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NOTES

A SUPERSIZED SOLUTION TO SUPERBUGS: PREVENTING A POST-ANTIBIOTIC ERA BY OPTIMIZING CONSUMER DEMAND

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NOTES

A SUPERSIZED SOLUTION TO SUPERBUGS: PREVENTING A POST-ANTIBIOTIC ERA BY OPTIMIZING CONSUMER DEMAND

Kayla A. Despenes*

> *The consumer . . . must be kept from discovering that, in the food industry—as in any other industry—the overriding concerns are not quality and health, but volume and price.*[1]

I. INTRODUCTION

"Catastrophic"[2] and "apocalyptic"[3] are just two of the rather ominous adjectives being used to describe the public health threat posed by so-called "superbugs"—a common term for antimicrobial resistant strains of bacteria or

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[1] WENDELL BERRY, *The Pleasures of Eating*, WHAT ARE PEOPLE FOR? 145, 148 (2010).

[2] CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES (2013) [hereinafter CDC, ANTIBIOTIC RESISTANCE THREATS], *available at* http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[3] Ian Sample, *Antibiotic-Resistant Diseases Pose "Apocalyptic" Threat, Top Expert Says*, THE GUARDIAN, Jan. 23, 2013, http://www.theguardian.com/society/2013/jan/23/antibiotic-resistant-diseases-apocalyptic-threat.

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infections that no longer respond to antibiotics.[4] Although the term "superbug" may seem better suited for a science fiction movie, the threat posed by antimicrobial resistance is far from fictitious.[5] Designated by both the Centers for Disease Control (CDC) and the World Health Organization (WHO) as a threat to global health security,[6] antimicrobial resistance has been dubbed by some scholars as "the greatest threat to global public health in the twenty-first century."[7] Recently, the British Chief Medical Officer echoed the CDC and WHO's warnings by urging the British government to add superbugs to the National Risk Register of Civil Emergencies, alongside terrorist attacks and massive flooding.[8]

Although the costs associated with the emergence of a post-antibiotic era may seem distant, the reality is that roughly twenty-three thousand Americans die of illnesses related to antimicrobial resistance each year and about two million more are sickened.[9] Additionally, the CDC estimates that antibiotic resistance costs the United States economy $20 billion per year in excess direct healthcare costs, with additional costs for lost productivity amounting to as much as $35 billion per year.[10] Although antibiotic use in general can lead to the development of

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[4] Cory Fox, Note, *Resisting Antibiotic Resistance: Legal Strategies to Maintain Man's Dominion over Microbes*, 12 HOUS. J. HEALTH L. & POL'Y 35, 35 (2011) (defining "superbugs" as diseases that can no longer be cured with antibiotics).

[5] *See* Patrick Boerlin & David G. White, *Antimicrobial Resistance and Its Epidemiology*, *in* ANTIMICROBIAL THERAPY IN VETERINARY MED. 21, 21–22 (Steve Giguère et al. eds., 5th ed. 2013) ("Antimicrobial resistance mechanisms have been reported for all known antibiotics currently available for clinical use in human and veterinary medicine."); *see also* Anne E. Clatworthy, Emily Pierson & Deborah T. Hung, *Targeting Virulence: A New Paradigm for Antimicrobial Therapy*, 3 NATURE CHEMICAL BIOLOGY 541, 541 (Sept. 2007), *available at* http://www.nature.com/nchembio/journal/v3/n9/pdf/nchembio.2007.24.pdf ("Clinically significant antibiotic resistance has evolved against virtually every antibiotic deployed. . . . Given the current gap between our ability to develop novel antibiotics and the real need for such drugs, the threat of a post-antibiotic era is looming large on the horizon.").

[6] WORLD HEALTH ORG., STRATEGIC AND TECHNICAL ADVISORY GROUP ON ANTIMICROBIAL RESISTANCE: REPORT OF THE FIRST MEETING, 2 (Sept. 19–20, 2013), *available at* http://www.who.int/drugresistance/stag/amr_stag_meetingreport0913.pdf?ua=1; Ctrs. for Disease Control & Prevention, *Get Smart: Fast Facts About Antibiotic Resistance*, CDC.GOV, http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html (last updated Jan. 21, 2011) ("Antibiotic resistance has been called one of the world's most pressing public health problems.").

[7] Fox, *supra* note 4, at 35 (citing Richard D. Smith & Joanna Coast, *Resisting Resistance: Thinking Strategically About Antimicrobial Resistance*, 4 GEO. J. INT'L AFF. 135, 135 (2003)).

[8] Sample, *supra* note 3.

[9] CDC, ANTIBIOTIC RESISTANCE THREATS, *supra* note 2, at 11.

[10] *Id.*

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antimicrobial resistant strains of bacteria, the overuse of antibiotics in food-animals (i.e., animals raised for food) has been pegged as a primary culprit.[11] After virtually dismissing the issue for the past several decades, the Food and Drug Administration (FDA) has recently released guidance documents acknowledging the public health concerns raised by the injudicious administration of antibiotics to food-animals.[12] Yet, as acknowledged by a number of critics, the FDA's guidance has several glaring loopholes.[13] To begin with, it is merely nonbinding "guidance"—a voluntary phase-out plan with which industries need not comply.[14] Moreover, because the guidance recommends only that antimicrobial drugs no

[11] *See* Vanessa K.S. Briceño, *Superbug Me: The FDA's Role in the Fight Against Antibiotic Resistance*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 521, 523 (2006); *see also* Pew Commission on Industrial Farm Animal Production, *Putting Meat on the Table: Industrial Farm Animal Production in America: Executive Summary*, 5 (2008) [hereinafter Pew Comm'n on Industrial Farm Animal Prod.], *available at* http://www.ncifap.org/_images/PCIFAPSmry.pdf ("Because any use of antibiotics results in resistance, this widespread use of low-level antibiotics in animals, along with use in treating humans, contributes to the growing pool of antimicrobial resistance in the environment.").

[12] U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 20 (Apr. 13, 2012) [hereinafter GUIDANCE #209], *available at* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf ("It is in the interest of both human and animal health that we take a more proactive approach to considering how antimicrobial drugs are being used, and take steps to assure that such uses are appropriate and necessary for maintaining the health of humans and animals."); U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #213: NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 (Dec. 2013) [hereinafter GUIDANCE #213], *available at* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm299624.pdf.

[13] *See* Tim Fothergill, *Will New FDA Guidelines Reduce Threat from Superbugs?*, HUFFPOST HEALTHY LIVING, http://www.huffingtonpost.com/tim-fothergill-phd/superbugs-antibiotics_b_4557300.html (last updated Mar. 9, 2014, 5:59 PM) ("[T]he most significant caveat with this plan is that it is voluntary and as such is dependent on the cooperation of the drug producers and farmers."); *see also* Sabrina Tavernise, *F.D.A. Restricts Antibiotics Use for Livestock*, N.Y. TIMES, Dec. 11, 2013, at A1 (noting the criticisms espoused by a Johns Hopkins scientist, Dr. Keeve Nachman, and Congresswoman Louise M. Slaughter).

