require around ten years and an investment of \$800 million to \$1.7 billion.⁸¹

2. Social Costs

The greatest social cost is the suffering and death caused by antibiotic-resistant infections. Otherwise healthy adults and children can enter hospitals for routine procedures and die from MRSA and other antibiotic-resistant infections now prevalent in hospitals.⁸² In 2004, IDSA estimated that “[a]bout 2 million people acquire bacterial infections in U.S. hospitals each year and 90,000 die as a result.”⁸³ These diseases are even more dangerous to individuals with already compromised immune systems.⁸⁴ Seventy percent of hospital-acquired infections are resistant to at least one antibiotic.⁸⁵ When a patient has an antibiotic-resistant infection, hospital stays are extended by an average of 6.4 to 12.7 days.⁸⁶ “During this time, patients are unable to work and . . . lose wages.”⁸⁷ Increased hospital stays cost U.S. households over thirty-five billion dollars annually in the form of lost wages.⁸⁸ The increased prevalence of antibiotic-resistant infections can transform hospitals, the places individuals go for health treatments, into health threats due to the presence of MRSA and other infections.

In addition to their negative effects on human health, factory farms have a negative impact on the environment and make life unpleasant for the animals themselves. “Globally, greenhouse gas emissions from all livestock operations account for 18% of anthropogenic greenhouse gas emissions, exceeding those from the transportation sector.”⁸⁹ Massive amounts of greenhouse gases are created due to improper management of animals, manure, and soil on factory farms.⁹⁰ Moreover, the amount of waste produced by mass confinement is a problem in and of itself.⁹¹ The waste must be disposed of properly, and over-fertilization of pastures can lead to

⁸⁰ Sara E. Cosgrove et al., *The Impact of Methicillin Resistance in Staphylococcus Aureus Bacteremia on Patient Outcomes: Mortality, Length of Stay, and Hospital Charges*, 26 INFECTION CONTROL & HOSP. EPIDEMIOLOGY 166, 171 (2005).

⁸¹ See INFECTIOUS DISEASES SOC’Y OF AM., *supra* note 76, at 3. The report also notes the incentive for pharmaceutical companies to produce new, more lucrative drugs that treat chronic conditions as opposed to developing new, less lucrative, antibiotics. For example, “[i]n 2002, out of 89 new drugs, no new antibiotics were approved.” *Id.* at 5.

⁸² *Id.* at 5.

⁸³ *Id.* at 5.

⁸⁴ *Id.* at 13.

⁸⁵ *Id.* at 3.

⁸⁶ ALLIANCE FOR THE PRUDENT USE OF ANTIBIOTICS, *supra* note 77, at 2.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ PEW COMM’N ON INDUS. FARM ANIMAL PROD., *supra* note 78, at 27.

⁹⁰ *Id.*

⁹¹ *Id.* at 23.

surface and ground water contamination with extra nutrients, which the land cannot absorb.⁹² Water and other energy resources are also expended at a much higher rate on factory farms.⁹³ These cramped and unsanitary conditions are particularly unpleasant for the animals, whose lives are truly unpleasant and short.⁹⁴ Chickens are debeaked and declawed, and pigs are kept in small confinement crates and can drop dead from the stress of being confined.⁹⁵ While cattle are generally allowed to graze freely, cattle raised for veal are fed a poor diet to stop certain types of development and placed in stalls too small for them to move in, hindering all muscle development.⁹⁶ The substantial economic and social effects of factory farming and antibiotic resistance make the factory farming model unsustainable, costly, and detrimental to both human and animal health.⁹⁷

D. Overview of Food and Drug Regulations

While factory farming methods are not directly regulated, the federal government does play a role in regulating meat,⁹⁸ milk,⁹⁹ and eggs¹⁰⁰ before they are consumed by Americans. These regulations have been strengthened over time, but are far from perfect. Federal regulation of food and drugs started with the signing of the Food and Drugs Act (Wiley Act) on June 30, 1906 by President Roosevelt.¹⁰¹ Administered by the Bureau of Chemistry under the federal commerce clause power,¹⁰² the Act prohibited the interstate transportation of unlawful food and drugs.¹⁰³ The law sought

⁹² *Id.*

⁹³ *Id.* at 27, 29. Water resources are stressed by possible contamination and the sheer amount of water necessary to keep the animals hydrated. *Id.* at 27. Fossil fuels are also expended at a much higher rate along with industrial fertilizers and other synthetic chemicals. *Id.* at 29.

⁹⁴ Barbra O'Brien, Comment, *Animal Welfare Reform and the Magic Bullet: The Use and Misuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 414–21 (1996).

⁹⁵ *Id.* at 415–19. This is called porcine stress syndrome. *Id.* at 418–19. Pigs are stressed and confused by crowding and being ushered from pen to pen. *Id.* at 419. This can overwhelm the animals' senses and lead them to bite the tails of other pigs or accidentally trample their own young. *Id.* at 418–19.

⁹⁶ *Id.* at 420–21.

⁹⁷ See generally THE PEW COMM'N ON INDUS. FARM ANIMAL PROD., *supra* note 78.

⁹⁸ 7 C.F.R. pt. 54 (West 2014).

⁹⁹ 21 C.F.R. pt. 131 (West 2014).

¹⁰⁰ 7 C.F.R. pt. 57 (West 2014).

¹⁰¹ John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN. (Jan. 23, 2014), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm>; see also *FDA History - Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (June 18, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm>; see also Federal Food and Drugs (Wiley) Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

¹⁰² U.S. CONST. art. I, § 8, cl. 3; Wiley Act § 4.

¹⁰³ *FDA History - Part I*, *supra* note 101.

to promote proper labeling and also prohibited the addition of any ingredients that would substitute for food, conceal damage, pose a health hazard, or constitute a filthy or decomposed substance.¹⁰⁴ However, the head of the Bureau of Chemistry, Harvey Washington Wiley, often clashed with Secretary of Agriculture James Wilson due to Wiley's skepticism of chemical additives.¹⁰⁵ In an effort to undercut his administrative authority, Wilson created the Board of Food and Drug Inspection in 1907 to establish agency policy and enforce the law.¹⁰⁶ During this time, Congress passed numerous other laws governing specific foods, and the Bureau of Chemistry developed many specific unofficial standards.¹⁰⁷ This confusion made it difficult for manufacturers to comply and for the courts to know which standards to enforce.¹⁰⁸

1. The Food, Drug, and Cosmetic Act

The confusion over regulations left a clear need for legally mandated, specific, and uniform standards. This gap was filled by the Federal Food, Drug, and Cosmetic Act (FFDCA) enacted in 1938. The FFDCA gave the U.S. Food and Drug Administration (FDA) the authority to oversee the safety of food, drugs, and cosmetics.¹⁰⁹ The FFDCA sought to fix the shortcomings of the Wiley Act by meeting the need for legally mandated quality and identity standards for foods and by expanding the authority to regulate false claims.¹¹⁰ The FFDCA helped prevent harmful drugs from entering the market by mandating pre-market approval of all drugs and formally authorizing factory inspections.¹¹¹ Additionally, the Act provided the FDA with injunctive abilities and enforcement tools.¹¹²

Since its passage, the FFDCA has been supplemented by several amendments. The 1958 Food Additives Amendment expanded the FDA's regulatory authority over animal food additives and drug residues in animal-derived foods.¹¹³ Under the

¹⁰⁴ *See id.*

¹⁰⁵ *See id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *FDA History - Part II: The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Sept. 24, 2012), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>; *see also* Federal Food, Drug, and Cosmetic Act § 1, 21 U.S.C.A. § 301 (West 2014).