[14] HHS, GUIDANCE #209, *supra* note 12, at 4 ("FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word 'should' in Agency guidances means that something is suggested or recommended, but not required.").

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longer be given to food-producing animals for growth promotion purposes, it allows for the same dosage to be administered for disease prevention purposes.[15]

In light of the FDA's lethargic and lackluster response to this pressing issue, this Note argues that a more effective solution can be found by focusing on the consumer demand-side of the equation. Although government regulation is an important factor in limiting the supply of antibiotics to food-animals, demand-side influences, such as those spawned by major restaurant chains including McDonald's, Chipotle Mexican Grill, Panera Bread, and Chick-fil-A, can play a powerful role in preventing the emergence of a post-antibiotic era. In arriving at this conclusion, this Note begins with a brief overview of the superbug phenomenon and the FDA's interaction (and lack thereof) with the practice of giving antibiotics to food-producing animals. This Note then analyzes FDA Guidance #209 and Guidance #213 and compares them to the efficacy of other supply-side solutions, such as the European Union's ban on the use of growth-promoting antibiotics. Finally, this Note considers the recently increased demand for antibiotic-free meat and the critical role that industries and consumers play in ensuring the continued viability of antibiotics. In that context, this Note will demonstrate that policymakers should optimize demand-side solutions by reducing information asymmetries about food quality and production rather than focusing their efforts on supply-side regulation.

II. THE SUPERBUG PHENOMENON

That antibiotics[16] have become indispensable to modern medicine can hardly be disputed.[17] Diseases and injuries which once threatened the lives of thousands of people are now little more than horror stories of the past,[18] with the rise of

[15] *Id.* at 22 ("In light of the risk that antimicrobial resistance poses to public health, FDA believes the use of medically important antimicrobial drugs in food-producing animals for production purposes . . . represents an injudicious use of these important drugs. . . . In contrast, FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals.").

[16] Throughout this Note, "antibiotic" is used interchangeably with "antimicrobial" to refer to substances that destroy microorganisms or inhibit their growth.

[17] *See* Boerlin & White, *supra* note 5, at 21 ("Antimicrobials have become indispensable in decreasing morbidity and mortality associated with a host of infectious diseases. . . .").

[18] In 1900, tuberculosis was one of the leading causes of death in the United States. *See* Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900–1999: Control of Infectious Diseases*, 48 MORBIDITY & MORTALITY WKLY. REP. 621 (July 30, 1999), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm. However, between 1993 and 2012 alone, there has been an

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antibiotics likely now accounting for an increased life expectancy of two to ten years.[19] However, these powerful disease-fighting tools have revealed themselves to be fragile, and at least in some cases, self-defeating. Early on, Alexander Fleming, who discovered penicillin in 1928, expressed concerns that easy access to the "wonder-drug" would eventually result in the rise of resistant strains of bacteria.[20] Indeed, scientists observed the first cases of penicillin resistance by 1946.[21] Since then, the timespan between the deployment of a new antibiotic and the observance of resistance to that antibiotic has only shortened.[22] This problem has been compounded by our inability to develop new antibiotics to supplement our dwindling arsenal.[23]

Antimicrobial resistance occurs when a microorganism adapts in such a way that it becomes able to withstand or reduce the efficacy of normal concentrations of an antimicrobial agent.[24] Bacteria can resist the effects of an antibiotic through several mechanisms, such as by reducing the antibiotic's penetration into the bacterial cell and thus preventing it from reaching its intended target.[25] Although

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81 percent decrease in tuberculosis cases among United States-born persons. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, REPORTED TUBERCULOSIS IN THE UNITED STATES, 2012, at 4 (Oct. 2013), *available at* http://www.cdc.gov/tb/statistics/reports/2012/pdf/report2012.pdf.

[19] Aidan Hollis & Ziana Ahmed, *Preserving Antibiotics, Rationally*, NEW ENG. J. MED. 2474, 2474 (2013).

[20] *Penicillin's Finder Assays its Future: Sir Alexander Fleming Says Improved Dosage Method Is Needed to Extend Use*, N.Y. TIMES, June 26, 1945, at 21 ("The greatest possibility of evil in self-medication is the use of too-small doses, so that, instead of clearing up the infection, the microbes are educated to resist penicillin and a host of penicillin-fast organisms is bred out which can be passed on to other individuals and perhaps from there to others until they reach someone who gets a septicemia or a pneumonia which penicillin cannot save.").

[21] *See* Colin Robert Crossman, *Arming Our Enemies: How Parallel Imports Could Increase Antimicrobial Resistance*, 31 N.C. J. INT'L L. & COM. REG. 823, 825 (2006).

[22] *See* Clatworthy, Pierson & Hung, *supra* note 5, at 542 Figure 1.

[23] *Id.* at 541 ("[W]ith the exception of the narrow-spectrum drugs daptomycin and linezolid, there have been no new classes of clinically relevant antibiotics discovered in over 40 years.").

[24] *See* Boerlin & White, *supra* note 5, at 21 ("[B]acterial antimicrobial resistance [is] defined as the ability of a microorganism to withstand the effect of a normally active concentration of an antimicrobial agent"); *see also* GUIDANCE #209, *supra* note 12, at 4 n.2 ("Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections.").

[25] *See* Boerlin & White, *supra* note 5, at 21–22 (classifying antimicrobial resistance mechanisms into four major categories); *see also* Ctrs. for Disease Control & Prevention, *Frequently Asked Questions (FAQ) About Antibiotics and Resistance*, NAT'L ANTIMICROBIAL RESISTANCE MONITORING SYS., http://

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some antimicrobial resistance has appeared to develop naturally, the general consensus is that much of it has been spurred on by indiscriminate human consumption.[26] For example, the speed with which microbes can evolve is accelerated when patients overuse antibiotics (by demanding that they be administered to treat nonbacterial infections) and when patients underuse antibiotics (by ceasing to take the antibiotic once they begin feeling better).[27] In this latter scenario, remaining microbes, which would have been eliminated had the patient taken the complete antibiotic dosage, become more likely to develop resistance because they have been exposed to the antibiotic but not killed by it.[28]

Another factor contributing to antimicrobial resistance is the use of therapeutic antimicrobial drugs in food-producing animals for the purpose of enhancing the animal's growth—so called nontherapeutic or production use of antibiotics.[29] Although the distinction is not always clear, production use is differentiated from both therapeutic use, which is employed to treat an animal that is known to have a clinically detectable disease, and prevention use, which is used prior to the appearance of disease symptoms in hopes of preventing the onset of disease.[30] Production use has been employed since the late 1950s[31] and is generally accomplished by adding low doses of antibiotics to the food or water of healthy

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www.cdc.gov/narms/faq.html (last updated Sept. 15, 2014) (describing several mechanisms though which bacteria can resist the effects of an antibiotic).

[26] *See* Nancy E. Halpern, *Antibiotics in Food Animals: The Convergence of Animal and Public Health, Science, Policy, Politics and the Law*, 14 DRAKE J. AGRIC. L. 401, 405 (2009); *see also Antimicrobial Resistance*, WORLD HEALTH ORG., http://www.who.int/mediacentre/factsheets/fs194/en/index.html (last updated Apr. 2014) (explaining that although the development of antimicrobial resistance is a natural phenomenon, it has been accelerated by certain human actions).