¹¹⁰ *See FDA History - Part II, supra* note 109.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ The term "food additive" is defined in 21 U.S.C.A. § 321(s) (West 2014), in pertinent part, as follows:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or

Food Additives Amendment, drugs used in feed were considered additives.¹¹⁴ “The Animal Drug Amendments of 1968 combined veterinary drugs and additives into a unified approval process under the authority of the Bureau of Animal Drugs in the FDA”¹¹⁵ The DES proviso of 1962 was a step backwards for food policy, permitting the use of possible carcinogens in food animals as long as residues did not remain in edible tissues.¹¹⁶ As determining that no residue remained in tissues proved impossible, the provision was amended to allow for an “insignificant amount of

experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include . . . a new animal drug.

21 U.S.C.A. § 321(s) (West 2014).

¹¹⁴ *FDA History - Part IV: Regulating Cosmetics, Devices, and Veterinary Medicine After 1938*, U.S. FOOD & DRUG ADMIN. (June 18, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055137.htm>.

¹¹⁵ *Id.*; see also Animal Drug Amendments of 1968, Pub. L. No. 90-399, § 101, 82 Stat. 342, 343; 21 U.S.C.A. § 348 (West 2014). The 1968 Animal Drug amendments were “the product of the work over four sessions of Congress of interested industry groups representing manufacturers and feed mill operators, veterinarians, and the [FDA]. It provides not only benefits for industry, but through improved procedures, benefits for the consumer in the more efficient and less costly production of [food].” H.R. REP. NO. 90-875, at 119 (1967); see also 21 U.S.C.A. § 360b (West 2014); Minor Use and Minor Species Animal Health Act of 2004, Pub. L. No. 108-282, 118 Stat. 891.

¹¹⁶ See *FDA History - Part IV, supra* note 114. The F.D.C.A. contains three anticancer (Delaney) clauses: 21 U.S.C.A. § 348(c)(3)(A) (West 2014); 21 U.S.C.A. § 360b(d)(1)(I) (West 2014); 21 U.S.C.A. § 379e(b)(5)(B) (West 2014). The Federal Register describes the changes in the DES proviso as follows:

each clause also contains an exception, termed the “Diethylstilbestrol (DES) Proviso,” that permits administration of such substances to food-producing animals where: (1) The food additive, color additive, or new animal drug will not adversely affect the animal and (2) no residue of the food additive, color additive, or new animal drug will be found in any edible portion of that animal by a method of examination prescribed or approved by the Secretary of Health and Human Services by regulation . . . S₀ is currently defined as the concentration of the compound of carcinogenic concern in the total diet of test animals that corresponds to a maximum lifetime risk of cancer to the test animals of 1 in 1 million . . . FDA will assume that the S₀ corresponds to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people. The concentration, derived from the S₀, of residues of carcinogenic concern in a specific edible tissue is termed the S_m. This rule changes the definition of S₀ so that it is primarily defined as “the concentration of a residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to the human consumer . . .” and secondarily as “the concentration of test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million.” The change in this rule to the definition of S₀ is intended to enable the Center for Veterinary Medicine to consider allowing the use of alternative procedures to satisfy the DES Proviso without requiring the development of a second, alternative, set of terminology.

Regulation of Carcinogenic Compounds in Food-Producing Animals, 77 Fed. Reg. 50,591 (Aug. 22, 2012) (citation omitted) (to be codified at 21 C.F.R. pt. 500).

residue.”¹¹⁷ The FDA has discretion to prohibit the use of an additive if there is no reliable method to measure and confirm whether the additive contains carcinogenic residues at or above the no residue level.¹¹⁸ These requirements were further broadened in 2012.¹¹⁹

The Food Safety Modernization Act (FSMA),¹²⁰ signed into law by President Obama on January 4, 2011,¹²¹ constitutes the most recent expansion of FDA powers. The law institutes sweeping reform and aims to ensure a safe food supply by shifting the focus from contamination response to contamination prevention.¹²² The FSMA provides the FDA with additional enforcement authority to promote compliance before problems occur and to more effectively respond to them when they do.¹²³ The law also directs the FDA to build an integrated national food safety system in partnership with state and local authorities and puts more responsibility on food producers to institute plans to make food safer.¹²⁴ FSMA provides the FDA with additional enforcement and prevention tools which, if properly utilized, could improve food safety.

2. The Food and Drug Administration

The FDA is charged with broad responsibility to regulate food, drugs, and cosmetics. The FDA is an executive agency within the Department of Health and Human Services at the same administrative level as the Center for Disease Control (CDC) and National Institute of Health (NIH).¹²⁵ The Agency plays a regulatory and policy role in promoting the public health by ensuring that “foods are safe, wholesome, sanitary and properly labeled,” and that “human and veterinary drugs are safe and effective.”¹²⁶ In addition to drugs used on humans, the FDA has a role in regulating drugs used in food animals before the animals are consumed.¹²⁷ Additionally, the Agency protects the financial interests of consumers by keeping

¹¹⁷ Regulation of Carcinogenic Compounds in Food-Producing Animals, 77 Fed. Reg. at 50,591.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Food Safety Modernization Act, 21 U.S.C. §§ 111–353 (West 2012).

¹²¹ *Id.*

¹²² *Food Safety Legislation Key Facts*, FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM263777.pdf> (last visited April 16, 2014).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *HHS Organizational Chart*, DEP’T OF HEALTH & HUMAN SERVICES, <http://www.hhs.gov/about/orgchart/#text> (last visited April 16, 2014).

¹²⁶ Food and Drug Administration, 21 U.S.C.S. § 393 (West 2012).

¹²⁷ *About the Center for Veterinary Medicine*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm> (last visited April 16, 2014).

food and drugs reasonably priced and readily available.¹²⁸ While the Agency has consistently relied on prevention and industry guidance, rather than periodic prosecutions, to promote health, legal and equitable remedies can be enforced both internally and through the courts.¹²⁹ Outsiders may also propose FDA regulatory action, which can be adopted or rejected.¹³⁰ The FDA's role in food policy and its power to enforce compliance have steadily expanded since the Agency's creation.

III. ARGUMENT

A. *Current Laws*

The authority to regulate animal feed and food animals is spread between the states, Congress, and several executive agencies. The manufacturing of animal feed is regulated by both state and federal agencies.¹³¹ FDA inspectors have authority under the FFDCFA to inspect the facilities of feed manufactures or to contract inspection duties out to state agencies, which conduct inspections in accordance with FDA procedures.¹³² All animal feed that contains a new animal drug is regulated by the FDA through the issuance of feed mill licenses.¹³³ The Animal Drug User Fee Act authorizes the FDA to collect fees for animal drug applications and other services and to channel those funds to collect information about antimicrobial drug use.¹³⁴ The Act also requires antimicrobial drug sponsors to self-report the amount of drugs sold annually and to provide the public with a copy of the report.¹³⁵

¹²⁸ “The FFDCFA and its legislative history make it clear that Congress intended the statute to protect the financial interests of consumers as well as their health.” *See United States v. Lane Labs*, 427 F.3d 219 (3rd Cir. 2005).

¹²⁹ *See, e.g.*, Current Good Manufacturing Practices for Finished Pharmaceuticals 21 C.F.R. § 211 (West 2012); *see also* 21 U.S.C.A. § 360b (West 2012). FDA regulations focus on preventing unsafe drugs from entering the market through a mandatory approval process and good manufacturing practice recommendations, which help inform manufacturers of minimum standards which must be met before a drug can enter the market.

¹³⁰ If an idea originates outside the FDA, it must get a sponsor within the FDA or a petition must be initiated, which can be filed by any person. 21 C.F.R. § 10.30 (West 2012). The FDA may call for specific adoption of a draft proposal by the Agency in the form of a proposed regulation. The regulation is circulated within the Agency and, if classed as “significant,” the FDA is required by the order to examine alternatives, study future cost consequences, and otherwise prepare itself to justify the proposed regulatory actions. *Id.*

¹³¹ There are several types of animal feed manufacturers. Feed mills are plants that combine ingredients, which may or may not include antibiotics, to produce an appropriate mix for a particular age or species of animal. There are operations that feed ruminant animals, rendering plants which process animals unfit for human consumption, and protein blenders who blend processed animal and vegetable protein. While the FDA is responsible for overseeing these manufacturers, states often have added regulations. GENERAL ACCOUNTING OFFICE, GOV'T ACCOUNTABILITY OFFICE, GAO/RCED-00-255, FOOD SAFETY: CONTROLS CAN BE STRENGTHENED TO REDUCE THE RISK OF DISEASE LINKED TO UNSAFE ANIMAL FEED (2000), available at <http://www.gao.gov/new.items/rc00255.pdf>.

¹³² *Id.* at 6–7.

¹³³ *Id.* at 6.

¹³⁴ Animal Drug User Fee Act of 2003, Pub. L. No. 108-130, 117 Stat. 1361; *see also*, Animal Drug User Fee Program – Revision and Extension, Pub. L. No. 110-316, 122 Stat. 3509; *see also*, *ADUFA Law*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/User>

Several other executive agencies also play a role in the regulation of animal feed. The Environmental Protection Agency sets legal limits on the amount of pesticide residue in or on animal feed, and the FDA enforces these limits.¹³⁶ The Department of Transportation regulates the transportation of animal feed, and the United States Department of Agriculture's Animal and Plant Health Inspection Service regulates the health and care of food animals.¹³⁷ Finally, the CDC is charged with monitoring, investigating, controlling, and preventing public health problems.¹³⁸

Within the FDA, the Center for Veterinary Medicine (CVM) ensures that animal drugs and medicated feeds are safe and effective for their intended uses and that food from treated animals is safe for human consumption.¹³⁹ The CVM approves new animal drugs which have been shown to be safe and monitors drug use through surveillance and compliance programs.¹⁴⁰ Animal feed must be "pure and

Fees/AnimalDrugUserFeeActADUFA/ucm042890.htm (last visited Jan. 26, 2013). ADUFA was originally passed in 2003 and was renewed on August 14, 2008 by President Bush. As the FDA explains:

[t]he new amendments extend ADUFA until 2013. ADUFA amends the Food, Drug and Cosmetic Act to authorize FDA to collect fees to enhance the performance of the new animal drug review process and ensure that new animal drug products are safe and effective for animals as well as for the public with respect to animals intended for food consumption In addition, this reauthorization encourages increased communications between FDA and industry, and also provides for improvements to the information technology infrastructure of animal drug review, providing a tool which enables industry to submit drug applications electronically and gives reviewers the ability to evaluate those applications online. The reauthorization of ADUFA will generate \$98 million in user fees over five years (FY 2009 – FY 2013).

Id.

¹³⁵ See *ADUFA Law*, *supra* note 134.

¹³⁶ See GOV'T ACCOUNTABILITY OFFICE, *supra* note 131; see also 21 U.S.C.A. § 346a (West 2013).

¹³⁷ See GOV'T ACCOUNTABILITY OFFICE, *supra* note 131. The U.S.D.A. is also responsible "for improving agricultural productivity while contributing to the nation's economy and public health." *Id.*

¹³⁸ *Id.*

¹³⁹ See FOOD & DRUG ADMIN., *supra* note 127.

¹⁴⁰ The United States General Accounting Office has written a memo pointing out some of the shortcomings with these current regulations. The memo states, in pertinent part:

FDA has taken some actions to better ensure the safety of animal feed, but problems such as lack of awareness of FDA's regulation, delays in issuing a new FDA regulation to strengthen controls over the bacterial contamination of feed, and the Department of Transportation's failure to issue regulations for the safe transport of animal feed, could lead to human illnesses. In 1997, FDA issued a regulation to prevent BSE [(mad cow disease)] in the United States. To assess compliance with this regulation, FDA and state inspectors have visited over 9,100 firms . . . nearly 1,700 firms were not aware of the regulation and thus could produce or use animal feed that was not in compliance.

See GOV'T ACCOUNTABILITY OFFICE, *supra* note 131.

wholesome, produced under sanitary conditions, truthfully labeled, without any harmful substances.”¹⁴¹ The CVM has worked closely with the interagency Task Force on Antimicrobial Resistance, composed of representatives from the FDA, the CDC, and the NIH,¹⁴² to research antibiotic resistance, monitor antibiotic resistance,¹⁴³ and develop industry guidances.¹⁴⁴ However, these studies have not been translated into action.

B. Shortcomings of Current Food Policy

1. Limits of FDA Action

The FDA is an executive administrative agency that shares powers with, and may be regulated by, all three branches of the federal government, as well as the Administrative Procedures Act (APA).¹⁴⁵ As an executive agency, the FDA was created by an enabling act of Congress¹⁴⁶ and may make rules regulating food and drugs within the scope of authority delegated.¹⁴⁷ It is subject to legislative oversight and often has to answer tough questions from Congress and consider Congress’s recommendations.¹⁴⁸ In addition to its legislative role, the FDA is an executive agency with the power to enforce compliance within its field, subject to presidential oversight.¹⁴⁹ Although the FDA possesses some internal judicial power, almost all administrative agency procedures are subject to review by the federal courts.¹⁵⁰ In

¹⁴¹ *FDA Related Laws, Regulations, and Guidances*, FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm052866.htm> (last visited April 16, 2014).

¹⁴² ROSEANN B. TERMINI, *FOOD AND DRUG LAW: FEDERAL REGULATION OF DRUGS, BIOLOGICS, MEDICAL DEVICES, FOODS, DIETARY SUPPLEMENTS, COSMETICS, VETERINARY AND TOBACCO PRODUCTS* 17 (5th ed. 2012).

¹⁴³ The taskforce monitored antimicrobial resistance through the National Antimicrobial Resistance Monitoring System (NARMS). NARMS monitors trends in antibiotic resistance, targeting key bacteria such as Salmonella and E. coli. The Agency gathers animals isolated from a variety of sources around the country and tests for antimicrobial resistance and then reports on their findings. *NARMS Program*, FOOD & DRUG ADMIN. (Sept. 8, 2010), <http://www.FDA.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059089.htm>.

¹⁴⁴ See TERMINI, *supra* note 142.

¹⁴⁵ *Id.* (Administrative agencies are sometimes called the fourth branch of government due to their excessive power and limited direct supervision.).

¹⁴⁶ The ceding of legislative rulemaking authority to an executive branch is justified under the Necessary and Proper Clause to ensure that food and drugs which are within interstate commerce are appropriately regulated. See U.S. CONST. art 1, § 8. Congress delegates this authority to the FDA through an enabling act. 21 U.S.C.A. 393b.

¹⁴⁷ See TERMINI, *supra* note 142, at 24.

¹⁴⁸ See *id.* at 22.

¹⁴⁹ *Id.* at 21.

¹⁵⁰ *Id.* at 21.

addition to case law, executive review, and congressional review, the FDA is governed by the APA, which has standardized procedures agencies must follow.¹⁵¹

Congressional oversight has had a detrimental effect on the FDA's formation of new animal feed policy. In 1977, the FDA announced its intent to withdraw approval of the use of certain antibiotics for growth promotion and feed efficiency, noting that such practices are detrimental to human health.¹⁵² The FDA issued legal notices of hearings, giving the public the opportunity to prove that the drugs were in fact safe.¹⁵³ However, no hearings or further action resulted, despite citizen petitions urging the Agency to follow through.¹⁵⁴ This abrupt shift in momentum was likely due to congressional pressure. During the 1970's and 1980's, congressional committees issued three reports which the FDA interpreted as requests to postpone the withdrawal hearings pending further research.¹⁵⁵ In response to these requests, the FDA commissioned more research instead of moving forward with hearings.¹⁵⁶ While the FDA has never said they postponed the hearings due to congressional requests, the FDA's dependence on Congressional funding, along with its reliance on Congress as a source of authority, provides a strong motive to take Congress's wishes into account.¹⁵⁷ The sequence of events suggests that congressional oversight has hindered, rather than supported, FDA policy.