[27] *See* Crossman, *supra* note 21, at 832–33.

[28] *Id.* at 833.

[29] *See* Halpern, *supra* note 26, at 413–14; Fox, *supra* note 4, at 44; *see also* GUIDANCE #209, *supra* note 12, at 4 n.3 (preferring the term "production use" over "nontherapeutic" or "subtherapeutic" use).

[30] *See* Charles L. Hofacre, Jenny A. Fricke & Tom Inglis, *Antimicrobial Drug Use in Poultry*, *in* ANTIMICROBIAL THERAPY IN VETERINARY MED. 569, 569–70 (Steeve Giguère et al. eds., 5th ed. 2013) (describing the three categories of antimicrobial use as they apply to the poultry industry and noting that the distinction between each category is not always clear); *see also* Terence J. Centner, *Regulating the Use of Non-Therapeutic Antibiotics in Food Animals*, 21 GEO. INT'L ENVTL. L. REV. 1, 10–11 (2008) (explaining that it is sometimes difficult to distinguish between production and prevention use because the same agents can prevent disease while promoting growth).

[31] *See* Fox, *supra* note 4, at 43.

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animals.[32] Although the causative link between antibiotic administration to food-animals and their subsequent increase in growth is not fully understood,[33] production use accounts for about 70 percent of all antibiotics sold in the United States.[34] Of primary concern is that the indiscriminate use of antibiotics in food-producing animals will result in the transmission of resistant bacterial strains to humans who have contact with or ingest contaminated food.[35] Additionally, because 75 percent of the antimicrobials that food-producing animals consume are excreted unchanged, they can disseminate into the environment and spread to crops which are fertilized with the contaminated manure.[36] Furthermore, several of these production-use antibiotics are medically important to treating human infections, with some of them ranked "critically important" by the FDA.[37]

[32] *See* Halpern, *supra* note 26, at 414 ("Subtherapeutic treatment occurs when food animals are fed low dosages of antibiotics in medicated feeds for the labeled purpose to enhance growth while improving feed efficiency. Subtherapeutic dosages are generally, but not always lower than concentrations used for disease treatment, and are often fed for at least two weeks."); *see also* Centner, *supra* note 30, at 10 (explaining that nontherapeutic use involves administering low concentrations of antibiotics to the food or water of healthy animals for more than fourteen days).

[33] *See* Scott A. McEwen & Paula J. Fedorka-Cray, *Antimicrobial Use and Resistance in Animals*, 34 CLINICAL INFECTIOUS DISEASES S93, S98 (Supp. 3, 2002) (noting the complexity of the issue and summarizing several possible explanations for how antimicrobials improve growth efficiencies in farm animals).

[34] *See also* Pew Comm'n on Industrial Farm Animal Prod., *supra* note 11, at 5.

[35] Boerlin & White, *supra* note 5, at 30; *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11–801, ANTIBIOTIC RESISTANCE: AGENCIES HAVE MADE LIMITED PROGRESS ADDRESSING ANTIBIOTIC USE IN ANIMALS, 5 (Sept. 2011), http://www.gao.gov/assets/330/323090.pdf [hereinafter GAO REPORT] ("Once bacteria in an animal or human host develop resistance, the resistant strain can spread from person to person, animal to animal, or from animals to humans.").

[36] Meghan F. Davis & Lainie Rutkow, *Regulatory Strategies to Combat Antimicrobial Resistance of Animal Origin: Recommendations for a Science-Based U.S. Approach*, 25 TUL. ENVTL. L.J. 327, 339–40 (2012); *see also* GAO REPORT, *supra* note 35, at 5 ("Resistant bacteria may also spread to fruits, vegetables, and fish products through soil, well water, and water runoff contaminated by fecal matter from animals harboring these bacteria.").

[37] GAO REPORT, *supra* note 35, at 7 (explaining that the fuoroquinolone class of antibiotics is critically important to human medicine but is also approved to treat respiratory infections in cattle).

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III. REGULATING PRODUCTION USE OF ANTIBIOTICS

A. FDA Regulatory Framework and Interaction with Other Governmental Agencies

The Federal Food, Drug, and Cosmetic Act (FDCA) delegates to the FDA the authority to approve for sale and regulate the manufacture and distribution of antibiotics administered to animals and used in animal feed.[38] Under the Act, pharmaceutical companies must demonstrate the safety and efficacy of a new animal drug before the FDA will approve its label.[39] In determining the safety of a new animal drug, the agency must also take into consideration the safety risk posed to human health.[40] Additionally, the Act gives the FDA authority to withdraw an animal drug from the marketplace.[41] However, the procedure for approval withdrawal places the initial burden on the FDA, rather than the drug sponsor.[42] The result is a long and expensive process, as demonstrated by the proceedings surrounding the only incidence of such action in response to concerns about resistance—the FDA's withdrawal of approval for fluoroquinolone in poultry production.[43]

As early as the 1960s, the FDA began struggling with how best to regulate antibiotic use in animals. In 1977, the FDA first indicated that nontherapeutic use of penicillin and tetracycline in livestock could lead to the development of antibiotic-resistant superbugs.[44] However, facing opposition from the industry and Congress, the proposed ban was held in abeyance.[45] Acquiescing to Congress' direction to conduct further studies of the issue, the FDA subsequently contracted with the National Academy of Science to study the safety issues surrounding the

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[38] 21 U.S.C. §§ 301–399 (2012).

[39] *See id.* § 360b(a).

[40] *Id.* § 321(u) (defining the term "safe," as used in the sections of the FDCA relating to animal drugs, as referring "to the health of man or animal").

[41] *Id.* § 360b(e).

[42] *Id.* § 360b(e)(1).

[43] *See* Ariele Lessing, *Killing Us Softly: How Sub-Therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 482 (2010) (describing the FDA procedure for withdrawing approval for an animal drug); *see also* GAO REPORT, *supra* note 35, at 25 (describing the FDA's five-year effort to withdraw approval of fluoroquinolones in poultry).

[44] GUIDANCE #209, *supra* note 12, at 6–7.

[45] *Id.*

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use of antimicrobials in animal feed.[46] In 1980, the National Academy of Science issued a study report concluding that the available evidence could neither prove nor disprove that the sub-therapeutic use of antimicrobials in animal feed endangered human health, but cautioning that the lack of data did not mean that such dangers did not exist.[47]

This rather impotent experience characterized the FDA's actions for the next several years. Although the government did undertake several research and surveillance efforts, little was done to provide a legal mechanism to restrict the use of antibiotics in food-animals. For example, in 1996, the FDA, CDC, and USDA partnered to launch the National Antimicrobial Resistance Monitoring Program (NARMS) as a surveillance network for antimicrobial resistance in foodborne bacteria.[48] NARMS was further strengthened in 1997 through the President's Food Safety Initiative (FSI), which approached the potential problem of antimicrobial resistance through the process of risk assessment.[49] In 1999, several agencies, including the CDC and the FDA, came together to form the Interagency Task Force on Antimicrobial Resistance, which eventually published A Public Health Action Plan to Combat Antimicrobial Resistance, a blueprint for coordinating federal actions to address the threat of antimicrobial resistance.[50] Yet this document, like its predecessors, was powerless to do more than encourage regulatory action and enforcement.[51]

The FSI was eventually formalized in the "Framework Document,"[52] which grew into FDA Guidance for Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of

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[46] *Id.* at 7 (listing the four particular issues the FDA asked the National Academy of Science to study).

[47] *Id.*

[48] U.S. Food & Drug Admin., *Introduction to NARMS*, NAT'L ANTIMICROBIAL RESISTANCE MONITORING SYS., http://www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialresistancemonitoringsystem/default.htm (last updated Oct. 11, 2014).

[49] President's National Food Safety Initiative, 62 Fed. Reg. 13, 589, 590 (Mar. 21, 1997).

[50] CDC, INTERAGENCY TASK FORCE ON ANTIMICROBIAL RESISTANCE, A PUBLIC HEALTH ACTION PLAN TO COMBAT ANTIMICROBIAL RESISTANCE, 2, http://www.cdc.gov/drugresistance/actionplan/aractionplan-archived.pdf (last visited Feb. 21, 2015) (archival version of the action plan).

[51] *See id.* at 7–8 (listing the Task Force's top priority action items); *id.* at 11 ("The agencies recognize that a number of the items may require either new statutory authority or changes in regulatory requirements. The extent to which such measures may be needed to implement a given action item will be considered by the agencies involved.").

[52] *See* Davis & Rutkow, *supra* note 36, at 343.

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Human Health Concern.[53] This document, published in 2003, explicitly stated the FDA's intent to consider the impact of new antimicrobial animal drugs on human health.[54] It further recommended that drug sponsors, as part of the new animal drug application process, take a risk assessment approach to evaluating the microbial food safety of these proposed drugs.[55] However, by its nature, Guidance #152 was never intended to be binding.[56] In fact, the document itself encourages drug sponsors to discuss alternatives to the risk assessment method with FDA officials.[57]

B. Banning Fluoroquinolone Use in Poultry

Finally, in 2005, after decades of inaction, the FDA implemented a ban on fluoroquinolone use in poultry.[58] Fluoroquinolones are a critically important class of antibiotics used to treat foodborne illnesses caused by the bacteria *Campylobacter*.[59] The first fluoroquinolone was approved for use in humans in 1986, and by the late 1980s, fluoroquinolone resistance was already detected in Europe.[60] Yet, in the mid-1990s, the FDA approved two fluoroquinolones, sarafloxacin and enfrofloxacin, for use in poultry flocks to control infections caused by *E. coli*.[61] The antimicrobial was typically administered to the entire flock through drinking water, which resulted in both sick and healthy birds receiving

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[53] U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #152: EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH CONCERN (Oct. 23, 2003), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf.

[54] *Id.* at 3.

[55] *Id.* at 2.

[56] *Id.*

[57] *Id.* at 3.

[58] Animal Drugs, Feeds, and Related Products; Enrofloxacin for Poultry; Withdrawal of Approval of New Animal Drug Application, 70 Fed. Reg. 44,048 (Aug. 1, 2005) (codified at 21 C.F.R. pts. 520 & 556).

[59] *See* GAO REPORT, *supra* note 35, at 25; *see also* Amita Gupta et al., *Antimicrobial Resistance Among Campylobacter Strains, United States, 1997–2001*, 10 EMERGING INFECTIOUS DISEASES 1102, 1102 (2004), *available at* http://wwwnc.cdc.gov/eid/article/10/6/pdfs/03-0635.pdf ("*Campylobacter* is the most common cause of bacterial gastroenteritis in the United States, causing an estimated 2.4 million human infections annually.").

[60] Gupta et al., *supra* note 59, at 1102.

[61] *See id.*; GAO REPORT, *supra* note 35, at 25.

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varying concentrations of the drug.[62] In 2003, following studies that indicated a correlation between the approval of fluoroquinolones for use in poultry and the development of fluoroquinolone-resistant strains of *Campylobacter* in humans and animals, the FDA proposed the withdrawal of approval of fluoroquinolones for use in poultry.[63] Although one pharmaceutical company voluntarily complied with the FDA's proposal, Bayer (the producer of Baytril®, or enrofloxacin) challenged the decision.[64] It was not until March 16, 2004, after the FDA has spent approximately $3.3 million gathering resources and defending its decision, that an administrative law judge finally determined that enrofloxacin had not been "shown to be safe under the conditions of use upon the basis of which the application was approved" and ordered that approval of the drug be withdrawn.[65] In accordance with the FDA Commissioner's issuance of the final order withdrawing approval for its use, the FDA amended the animal drug regulations accordingly.[66]

C. FDA Draft Guidance #209

Following this prolonged administrative battle with Bayer, the FDA told the Government Accountability Office "that conducting individual postapproval risk assessments for all of the antibiotics approved prior to 2003 would be prohibitively resource intensive, and that pursuing this approach could further delay progress on the issue."[67] In June 2010, presumably preferring a voluntary strategy to promote the "judicious use" of antibiotics over a risk assessment approach, the FDA issued Draft Guidance #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.[68] In particular, the draft hinted that the FDA was interested in pursuing a more aggressive stance against the use of antibiotics for production purposes:

> In light of the risk that antimicrobial resistance poses to public health, FDA believes that the use of medically important antimicrobial drugs in food-producing animals for production purposes (e.g., to promote growth or improve

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[62] *See* Gupta et al., *supra* note 59, at 1107.

[63] *See id.*

[64] *See supra* note 58.

[65] *Id.*; GAO REPORT, *supra* note 35, at 25.

[66] *See supra* note 58.

[67] GAO REPORT, *supra* note 35, at 25.

[68] GUIDANCE #209, *supra* note 12.

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> feed efficiency) represents an injudicious use of these important drugs. Production uses are not directed at any specifically identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products.[69]

The document also urged greater veterinary oversight in the use of medically important antibiotics.[70]

Perhaps unsurprisingly, the Draft Guidance received a less than warm welcome, and the FDA found itself bombarded by critics on both sides of the aisle. In its comment on the Draft Guidance, the American Veterinary Medical Association (AVMA) stated that it "does not concur with the agency's assertion that all production uses of medically important antimicrobials are necessarily injudicious (inappropriate or unnecessary)."[71] It also indicated that any drugs which are currently labeled for production use, but which could also be used for prevention of disease, should be relabeled accordingly, essentially circumventing the Guidance.[72] At the same time, a number of interested parties submitted comments on the Draft Guidance expressing their dismay at the impotency of the FDA's strategy. They primarily took issue with the voluntary nature of the Guidance and the obvious loophole created by the allowance for prevention use of antibiotics.[73]

d. FDA Final Guidance for Industry #209

Amongst this barrage of criticism, the FDA moved forward and, on April 11, 2012, issued Final Guidance for Industry #209.[74] In its final form, Guidance #209 endorses scientific studies establishing links between antibiotic-resistant infections

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[69] *Id.* at 27.