Since 1977, the FDA has refused to take a firm stance on subtherapeutic antibiotic use, issuing interpretive rules on usage instead of substantive legally binding rules.¹⁵⁸ Executive agencies create three types of rules: substantive,

¹⁵¹ *Id.* at 18.

¹⁵² *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 132 (S.D.N.Y. 2012). The determination to withdraw approval was based upon the recommendations of a 1970 commission composed of members of the FDA, NIH, U.S. Dept. of Agriculture, and CDC, as well as industry members. In 1972, the task force concluded that: (1) subtherapeutic antibiotic use in animal feed favors the development of antibiotic resistance, (2) animals can pass these bacteria on to humans, (3) the number of bacteria resistant to multiple antibiotics has increased due to subtherapeutic use, (4) antibiotic-resistant bacteria has been found in meat, and (5) "the prevalence of antibiotic resistant bacteria in humans has increased." *Id.* The commission recommended "antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by the FDA and several specific drugs, including penicillin and tetracyclines, be reserved for therapeutic use . . ." *Id.* at 132-33.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ See *TERMINI*, *supra* note 142, at 22. Not only does Congress hold the "power of the purse" but they can also define the scope of the Agency's power through legislation. *Id.* Added complications arise as the FDA is one department within the Department of Health and Human Services and requests for additional funds must go through the department bureaucracy and the Office of Management and Budget. *Id.*

¹⁵⁸ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 132 (S.D.N.Y. 2012).

interpretive, and procedural.¹⁵⁹ Substantive rules are legally binding and enforceable regulations which define “the legal obligations and rights of those who are subject to the agencies authority.”¹⁶⁰ In contrast, interpretive rules have no binding legal effect and are merely suggestions to the industry.¹⁶¹ Instead of creating legally binding substantive rules, the FDA has issued a number of Guidances, a type of interpretive rule.¹⁶² Guidance for Industry #152 discusses a recommended approach for assessing the safety of antimicrobial new animal drugs.¹⁶³ The Guidance reaffirms the FDA’s belief that human exposure to antibiotic-resistant bacteria is harmful to human health and recommends that producers consider such risks when using antimicrobials.¹⁶⁴ However, the Guidance does not create any legally binding responsibilities or recommendations, and explicitly states that it “describes the Agency’s current thinking on the topic and should be viewed only as guidance, unless specific regulatory or statutory requirements are cited.”¹⁶⁵ Likewise, Guidance for the

¹⁵⁹ Procedural rules are largely defined in the A.P.A. to promote uniformity among executive agencies and will be further discussed in the next subsection. See NRDC, *infra* Part III(B)(2).

¹⁶⁰ See TERMINI, *supra* note 142, at 19.

¹⁶¹ See *id.* at 19.

¹⁶² U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE INDUSTRY #152: EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN (2003), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>. The guidance contains a clear disclaimer which reads as follows:

This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statute and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing the guidance. If you cannot identify the appropriate staff, call the appropriate number listed on the title page of this guidance.

Id.

¹⁶³ *Id.*

¹⁶⁴ *Id.* The guidance ranks certain antimicrobial agents by their importance to human medicine and asks that the critically important antimicrobials be used less frequently. The FDA also provides the following summary of the guidance:

FDA recommends that sponsors choosing to use this process:

- Prepare a hazard characterization (described in pages 7 through 8) and submit the characterization to the FDA for review.
- After review of the hazard characterization, FDA and the sponsor may discuss whether a risk assessment needs to be completed and, if so, what information is recommended for completion of the risk assessment.
- Prepare the risk assessment and submit the assessment to the FDA for review.
- Following review of the safety package as a whole, including the risk assessment, FDA will determine the risk estimation and associated risk management steps applicable to the proposed conditions of use for the antimicrobial new animal drug.

¹⁶⁵ *Id.* (The use of the word “should” in Agency guidance means that something is suggested or recommended, but not required).

Industry #209 explains the importance of the judicious use of antimicrobials, even going so far as to state “the use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for animal health.”¹⁶⁶ This Guidance lacks legal authority and leaves room for loopholes. For example, a farmer could simply state that subtherapeutic use was medically necessary.¹⁶⁷ The fact that the food animal industry has largely ignored these Guidances, without any legal consequences, makes the need for binding substantive rules to combat antibiotic resistance apparent.

2. National Resources Defense Council v. Food and Drug Administration

One court recently attempted to force the FDA to take action by enforcing procedural rules.¹⁶⁸ In May 2011, the Natural Resources Defense Council (NRDC) filed a citizen petition seeking a court order to compel the FDA to follow through on the proceedings it initiated in 1977.¹⁶⁹ The court considered (1) whether the FDA was legally required to act and (2) whether the court could legally compel them to act.¹⁷⁰ The APA authorizes suits by “a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute.”¹⁷¹ Reviewing courts can compel agency action unlawfully withheld or unreasonably delayed under this provision if the action was a discrete action that the Agency was legally required to take.¹⁷² The United States District Court for the Southern District of New York granted the plaintiffs’ motion for summary judgment and held that, pursuant to 21 U.S.C. 360b(e)(1), once the FDA found that the subtherapeutic use of penicillin and tetracyclines in animal feed was unsafe to humans, the Agency was statutorily obligated to withdraw approval of those uses unless drug sponsors demonstrated the safety of those drugs.¹⁷³

¹⁶⁶ See GUIDANCE #209, *supra* note 7.

¹⁶⁷ *Id.* A firm definition of what constitutes subtherapeutic use could help to close some of these loopholes, although the FDA and the courts will likely play a role in determining if use is medically necessary, on a case-by-case basis.

¹⁶⁸ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012).

¹⁶⁹ *Id.* at 137.

¹⁷⁰ *Id.* at 137–38.

¹⁷¹ *Id.* at 131; *see also*, 5 U.S.C.A § 702 (West, 2014); *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 61 (2004).

¹⁷² NRDC, 884 F. Supp. 2d at 138–40. Limiting court review to discrete actions serves an important policy purpose as it “precludes a court from authorizing ‘broad programmatic attack[s]’” on agency policy, and the limit to legally required actions ensures that a court will not interfere with an agency’s discretionary functions. *Id.* (quoting *SUWA*, 542 U.S. at 64–65). Here, the court found that once an animal drug was deemed unsafe, several discrete actions were required including issuing notice of intent to withdraw approval, announcing the opportunity for hearing, holding a hearing, and finally withdrawing approval.

¹⁷³ *Id.* at 151.