[70] *Id.* at 28–29.

[71] Letter from W. Ron DeHaven, Exec. Vice President & CEO, Am. Veterinary Med. Ass'n, to FDA, *3 (Aug. 30, 2010), *available at* https://www.avma.org/Advocacy/National/Documents/10-08_fda_draft_guidance_209_avma_comments.pdf.

[72] *Id.*

[73] *See* Letter from Laura Rogers, Project Director, Pew Campaign on Human Health and Industrial Farming, to FDA, *2–3 (July 10, 2012), *available at* http://www.pewtrusts.org/~/media/Assets/2012/07/10/Pew-Guidance-209-071012.pdf; *see also* Letter from Michael Hansen, Senior Scientist, Comments of Consumers Union on Food and Drug Administration (FDA) Draft Guidance (Aug. 30, 2010), *available at* http://consumersunion.org/pdf/FDA-comments-Antimicrobial-Drugs-0810.pdf.

[74] GUIDANCE #209, *supra* note 12.

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and antibiotic use in food-animals and calls for the adoption of practices that will ensure the judicious use of these drugs in food-producing animals.[75] To this end, it provides a framework for the voluntary phase out of medically important antibiotics for growth promotion purposes.[76] Specifically, the document outlines two principles: first, that medically important antibiotics in food-animals should only be used when necessary for assuring animal health, and second, that their use should be subject to veterinary oversight or consultation.[77] These principles are, however, subject to the rather significant caveat that the "FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals."[78]

e. FDA Final Guidance for Industry #213 and Proposed Rule on the Veterinary Feed Directive

Most recently, in December 2013, the FDA issued two additional policy documents, which the FDA claims "will help veterinarians, farmers and animal producers use medically important antibiotics judiciously in food-producing animals by targeting their use to only address diseases and health problems."[79]

The first of these, Final Guidance for Industry #213, reiterates the FDA's conviction that a voluntary approach will be the most effective at achieving the more judicious use of medically important antibiotics in food-producing animals.[80] The guidance elaborates on the principles set out in Guidance #209 (i.e., the call for veterinary oversight and the determination that the use of antibiotics for growth promotion or protection purposes is inappropriate while the use of antibiotics for disease prevention and control may be judicious) and provides guidance to drug companies on how to bring their applications for new animal drugs into alignment with Guidance #209.[81] Specifically, Guidance #213 requests that, within three months from the date of its publication, affected drug companies inform the FDA

[75] *See generally id.* at 3–18.

[76] *Id.* at 3.

[77] *Id.* at 20–22.

[78] *Id.* at 21.

[79] News Release, U.S. Food & Drug Admin., *FDA Takes Steps to Protect Public Health* (Apr. 11, 2012), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm299802.htm.

[80] GUIDANCE #213, *supra* note 12, at 5.

[81] *See generally id.*

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of their intention to voluntarily remove "growth promotion" from their product labels.[82] The guidance also asks that these companies transition the marketing status of medicated feed products from over-the-counter to a veterinary feed directive and the status of medicated drinking water products from over-the-counter to veterinary prescription.[83] Furthermore, Guidance #213 outlines the FDA's intention to make available to the public information regarding the antibiotics affected by the guidance, the level of engagement of affected drug sponsors, and completed changes to affected products.[84] The FDA anticipates that affected drug companies should be able to implement these changes within three years from final publication of the guidance; after that time has elapsed, the FDA will evaluate the progress of its voluntary strategy and the adoption rate of the proposed changes.[85] According to the guidance, the FDA will then consider whether further action will be necessary.[86]

Additionally, Guidance #213 offers several "clarifications" of the principles set out in Guidance #209. For instance, it elaborates on the appropriate disease-prevention use of medically important antibiotics by outlining several factors that veterinarians should consider when determining whether prescriptions for such purposes are "judicious."[87] Guidance #213 also clarifies that in the event that scientific evidence demonstrates that there is actually a therapeutic benefit associated with the production use of an antibiotic, drug companies must submit additional safety and effectiveness data if they wish to add new uses or to change the drug's components.[88] The FDA will approve new antibiotics only if they have specific dosing durations and levels for identified diseases and specific animals, not for entire herds or flocks.[89]

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[82] *Id.* at 6.

[83] *Id.* at 7.

[84] *Id.* at 9.

[85] *Id.*

[86] *Id.*

[87] *Id.* at 7 ("[I]mportant factors . . . include whether (1) there is evidence of effectiveness, (2) such a preventive use is consistent with accepted veterinary practice, (3) the use is linked to a specific etiologic agent [disease origin], (4) the use is appropriately targeted to animals at risk of developing a specific disease, and (5) no reasonable alternatives for intervention exist.").

[88] *Id.* at 11–15.

[89] *Id.* at 13.

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The second policy document, the proposed rule on the Veterinary Feed Directive (VFD), is intended to improve the efficacy of the existing VFD regulations to facilitate the transition of animal drug products into the VFD system.[90] If finalized, the proposed rule will make several changes to the current VFD regulations. This includes "increas[ing] flexibility for licensed veterinarians issuing VFDs" by removing the "one-size-fits-all" federally defined code of veterinary professional conduct (known as the veterinarian-client-patient relationship or VCPR) and deferring instead to the individual states' criteria for acceptable veterinary conduct.[91] Additionally, it proposes setting a default expiration date of six months for a VFD, unless otherwise indicated.[92] In keeping with the "efficiency" theme, it also proposes streamlining administrative procedures and reducing recordkeeping requirements.[93]

IV. CRITICISM OF THE FDA'S REGULATORY STRATEGY

Although criticisms of the FDA's regulatory strategy abound,[94] they generally can be condensed into three central concerns. First, Guidance #209 and Guidance #213 have fallen under significant attack for their voluntary nature.[95] It is true that if pharmaceutical companies remove "growth promotion" or "feed efficiency" from their labels, any subsequent use of those drugs for production purposes would be considered "extralabel use" and thus, illegal.[96] The problem is, however, that there

[90] Veterinary Feed Directive, 78 Fed. Reg. 75515, 75515 (proposed Dec. 12, 2013).

[91] *Id.* at 75516.

[92] *Id.* at 75521.

[93] *Id.* at 75516.

[94] *See generally* Avinash Kar, *FDA Announces Finalization of Voluntary Guidance on Antibiotic Misuse in Livestock Industry*, SWITCHBOARD NAT'L RES. DEF. COUNCIL STAFF BLOG (Dec. 11, 2013), http://switchboard.nrdc.org/blogs/akar/fda_announces_finalization_of.html; Charles Kenny, *FDA Inaction on Antibiotics Is Making the World Deadlier*, BLOOMBERG BUSINESSWEEK (Dec. 23, 2013), http://www.businessweek.com/articles/2013-12-23/fda-inaction-on-antibiotics-is-making-the-world-deadlier; David Wallinga, *FDA Underwhelms With Response to Super-Resistant Infections Rise*, HUFFINGTON POST, Dec. 30, 2013, *available at* 2013 WLNR 32563345; Venessa Wong, *Why Antibiotic Makers Aren't Worried About FDA's Livestock Rules*, BLOOMBERG BUSINESSWEEK (Dec. 12, 2013), http://www.businessweek.com/articles/2013-12-12/why-antibiotic-makers-arent-worried-about-fdas-livestock-rules.

[95] *Id.*

[96] *See* GUIDANCE #213, *supra* note 12, at 8.

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is nothing mandating that these companies alter their labels in the first place.[97] This has led critics such as Avinash Kar, an attorney with the Natural Resources Defense Council, to express cynicism about the efficacy of a voluntary program, asking whether "we really think the pharmaceutical industry is going to voluntarily walk away from such a big chunk of its customer base[.]"[98] Yet, despite concerns that politely asking Big-Pharma to cooperate with the FDA would be the equivalent of giving a free pass to the industry, the two largest drug companies, Elanco and Zoetis, indicated early on that they will follow the FDA's advice.[99] Furthermore, in keeping with the FDA's request that drug companies notify the agency of their intent to cooperate within three months from the date of publication of the guidance, on March 10, 2014, members of the Animal Health Institute (AHI) and the Generic Animal Drug Alliance (GADA) announced their written commitments to comply with the guidance.[100] Thus, concerns about their voluntary nature actually may be the weakest criticism associated with Guidance #209 and Guidance #213.

Of more pressing concern is the oft-mentioned "loophole" created by the FDA's approval of these antibiotics in animals for the purpose of preventing disease.[101] Given that six out of eight medically important antibiotics are currently approved by the FDA for both growth promotion purposes and disease prevention in some species,[102] this loophole allows the industry to continue the same practice (adding low doses of antibiotics to the feed and water of healthy animals on a daily basis) but under a different name.[103] As reported by the United States Government

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[97] *See* GUIDANCE #209, *supra* note 12, at 3 (explaining that *Guidance #209* is merely a recommendation and that it does not establish any legally enforceable responsibilities); GUIDANCE #213, *supra* note 12, at 4 (reiterating the nonbinding nature of agency guidance).

[98] Kar, *supra* note 94.

[99] *See* Dan Charles, *Drug Companies Accept FDA Plan to Phase Out Some Animal Antibiotic Uses*, NPR (Dec. 11, 2013, 5:00 PM), http://www.npr.org/blogs/thesalt/2013/12/11/250239604/drug-companies-accept-fda-plan-to-phase-out-some-animal-antibiotic-uses.

[100] *See Animal Drug Companies Formally Agree to Phase Out Growth Promotion Antibiotics*, 6 INSIDE HEALTH REFORM 11 (Mar. 12, 2014), *available at* 2014 WLNR 6721186.

[101] *See* GUIDANCE #209, *supra* note 12, at 21 ("FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals.").

[102] *See* GAO REPORT, *supra* note 35, at 27.

[103] *See* Kar, *supra* note 94.

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Accountability Office, there is an economic incentive to side-step the labeling changes:

> One veterinarian told us that if FDA withdrew an antibiotic's approval for growth promotion, he could continue to give the antibiotic to the animals under his care at higher doses for prevention of a disease commonly found in this species. The veterinarian stated that there is an incentive to do so because using an animal antibiotic can help the producers he serves use less feed, resulting in cost savings.[104]

The futility of the FDA's strategy is compounded by its inability to address what is likely the root cause of the widespread prevention use of antibiotics—the unsanitary conditions in which food-producing animals are raised on factory farms.[105] The FDA claims it is concerned "that giving antimicrobial drugs to food-producing animals at low levels for long periods of time and in large numbers of animals may contribute to antibiotic resistance."[106] Yet, in the absence of a regulatory strategy that addresses the practical similarity between production use and prevention use (much less, one that addresses the problem from which the need for widespread prevention use stems in the first place), the FDA should not be surprised to find that Guidance #209 and Guidance #213 have a limited impact on the spread of antibiotic-resistant superbugs.

Finally, the FDA has been criticized for its continued lethargic response to concerns about antibiotic resistance.[107] Despite the mounting evidence of a link between antibiotic use in food-producing animals and antibiotic resistance in humans,[108] these recent guidances demonstrate that the FDA does not plan to abandon its "wait-and-see" approach anytime soon. Although the very issuance of

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[104] GAO REPORT, *supra* note 35, at 27–28.

[105] *See* Anastasia S. Stathopoulos, *You Are What Your Food Eats: How Regulation of Factory Farm Conditions Could Improve Human Health and Animal Welfare Alike*, 13 N.Y.U. J. LEGIS. & PUB. POL'Y 407, 418–19 (2010) ("One major downside to raising animals in extreme confinement, from the perspective of industrial agriculture, is that the animals have an abnormally high risk of illness. In order to combat this self-created problem, factory farmers mix low doses of antibiotics into the animals' feed and water as a precautionary measure. Without these antibiotics, the animals would likely die from disease before they could be slaughtered.").

[106] GUIDANCE #213, *supra* note 12, at 13.

[107] *See* Kar, *supra* note 94.

[108] *See* discussion *supra* Part II.

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these guidances could be hailed as progress, the FDA is allowing the voluntary program to proceed for three years before evaluating whether binding regulations will be necessary in the future.[109] Given that it has taken over three decades (and the not so gentle nudging of a lawsuit[110]) for the FDA to get to this point, it is unsurprising that many lack faith in the FDA's ability to efficiently implement more stringent regulations anytime soon.

V. COMPARISON TO OTHER SUPPLY-SIDE SOLUTIONS: EUROPEAN BANS ON GROWTH-PROMOTING ANTIBIOTICS

Of course, a complete ban on antibiotic use in food-producing animals may not be any more desirable of a solution than the voluntary approach taken by the FDA. Fortunately, this debate no longer must be played out exclusively in the realm of hypothetical scenarios. Europe has provided a real-world example of the consequences—both positive and negative—of a regulatory scheme that seeks to address antibiotic resistance by choking off the antibiotic supply for growth promotion purposes in food-producing animals. Moreover, European countries make for a particularly apt comparison to the United States given the similarity of their economic levels and methods of agricultural production.[111]

Following a recommendation by the Swedish Farmers Organization, Sweden first implemented a ban on all growth-promoting antibiotics in 1986.[112] Within ten years, Denmark, Norway, and Finland followed suit.[113] The research conducted in these countries subsequently formed the basis of the European Union's decision to pass legislation in 2003 banning all use of antibiotic growth promoters (AGPs) beginning in 2006.[114]

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[109] *See* GUIDANCE #213, *supra* note 12, at 9.

[110] Nat. Res. Def. Council, Inc. v. FDA, 872 F. Supp. 2d 318, 342 (S.D.N.Y. 2012) (holding that the FDA arbitrarily denied petitions filed by advocacy organizations in 1999 and 2005 seeking the withdrawal of the FDA's approval of the use of certain antibiotics in livestock for nontherapeutic purposes).

[111] *See* Davis & Rutkow, *supra* note 36, at 364.

[112] Hans H. Stein, *Experience of Feeding Pigs Without Antibiotics: A European Perspective*, 13 ANIMAL BIOTECHNOLOGY 85, 85 (2002), *available at* http://nutrition.ansci.illinois.edu/sites/default/files/AnimBiotech13.85-95.pdf.