The 1977 withdrawal procedures were initiated based on the FDA's findings that the use of certain drugs was unsafe for humans pursuant to 21 U.S.C. 360b(e)(1).¹⁷⁴ Guidance #152 and Guidance #209 described the serious health threat that antimicrobials pose and suggested non-binding recommendations for combatting antibiotic resistance.¹⁷⁵ Accordingly, the FDA issued a proposal to withdraw approval of subtherapeutic use in animal feed unless data was submitted within the next two years which conclusively proved use was not a threat to human health.¹⁷⁶ Over the next two years, the CVM reviewed evidence submitted by interested parties and recommended continuing withdrawal procedures for subtherapeutic use of penicillin and tetracycline.¹⁷⁷ The FDA then issued notice of withdrawal hearings and received twenty requests for hearings.¹⁷⁸ The District Court ruled that once the CVM and the FDA followed procedures which proscribed clear and discrete actions for withdrawal of approval, the statutory language, "shall," legally required the Secretary of Health to continue with the withdrawal proceedings, barring presentation of any important new information.¹⁷⁹ Although the findings were

¹⁷⁴ Once the Secretary found the drug to be unsafe, withdrawing the drug was required unless new evidence emerged during the hearing. 21 U.S.C. 360, in pertinent part, reads as follows:

the Secretary shall, after due notice and the opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds that . . . (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved . . . evaluated together with evidence available to the Secretary when the application was approved shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

21 U.S.C. 360.

¹⁷⁵ GUIDANCE #209, *supra* note 7; *see also* GUIDANCE #152, *supra* note 162.

¹⁷⁶ NRDC, 884 F. Supp. 2d at 130.

¹⁷⁷ *Id.* at 133.

¹⁷⁸ *Id.* at 133–34.

¹⁷⁹ *Id.* at 141. The court relied on a plain reading of the text based on grammatical rules as described below:

The "after due notice and opportunity for hearing" clause is setoff by commas and immediately precedes the words "issue an order withdrawing approval," indicating that the "notice" clause modifies the "issue an order" clause and not the findings clause. *See United States v. Liranzo*, 729 F.Supp. 1012, 1014 (S.D.N.Y.1990) (interpreting a modifier to apply to the verb closest to it) (citing W. Strunk, Jr. & E.B. White, *The Elements of Style* 30 (3d ed. 1979)). Accordingly, the statute only requires the Secretary to give notice and provide an opportunity for a hearing before issuing an order of withdrawal and *not* before making findings. Under this reading, if the Secretary finds that an animal drug has not been shown to be safe, he is statutorily required to withdraw approval of that drug, provided that the drug sponsor has notice and an opportunity for a hearing . . . If, after a hearing, the drug sponsor has not met his burden of proving the drug to be safe, the Secretary must issue a withdrawal order.

Id. at 141–42; *see also*, *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) ("If the FDA discovers after approval that a drug is unsafe or ineffective, it 'shall, after due notice and opportunity for hearing to the applicant, withdraw approval' of

initiated by the Director of the CVM, and not the Secretary of the FDA, the Director was delegated the authority to make statutorily enforceable findings with the authority to issue notice of hearings.¹⁸⁰ The CVM Director's finding that the drugs were unsafe initiated a legally binding mandate to continue the withdrawal proceedings.¹⁸¹

Accordingly, the court found that the FDA must re-issue a notice of the proposed withdrawals and provide an opportunity for a hearing to the relevant drug sponsors.¹⁸² If the drugs were not proven safe, approval must be withdrawn.¹⁸³ There were several limitations on this ruling. The court stipulated the limitations of its holding, emphasizing that it was not ordering the FDA to ban the drugs outright, only to continue their mandated procedures.¹⁸⁴ If the sponsors raised a substantial fact, the FDA must hold a public evidentiary hearing to determine if the sponsors could prove that the drug is safe.¹⁸⁵ Otherwise, the Commissioners had to issue a withdrawal order.¹⁸⁶ Additionally, the drugs at issue were only penicillin and tetracycline antibiotics, leaving many other medically important antibiotics on the market.¹⁸⁷

The N.R.D.C. filed a second suit against the FDA alleging a violation of the FDA's procedural duty to take the citizen petitions seriously.¹⁸⁸ Specifically, the NRDC alleged that the FDA violated section 706(2) of the Administrative Procedures Act, and section 360b(e) of the FDCA, when it denied two citizen petitions requesting withdrawal of approval for subtherapeutic use of certain classes of antibiotics in food-producing animals.¹⁸⁹ Both petitions provided credible scientific evidence to support their requests and both petitions received the same

the drug,") (quoting 21 U.S.C. § 355(e)(1)-(3)); *Mylan Lab., Inc. v. Thompson*, 389 F.3d 1272, 1281 (D.C. Cir. 2004)).

¹⁸⁰ N.R.D.C., 884 F. Supp. 2d at 145–46. While the statutory language is ambiguous, the court traced a clear path of delegation of authority from the Secretary of the Department of Health and Human Services, to the Commissioner of the FDA, to the Director of the BMV to issue notices. *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.* at 151.

¹⁸³ *Id.*

¹⁸⁴ *Id.* Judge Katz emphasized the limitations that the court is not ordering a particular outcome, if the drug companies prove the drug is safe approval cannot be withdrawn. *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 131–32.

¹⁸⁸ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 321 (S.D.N.Y. 2012).

¹⁸⁹ The first petition was in 1999 and requested that “the agency ‘rescind approvals for subtherapeutic uses in livestock of any antibiotic used in (or related to those used in) human medicine’ . . . it named several specific classes of antibiotics for which it sought withdrawal, including penicillin, tetracyclines, erythromycin, lincomycin, tylosin, and virginiamycin.” The 2005 petition made similar request. *Id.* at 324–26.

response from the FDA¹⁹⁰ The FDA provided an initial response detailing the complex nature of the problem, detailing the FDA's limited resources and the alternative means by which they were attempting to tackle the problem, and stating that withdrawal must be considered on a drug-by-drug basis.¹⁹¹ The FDA then proceeded to deny the requests based on the fact that no hearings had been held, based on the time and expense withdrawal would take, and based on the alternative strategy the FDA was pursuing.¹⁹² Under 5 U.S.C. § 706(2)(A), a court may set aside the FDA's findings, conclusions of laws, or actions if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."¹⁹³

The FDA still prefers a voluntary phasing out of subtherapeutic use. The Agency appealed both rulings and motioned for a continuance to allow the industry time to comply.¹⁹⁴ While the motion for a continuance was denied, both district court rulings were overruled in July 2014.¹⁹⁵ The Second Circuit Court of Appeals found that 21 U.S.C. § 360b(e)(1) was ambiguous, but ultimately agreed with the FDA:

[t]he statute requires the FDA to withdraw approval of an animal drug only "after due notice and opportunity for hearing" has been afforded, and then only "if the Secretary finds" that the drug is not shown to be safe. 21

¹⁹⁰ *Id.*

¹⁹¹ *Id.* These alternative methods are far from satisfactory as they only involved issuing Guidances. Although the FDA's plan seemed to be a step in the right direction they refused to mandate compliance and the industry had failed to self-regulate. The court opinion provides, in pertinent part:

Specifically, the FDA cited Draft Guidance # 209, entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," which recommends limiting the use of antibiotics in food-producing animals to judicious uses. Draft Guidance # 209 states that the FDA does not consider growth promotion or feed efficiency to be judicious uses. Draft Guidance # 209 also recommends that the use of medically-important antibiotics in food-producing animals should be limited to "uses that include veterinary oversight or consultation." The FDA explained that "[b]ased on feedback [the FDA] has received [regarding Draft Guidance # 209], FDA believes that the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to implement the principles recommended in [the Draft Guidance]." The FDA stated that it planned to phase-out over-the-counter use of medically-important antibiotics in animal feed and move to a veterinary feed directive ("VFD") status for such drugs. The FDA also stated that it planned to work cooperatively with industry to achieve this transition. "FDA believes that the strategy set out in draft guidance # 209 is a pathway to achieving the same goals as those advocated in [the 1999 Petition]" Accordingly, the FDA refused to initiate withdrawal proceedings for the drugs included in the 1999 Petition.

Id. at 326

¹⁹² *Id.*

¹⁹³ 5 U.S.C. § 706(2)(A) (West 2014).

¹⁹⁴ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 108 (S.D.N.Y. 2012).

¹⁹⁵ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 2d Cir. No. 12-2106-CV L, 2014 WL 3636283 (July 24, 2014).

U.S.C. § 360B(e)(1). That language most naturally refers to a finding that is issued as a result of the hearing. That interpretation, moreover, avoids injecting a second, unexpressed “finding” into the sequence of events mentioned in the statute.¹⁹⁶

This holding means that withdrawal is only mandatory after manufacturers have had a hearing and, after hearing the evidence, the FDA finds that the drug is unsafe. Since the FDA did not issue a finding after conducting hearings, the Second Circuit granted summary judgment to the FDA. The court also found that the decision to ignore the citizen petitions was not arbitrary or capricious.¹⁹⁷ The ruling was not unanimous, with Chief Judge Katzmann issuing a dissent vehemently opposing the majority opinion.¹⁹⁸

C. Proposed Changes

The economic and social costs of antibiotic resistance must be combated through congressionally mandated standards, mandatory FDA withdrawal of subtherapeutic antibiotic use in food animals, and enforcement through the courts. The District Court’s opinion illustrates the need for a joint effort by the courts, the FDA, and Congress to tackle the problem of antibiotic resistance.¹⁹⁹ While the court found that the FDA had a legal obligation to follow the procedures dictated by Congress, the opinion also emphasized that policy making was not the proper sphere of the courts.²⁰⁰ When interpreting an ambiguous statute, the court must interpret congressional intent, and for further guidance, defer to the Agency’s interpretation, as long as such interpretation is reasonable—essentially allowing the court to act as a legislative or executive body.²⁰¹ Even if the FDA had to fully comply with the court order, the ruling would have a limited effect—only approval for tetracyclines and penicillin would be withdrawn, allowing for subtherapeutic use of many other antibiotics.²⁰² In light of these overlapping roles, Congress must pass legislation with

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 142–49 (S.D.N.Y. 2012).

²⁰⁰ *Id.* at 151. Courts, the district court noted, must provide appropriate oversight without telling the agency the best way to do their job:

when an agency is compelled by law to act within a certain time period, but the manner of its action is left to the agency’s discretion, a court can compel the agency to act, but has no power to specify what the action must be.” The Court further explained that the purpose of the limitations under § 706(1) “is to protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve.

Id. at 138 (quoting *SUWA*, 542 U.S. at 65–66 (2004) (internal citations omitted)).

²⁰¹ *Id.* at 141.

²⁰² *Id.* at 151.

clear and concise definitions that makes elimination of subtherapeutic use a clear priority. This will create a clear mandate to combat the growing threat of antibiotic resistance that the FDA will execute and the courts will enforce, if necessary. The FDA should have broad autonomy to fulfill the legislative mandate as they see fit, except when there is a broad failure of mission.

1. Make Certain Standards Legally Binding Through Legislation

To combat antibiotic resistance, legislation should be enacted to compliment the FDA's efforts at eliminating harmful subtherapeutic antibiotic use. This legislation should include a three-tiered approach to battling antibiotic resistance in order to fulfill three goals: the immediate elimination of subtherapeutic use of medically important antibiotics, the complete phasing out of intensive confinement systems within ten years, and the eventual elimination of all subtherapeutic antibiotic use. The first phase of elimination entails defining and withdrawing approval of subtherapeutic use of all medically important antibiotics (those that are used to treat human illnesses). This phase should reinforce and expand upon the FDA's withdrawal of approval for penicillin and tetracyclines. The second phase involves supplementing the Food Safety Modernization Act's creation of state grants. Funds should be set aside for the FDA to administer to states, farms, or organizations that come up with creative or sustainable ways to eliminate all subtherapeutic use. Finally, the third phase requires the complete phasing out of intensive confinement systems and subtherapeutic antibiotic use within ten years of the Act's passage.

Phase 1: Define key terms and eliminate subtherapeutic use of medically important antimicrobials.

The Preservation of Antibiotics for Medical Treatment Act of 2011 (PAMTA) should serve as a foundation for defining and withdrawing use of medically important subtherapeutic antibiotics.²⁰³ PAMTA was proposed to the House of Representatives Committee on Energy and Commerce as a supplement to the Food, Drug, and Cosmetic Act.²⁰⁴ Although this Act had very little support within the Committee, the passage of parts of PAMTA could still serve as the first phase of a comprehensive legislative effort to combat antibiotic resistance. The first step in regulating harmful antibiotics must be to create uniform and legally enforceable definitions. These uniform definitions should be adopted by all U.S. regulatory agencies.

PAMTA procedures for withdrawing approval of all subtherapeutic use of medically important antimicrobials within two years should be enacted into law.²⁰⁵ In 2009, eighty percent of all antibacterial drugs disseminated in the United States were

²⁰³ See Preservation of Antibiotics for Medical Treatment Act of 2011 [hereinafter PAMTA], H.R. 965, 112th Cong. (2011).

²⁰⁴ *Id.*

²⁰⁵ Barbara O'Brien, recognizing the many barriers to change and government inaction, suggests an outright ban on all subtherapeutic uses as the most practical way to combat the problem of antibiotic resistance and animal cruelty. While total elimination must be the ultimate goal, it is impractical as the first step due to the industry's dependence on such drugs. This Note seeks to build on that approach and suggest a multifaceted approach as opposed to an outright ban. See O'Brien, *supra* note 94, at 412–14.

sold for use on food animals, and about eighty-four percent of farmers administered antimicrobials in food or water, many of which are closely related to human drugs.²⁰⁶ The sheer number of drugs used for this purpose, along with many industry studies,²⁰⁷ shows that subtherapeutic use of the same antimicrobials in both humans and food animals is the most serious cause of antibiotic resistance in humans.²⁰⁸ Switching from drugs used in humans to other antimicrobials should be mandated, especially as many alternative drugs that are not used in humans are readily available.²⁰⁹

The FDA procedures for withdrawal of certain medically important antimicrobials are consistent with the PAMTA requirements. PAMTA requires the Secretary to withdraw approval of subtherapeutic use of medically important antimicrobials within two years, unless during that time it can be demonstrated that there is no harm to human health.²¹⁰ Additionally, the Act forbids approval of any new medically important drugs for growth purposes unless there is reasonable certainty that there would not be harm to human health.²¹¹ Passing legislation that creates legally binding definitions and mandates procedures for withdrawing

²⁰⁶ PAMTA, *supra* note 203, at § 2 (finding that, in 2009, “13.1 million kilograms of antibacterial drugs were sold for use on food animals in the United States . . . [only] 3.3 million kilograms of antibacterial drugs were used for human health in 2009.”); *see also* Levy, *supra* note 13 at 140.

²⁰⁷ *See* Levy Testimony, *supra* note 61.

²⁰⁸ PAMTA, *supra* note 203, at 2–9. Other studies have provided more direct evidence of the link between subtherapeutic use in animals and human antibiotic-resistant infections, and of meat products contaminated with antibiotic-resistant bacteria. *See* Levy Testimony, *supra* note 61 (citing several studies that confirm the impact food animals have on antibiotic resistance including one study that found antibiotics present in 48% of streams tested nationwide, half of which were downstream from agricultural operations).

²⁰⁹ Much of the beef industry has already self-regulated and switched to non-human antimicrobials upon the recommendation by the American Cattleman’s Association. Additionally, much of Europe has already mandated this switch. These swift and easy transitions prove that the entire industry could switch if required to do so.

²¹⁰ PAMTA specifies:

[t]he Secretary shall withdraw the approval of a nontherapeutic use in food producing animals described in paragraph (1) on the date that is 2 years after the date of enactment of this subsection unless- (A) before the date . . . the Secretary makes a final written determination that the holder of the approved application has demonstrated that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part to the non-therapeutic use of the drug . . .