[113] *See* Centner, *supra* note 30, at 15 (discussing how these countries have taken action to eliminate the use of antimicrobial growth promoters in animals).

[114] Commission Regulation 1831/2003, art. 3, 2003 O.J. (L 268) 29 (EC).

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The Danish experience provides an instructive case study because its ban on AGPs has produced rather mixed results.[115] Defenders of Denmark's ban point to the positive impacts noted by the WHO's report on the termination of AGPs in food-animals in Denmark published in 2003.[116] Specifically, they point out that the quantity of antibiotics used in food-animals in Denmark declined by over 50 percent from the peak in 1992 to 2008.[117] Additionally, they claim that swine production in Denmark has actually increased by nearly 50 percent since 1992, that the ban did not have a direct impact on the growth rate and increased mortality of finisher hogs, and that the ban only increased the production cost of hogs by just over 1 percent.[118]

However, opponents of implementing a similar ban in the United States point to statistics indicating that Denmark's approach has not produced its intended benefits but has actually resulted in negative consequences, such as diminished animal welfare and increased production costs.[119] For example, following the implementation of the ban on AGPs, the therapeutic use of antibiotics increased significantly in order to compensate for the increased incidence of ailments such as diarrhea.[120] Ironically, the AGPs impacted by the ban actually have less use in human medicine than do the therapeutic antibiotics that replaced them.[121] Additionally, critics of Denmark's approach estimate that a similar ban in the United States would result in an increase in cost of approximately $4.50 per animal

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[115] Dan Charles, *Europe's Mixed Record on Animal Antibiotics*, NPR (Mar. 23, 2012, 4:53 PM), http://www.npr.org/blogs/thesalt/2012/03/23/149221287/europes-mixed-record-on-animal-antibiotics.

[116] *See generally Avoiding Antibiotic Resistance: Denmark's Ban on Growth Promoting Antibiotics in Food Animals*, PEW CHARITABLE TRUSTS [hereinafter *PEW Report on Denmark's Ban*], *available at* http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/Denmark Experiencepdf.pdf (last visited Feb. 12, 2015).

[117] *See id.* at *2.

[118] *Id.* at *3; *see also* Frank Aarestrup, *Get Pigs Off Antibiotics*, 486 NATURE 465, 465–66 (June 28, 2012), *available at* http://www.tufts.edu/med/apua/index_391_2586402622.pdf.

[119] *See generally The Antibiotic Ban in Denmark: A Case Study on Politically Driven Bans*, ANIMAL HEALTH INST., *available at* http://www.ahi.org/issues-advocacy/animal-antibiotics/the-antibiotic-ban-in-denmark-a-case-study-on-politically-driven-bans/ (last visited Feb. 12, 2015); Mark Casewell et al., *The European Ban on Growth-Promoting Antibiotics and Emerging Consequences for Human and Animal Health*, 52 J. ANTIMICROBIAL CHEMOTHERAPY 159 (July 1, 2003), *available at* http://www.ahi.org/wp-content/uploads/2011/06/Casewell-JAC-Aug-03.pdf; Dermot J. Hayes & Helen H. Jensen, *Lessons from the Danish Ban on Feed-Grade Antibiotics*, CTR. FOR AGRIC. & RURAL DEV. (June 2003), *available at* http://www.card.iastate.edu/publications/dbs/pdffiles/03bp41.pdf.

[120] Casewell et al., *supra* note 119, at 160; Hayes & Jensen, *supra* note 119, at 3–6.

[121] Hayes & Jensen, *supra* note 119, at 4–6.

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in the first year of implementation, with the total cost spread across a ten-year period estimated to be in excess of $700 million.[122]

VI. OPTIMIZING DEMAND-SIDE SOLUTIONS

Given the FDA's continued lethargic response to the issue of antibiotic resistance, it seems unlikely that the agency will resort to implementing a compulsory ban any time in the near future. According to Guidance #213, it will be at least another three years before the FDA even considers whether measures in addition to the voluntary program will be necessary.[123] Additionally, in light of the mixed results in Denmark, it is far from clear that Europe's approach to cutting off supply is a preferable course of action. Instead, the solution to combating antibiotic resistance may well lie in the private sector.

As information about the dangers of antibiotic resistance has become more widely available, consumers have placed increased pressure on food producers and retailers to meet their demand for antibiotic-free meat products.[124] In response to a 2012 survey, 86 percent of consumers reported that they thought antibiotic-free meat should be available in their local supermarket.[125] Additionally, 61 percent of consumers indicated that they would pay an additional five cents or more per pound for antibiotic-free meat, and 31 percent reported that they would pay an extra dollar or more per pound.[126] A number of producers, grocers, and restaurants have responded to this demand by implementing their own voluntary bans on the sale of meat products treated with antibiotic growth promoters.[127] In 2003, McDonald's adopted a policy "prohibit[ing] the use of antibiotics belonging to classes of compounds approved for use in human medicine when used solely for

[122] *Id.* at 7–9.

[123] *See* GUIDANCE #213, *supra* note 12, at 9.

[124] *See* Centner, *supra* note 30, at 23–24 (discussing the consumer movement for antibiotic-free meat products and its impact on retailers).

[125] Danielle Gould, *Survey Reveals Growing Consumer Demand for Antibiotic-Free Meat*, FORBES (June 26, 2012, 12:17 PM), http://www.forbes.com/sites/daniellegould/2012/06/26/survey-reveals-growing-consumer-demand-for-antibiotic-free-meat/.

[126] *Id.*

[127] *See Top Food Companies Moving Away From Overuse of Antibiotics on Industrial Farms*, PEW CHARITABLE TRUSTS, *available at* http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/other_resource/HIFFPrivateSectorABXFactsheetpdf.pdf (listing several food producers, supermarkets, restaurants, and food service providers in the United States that offer antibiotic-free products).

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growth promotion purposes."[128] Several other popular restaurant chains have followed suit, including Chipotle Mexican Grill,[129] Panera Bread,[130] and, most recently, Chick-fil-A.[131]

Chipotle has adopted one of the most aggressive policies, endeavoring to sell meat products that have never been given antibiotics, even for therapeutic purposes.[132] Even following reports that Chipotle would have to alter its policy to permit beef producers to use antibiotics for therapeutic purposes due to a scarcity of meat producers able to meet its demand, the chain's antibiotic ban continues to stand.[133] Chipotle does admit to serving conventional meat when it runs out of meat raised entirely without antibiotics.[134] Yet, in 2012 alone, Chipotle served more than 120 million pounds of antibiotic-free beef, pork, and chicken,[135] and the fact that such high demand is placing a strain on Chipotle's suppliers should be seen as a positive sign that consumers are creating a market niche for antibiotic-free meat products in the United States. In fact, while antibiotic-free chicken accounted for

[128] *McDonald's Global Policy on Antibiotic Use in Food Animals*, MCDONALD'S CORP., at 2 (2003), http://www.aboutmcdonalds.com/content/dam/AboutMcDonalds/Sustainability/Sustainability%20Library/antibiotics_policy.pdf. An updated version of McDonald's policy is scheduled to be released in 2015. *Id.* As of the writing of this Note, an updated version has yet to be released.