See PAMTA, *supra* note 203, § 4(q)(2).

²¹¹ Once legislation deems subtherapeutic use unsafe, the new policy could be instituted under the FDA’s current new drug approval process. 21 U.S.C.A. § 360(b) provides that new animal drugs shall be deemed unsafe, and thus denied approval, unless they conform to current laws and are shown to be safe for the public. This provision applies both to drugs administered directly to the animals, or indirectly through feed. PAMTA, *supra* note 203, at § 4; 21 U.S.C.A. § 360(b) (West 2014) (delineating annual registration and approval requirements for drugs administered directly to animals, or indirectly through feed).

approval of subtherapeutic usage within two years of the Act's passage is the first and most important step in fighting antibiotic resistance. Congress should adopt a statute substantially similar to the following model:

DEFINITIONS - SECTION 201 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 321) IS AMENDED BY ADDING AT THE END THE FOLLOWING:

1. **ANTIMICROBIAL ANIMAL DRUG**—The term “antimicrobial animal drug” means: A substance that is composed wholly or partly of any drug or derivative of a drug that is used in or intended for use in food-producing animals.
2. **MEDICALLY IMPORTANT ANTIMICROBIAL ANIMAL DRUG**—The term “medically important antimicrobial animal drug” means: an antimicrobial animal drug that is used in humans or intended for use in humans to treat or prevent disease or infections caused by microorganisms.
3. **SUBTHERAPEUTIC USE**—The term “subtherapeutic use” means: The use of an antimicrobial in a food animal, in the absence of any clinical sign of disease or disease exposure in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention or other routine purpose.
4. **INTENSIVE CONFINEMENT**—The term “intensive confinement” means: any structure that would substantially restrict the natural movement and normal behaviors of an animal.

ELIMINATION OF DRUGS IMPORTANT FOR HUMAN HEALTH

1. **APPLICABILITY**—This subsection applies to the subtherapeutic use in a food-animals of a medically important antimicrobial animal drug.
2. **WITHDRAWAL**—The Secretary shall withdraw the approval of a subtherapeutic use in food-animals described in paragraph (1) 2 years after the date of enactment of this subsection.
3. **APPROVALS** —If an application for a drug that is a medically important antimicrobial animal drug is submitted to the Secretary under section 505(b), the Secretary shall rescind each approval of a nontherapeutic use in a food animal of the drug as of the date that is 2 years after the date on which the application is submitted to the Secretary.²¹²

²¹² These definitions are a combination of language from PAMTA and from the recommendation of the Pew Commission on Industrial Farm Animal production. PAMTA provides, in relevant part:

(ss) **CRITICAL ANTIMICROBIAL ANIMAL DRUG.**— The term ‘critical antimicrobial animal drug’ means a drug that—

- (1) is intended for use in food-producing animals; and
- (2) is composed wholly or partly of—
 - (A) any kind of penicillin, tetracycline, macrolide, lincosamide, streptogramin, aminoglycoside, or sulfonamide; or
 - (B) any other drug or derivative of a drug that is used in humans or intended for use in humans to treat or prevent disease or infection caused by microorganisms.

(tt) **NONTHERAPEUTIC USE.** — the term ‘nontherapeutic use’, with respect to a critical antimicrobial animal drug, means any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth

Phase 2: Create additional state grants to help farmers transition into total elimination of subtherapeutic antibiotic use.

While withdrawing approval for the use of medically important antimicrobials is an important first step, total elimination of subtherapeutic use must be the end goal to fully eliminate the problem of antibiotic resistance. However, as our modern meat industry is built around the low cost and high volume of meat that factory farms can produce, legislation must be careful to consider the effects on the meat industry, as a whole, of eliminating intensive confinement systems.²¹³ These systems must be phased out gradually so the industry has time to adjust.

In order to make the process easier, the new legislation should immediately supplement the Food Safety Modernization Act's creation of state grants. The FDA should receive grants to distribute to state governments, farms, or other entities that attempt to institute creative and sustainable models that eliminate intensive confinement systems or subtherapeutic antibiotic use. These subsidies provide an incentive for farmers to be innovative and start to move towards more sustainable practices.

Phase 3: Eliminate intensive confinement systems factory farms and ban all subtherapeutic antibiotic usage.

The eventual elimination of all intensive confinement systems must be legally mandated to slow the development of antibiotic-resistant bacteria. The new legislation should require the FDA to set the goal of eliminating all intensive confinement systems, those which restrict the natural movement and normal behaviors of animals,²¹⁴ within ten years of the act's passage. Although eliminating the use of medically important antibiotics for growth promotion is a key first step, it

promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.

PAMTA, *supra* note 203, § 4 (ss–t). The Pew Commission suggests similar, but not identical, definitions in its report:

- a. The Commission defines as nontherapeutic any use of antimicrobials in food animals in the absence of microbial disease or known (documented) microbial disease exposure; thus, any use of the drug as an additive for growth promotion, feed efficiency, weight gain, routine disease prevention in the absence of documented exposure, or other routine purpose is considered nontherapeutic.
- b. The Commission defines as therapeutic the use of antimicrobials in food animals with diagnosed microbial disease.

PEW COMM'N, *supra* note 78, at 63. I would not recommend listing specific types of drugs—as PAMTA does—because a basic rule of statutory interpretation indicates that listing some drugs seems to exclude other drugs; instead, the act can provide a dynamic definition that the courts can then interpret. *See supra* Section III(C)(3).

²¹³ *See supra* Part II.

²¹⁴ *See* PEW COMM'N, *supra* note 78, at 33.

is not alone sufficient to combat the threat of antibiotic resistance. When bacteria select, they can build up resistance to multiple antibiotics²¹⁵ and, therefore, may still pose a threat in the future. Thus, a comprehensive plan must address the root cause of what makes subtherapeutic use necessary on the factory farm: close confinement. If animals were not kept in such close quarters, disease would not have the potential to quickly spread throughout the entire population.²¹⁶ Additionally, smaller-scale farms could keep better records of the health of each individual animal and respond to outbreaks more efficiently.²¹⁷ Once intensive confinement systems are eliminated, the subtherapeutic use of all antibiotics should be banned as well. The following statutory language should be added to the end of the proposed regulation in Part C(1)(a) of this Note:

C. ELIMINATION OF INTENSIVE CONFINEMENT SYSTEMS

1. **APPLICABILITY**—This subsection applies to the regulation of the intensive confinement of food-animals.
2. **WITHDRAWAL**—All intensive confinement systems described in paragraph (1) shall be eliminated within 10 years after the date of the enactment of this subsection.

D. ELIMINATION OF SUBTHERAPEUTIC USE IN FOOD-ANIMALS.

1. **APPLICABILITY**—This subsection applies to the subtherapeutic use in a food-animals of an antimicrobial animal drug.
2. **WITHDRAWAL**—The Secretary shall withdraw the approval of a subtherapeutic use in food-animals described in paragraph (1) 10 years after the date of enactment of this subsection.
3. **APPROVALS** —If an application for a drug that is an antimicrobial animal drug is submitted to the Secretary under section 505(b), the Secretary shall rescind each approval of a nontherapeutic use in a food animal of the drug, as of the date that is 2 years after the date on which the application was submitted to the Secretary.