[129] *Food with Integrity*, CHIPOTLE MEXICAN GRILL, https://www.chipotle.com/en-us/fwi/animals/animals.aspx (last visited Feb. 12, 2015).

[130] Panera Bread, *Antibiotic-Free Answers*, *available at* http://marketing.panerabread.com/liveconsciouslyeatdeliciously/#!articles/antibiotic_free_answers (last visited Mar. 13, 2014).

[131] *Our Journey: Antibiotic-Free Chicken*, CHICK-FIL-A, http://www.chick-fil-a.com/antibiotic-free (last visited Feb. 12, 2015).

[132] *Food with Integrity*, *supra* note 129.

[133] Dan Charles, *Chipotle Is Keeping Its Meat Antibiotic-Free After All*, NPR (Aug. 13, 2013, 4:22 PM), http://www.npr.org/blogs/thesalt/2013/08/13/211717907/chipotle-changes-antibiotic-free-policy-oops-no-it-doesnt.

[134] *Id.*; *see also* Candice Choi, *Chick-fil-A: No More Antibiotics In Our Chicken Within Next 5 Years*, HUFFINGTON POST (last updated Apr. 13, 2014, 5:59 AM), http://www.huffingtonpost.com/2014/02/11/chick-fil-a-antibiotics-chicken_n_4768303.html (reporting that less than 1% of Chipotle's chicken was raised conventionally in 2013).

[135] Venessa Wong, *There Aren't Enough Antibiotic-Free Cows for Chipotle*, BLOOMBERG BUISNESSWEEK (Aug. 14, 2013), http://www.businessweek.com/articles/2013-08-14/there-arent-enough-antibiotic-free-cows-for- chipotle.

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only about 9 percent of the market in 2013, the antibiotic-free meat business has been repeatedly hailed as a fast-growing sector.[136]

As demonstrated above, the corporate reaction to the increased popularity of antibiotic-free meat has been strong, and as more retailers join the antibiotic-free movement, they are likely to spur a chain reaction among their competitors. As Chipotle spokesman Chris Arnold aptly noted in response to Chick-fil-A's recent plans to phase out chicken raised with antibiotics, "[t]he more people are raising the bar, the more the food chain will shift, and the more consumers will become knowledgeable about issues surrounding food production and why these things matter."[137] Indeed, it is not unlikely that Chick-fil-A's decision was prompted, at least in part, by the fact that shares of Chipotle were the best-performing in 2013 among fast-food restaurants.[138] Given the rate at which the market is responding to consumer demand for antibiotic-free products, it is foreseeable that the private sector will continue to take a more proactive approach to preventing the spread of antibiotic resistance than the FDA.[139]

Although the private sector appears to be addressing concerns about antibiotic resistance in a rather efficient manner (at least in comparison with the FDA's lackluster response), there remains a useful role for regulation—specifically, regulation that focuses on optimizing demand for antibiotic-free meats, rather than regulation that focuses on strangling the supply. In addition to concluding that consumers are willing to place substantial premiums on pork produced without antibiotics, a 2006 study suggested that legislation that focuses on the demand-side of the equation, i.e., by focusing on reducing information asymmetries about product quality, may be more justifiable than legislation that focuses on the supply-

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[136] *See* Maria Godoy, *Americans Want Antibiotic-Free Chicken, And The Industry Is Listening*, NPR (Feb. 19, 2014, 4:13 PM), http://www.npr.org/blogs/thesalt/2014/02/14/276976353/americans-want-antibiotic-free-chicken-and-the-industry-is-listening; Allison Aubrey, *Antibiotic-Free Meat Business is Booming, Thanks To Chipotle*, NPR (May 31, 2012, 5:48 PM), http://www.npr.org/blogs/thesalt/2012/05/31/154084442/antibiotic-free-meat-business-is-booming-thanks-to-chipotle.

[137] Godoy, *supra* note 136.

[138] *See* Andrew Martin, *Read Our Beaks: Chick-fil-A Takes 'No Antibiotics' Vow*, BLOOMBERG BUSINESSWEEK (Feb. 12, 2014), http://www.businessweek.com/articles/2014-02-12/chick-fil-a-exec-vows-no-antibiotics-ever-in-chicken-sandwiches. Chick-fil-A acknowledged that its decision was influenced largely by the fact 70 percent of its customers rated antibiotic-free meat as a top issue in surveys. *Id.*

[139] *Cf.* Fothergill, *supra* note 13 ("[I]t is to be hoped that increased demand from major chains like Chipotle, McDonald's and KFC will help. If they were to make this demand then cattle production would change at a much faster pace than that proposed currently [by the FDA].").

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side, i.e., compulsory bans on antibiotic use in food-producing animals.[140] This conclusion is based partly on the idea that consumers who are not knowledgeable about current production practices will not respond in the event that a ban on sub-therapeutic antibiotics is implemented.[141] Unaware of the value in reducing antibiotic resistance, consumers would be less likely to pay the increased pork prices that flow from the increased production costs associated with raising antibiotic-free pork.[142] This would ultimately result in surplus losses to producers and consumers.[143] Thus, it appears that policymakers could best optimize their efforts at reducing antibiotic resistance by tailoring future regulation toward increasing consumer awareness of food quality and production practices.

VII. CONCLUSION

Antibiotic resistance is not only a public health concern, but also an economic one. Although science has not yet pinpointed a direct link between the administration of antibiotics to food-producing animals and the increase in antibiotic resistance in humans, the evidence establishing such a link is mounting and, at long last, has been acknowledged by the FDA. With the issuance of Guidance #209 and Guidance #213, the FDA has opted to employ a voluntary program through which pharmaceutical companies can begin phasing out the use of antibiotics for growth promotion purposes in animals. Although it is encouraging to see that the FDA has acknowledged the antibiotic resistance problem, the agency has fallen under heavy criticism for the voluntary nature of its solution and its failure to address the equally concerning therapeutic use of antibiotics in food-producing animals.

In light of the FDA's less than optimal response to this major health concern, it should be remembered that Guidance #209 and Guidance #213 offer but one approach to the solution. As consumer demand for antibiotic-free products has increased, pressure has been mounting for food producers and retailers to voluntarily change their own policy regarding these products. A number of influential companies and restaurants have already reacted to the increasing popularity of these products and have made great strides in eliminating antibiotic-

[140] Jayson L. Lusk, F. Bailey Norwood & J. Ross Pruitt, *Consumer Demand for a Ban on Antibiotic Drug Use in Pork Production*, 88 AM. J. AGRIC. ECON. 1015, 1029–30 (2006).

[141] *Id.* at 1030.

[142] *Id.*

[143] *Id.*

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treated meats from their menus and shelves. This places pressure on competing companies to partake in the antibiotic-free meat business as well. In light of these trends in the private sector, the government would do well to focus its efforts on optimizing consumer demand for antibiotic-free meat rather than entrenching itself in the mires of supply-side regulation, whether voluntary or compulsory.

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