Outlawing intensive confinement systems will likely mean a decrease in efficiency, at least in the short term. Accordingly, production and prices would rise if intensive confinement systems were phased out (with the possible exception of beef which is less reliant on intensive confinement). This increase in prices is acceptable for several reasons. First, most Americans already eat more meat than ever before, and far more than the recommended daily amount.²¹⁸ Even if higher prices meant less meat for consumers, health could be further enhanced by a reduction in meat eating.²¹⁹ Moreover, as previously mentioned, the cost of antibiotic-resistant infections is massive. The rise in meat prices would be comparatively smaller and more manageable as the cost would be spread across all consumers.²²⁰ Many

²¹⁵ See Levy Testimony, *supra* note 61; PEW COMM'N, *supra* note 78, at 16.

²¹⁶ PEW COMM'N, *supra* note 78, at 13.

²¹⁷ *Id.* at 64.

²¹⁸ See Bittman, *supra* note 74.

²¹⁹ See Bittman, *supra* note 74.

²²⁰ See *supra* Part II(C)(1).

individuals already pay a four to five dollar premium price for meat that is “free range,” “hormone free,” or “organic.”²²¹ Over time, most individuals would find the additional cost manageable; low income households could receive assistance through government assistant programs which are already in place to combat hunger and malnutrition.²²²

In addition, wealth would likely increase in rural areas which have been driven into poverty largely by the rise of the factory farming system. Citizens of rural areas generally have lower incomes due to less educational attainment, fewer opportunities, and less diversity.²²³ This problem is amplified by factory farms, which drive small family-owned farms out of business. Rural communities benefit from locally owned and controlled farms as, in addition to hiring locals to work on the farm, they tend to buy other services and supplies locally.²²⁴ This “multiplier effect” keeps approximately seven dollars by dollars earned on local farms in the community.²²⁵ Many large factory farms are vertically integrated with large suppliers, making their multiplier substantially lower.²²⁶ Additionally, “reduced civic participation rates, higher levels of stress, and other less tangible impacts have all been associated with high concentrations of industrial farm production.”²²⁷ Thus, although breaking up intensive confinement systems could increase the cost of meat, the economies of many rural areas would greatly benefit from this policy—as would the health of Americans, thereby offsetting some of the cost.

2. Develop Clear FDA Definitions and Guidelines

The FDA should consult with industry experts, manufacturers, and veterinarians to convert Guidance #152 and Guidance #209 into binding minimum standards. The FDA must follow the withdrawal procedures and timetables dictated by Congress and can use industry Guidances to fill in the instructional gaps in legislation. While the Guidance letters are an excellent way to provide manufacturers with pertinent information, they must have some legal backing to ensure compliance.²²⁸ The Guidances should be converted from non-binding recommendations to binding industry standards. In addition to the immediate review of existing approvals, which must be withdrawn, the FDA should create a permanent schedule for reviewing existing approvals. In this way, the FDA could translate the congressional mandate for change into workable minimum standards based on a reasonable timetable.

Total compliance must be phased in, and the FDA will likely not choose to prosecute all firms who fail to meet these guidelines during the first few years. Firms

²²¹ John Robbins, *The Truth About Grassfed Beef*, FOOD REVOLUTION NETWORK BLOG (Dec. 19, 2012), <http://foodrevolution.org/blog/the-truth-about-grassfed-beef/>.

²²² See generally *Programs and Services*, DEPT. OF AGRIC. FOOD & NUTRITION SERV., <http://www.fns.usda.gov/programs-and-services> (last visited Aug. 1, 2014).

²²³ PEW COMM’N, *supra* note 78 at 41.

²²⁴ *Id.* at 41.

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.* at 59.

²²⁸ *Id.*; see also GUIDANCE #209, *supra* note 7.

should self-report how they met, or strived to meet, the good manufacturing practices guidelines, and report any problems they may have. If firms have not met these guidelines, they should have to submit a comprehensive plan on how to meet them in the future. Such a system allows the FDA to work with the industry towards voluntary compliance, as the FDA prefers, while also establishing clear goals and guidelines.

3. The Role of the Courts

While the courts should generally defer to the FDA's policy choices, they are still an important check on the Agency's power and play a key role in enforcing drug regulations. The courts must walk a fine line between hindering the FDA's policy-making ability and giving the Agency free reign to do what it wishes.²²⁹ On the one hand, discretion allows the FDA to predict the outcome of rulemaking and extend its power based on assurance of judicial support. However, as the court articulated in *American College of Neuropsychopharmacology v. Mathews*, "[b]ureaucratic power in any agency seems to grow to fill whatever bounds are permitted it by Congress and the courts, and the courts do rein in the exuberant jurisdiction-extending agencies, when they determine that zeal has exceeded legal authority."²³⁰ In the case of antibiotic resistance, the courts have recognized a serious threat to public health and have ordered the FDA to act accordingly.²³¹ The courts should continue to recognize the rights of citizens to petition the FDA to fulfill their regulatory responsibilities when such requests are backed by firm scientific foundations, but continue to filter out frivolous lawsuits.

If the proposed legislation is passed, the courts will need to ensure that the FDA follows the law. Although the FDA can use their discretion in withdrawing use, they must determine which antibiotics are subject to removal.²³² If a company disputes the legality of their antibiotic use, the court would have to interpret and apply the new law. The definition of "subtherapeutic" is based on whether or not the purpose of the drug use is to treat illness or promote growth, forcing the courts to look at key indicators to determine whether or not drug was intended for subtherapeutic use. However, the increase in legislation should not be substantial as many farmers may be hesitant to sue the FDA for fear of reprisals in their licensing actions, and the FDA rarely brings cases they are not sure they can win. Therefore, the courts should be sure to enforce the new legislation while being careful to grant the FDA sufficient discretion.

²²⁹ *Am. Coll. of Neuropsychopharmacology v. Mathews*, Food Drug Cosm. L. Rep. (CCH) ¶ 38025 (D.D.C. 1975); *see also* *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 631–32 (1973).

²³⁰ *Am. Coll. of Neuropsychopharmacology v. Mathews*, Food Drug Cosm. L. Rep. (CCH) ¶ 38025 (D.D.C. 1975).

²³¹ *Natural Res. Def. Council*, 884 F. Supp. 2d at 151 (S.D.N.Y. 2012).

²³² Based on the definitions in the new legislation as well as their own initiated proceedings. For instance, FDA Guidance #152 defines an antibiotic as potentially important in human medicine if FDA issues an Investigational New Drug determination or receives a New Drug Application for the compound. *See* GUIDANCE #152, *supra* note 162.

IV. CONCLUSION

The economic and social costs of antibiotic resistance must be combated through the joint efforts of Congress, executive agencies, and the courts using congressionally mandated standards, FDA approval withdrawal procedures, and the court system. Now, more than ever, scientists and government officials alike are recognizing the serious economic, social, and health costs created by antibiotic-resistant bacteria.²³³ Antibiotic overuse has led to the creation of “superbugs” that are more difficult and costly to treat, and an increase in the prevalence of allergies, asthma, and autoimmune diseases.²³⁴ Current food and drug legislation does nothing to eliminate this threat, and the FDA has refused to provide clear, consistent, and binding guidelines to address the problem. A comprehensive, joint effort must be made by Congress, the FDA, other regulatory agencies, and the courts to eliminate the pervasive problem. The legislature must create legally binding standards that are easily followed by administrative agencies and enforced by the courts. At the same time, it must preserve the FDA’s discretion to implement such changes based on their expertise. Congress must create a uniform definition of subtherapeutic antibiotic usage, immediately mandate the withdrawal of approval of medically important antibiotics for subtherapeutic use, and eliminate all subtherapeutic use in the future. Such legislation will inevitably affect the price and quantity of meat produced. Therefore, these changes must be enacted in phases and special care should be taken to help ease the transition for farmers. While the public may be asked to pick up some of the cost increase, the amount saved in healthcare costs will lead to a net savings for the United States as a whole.

²³³ See GUIDANCE #209, *supra* note 7.

²³⁴ See *infra* Part II(B).