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FDA Industry Guidance Targeting Antibiotics Used in Livestock Will Not Result in Judicious Use or Reduction in Antibiotic-Resistant Bacteria

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**FDA INDUSTRY GUIDANCE TARGETING
ANTIBIOTICS USED IN LIVESTOCK WILL NOT
RESULT IN JUDICIOUS USE OR REDUCTION
IN ANTIBIOTIC-RESISTANT BACTERIA**

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This note evaluates the recent Food and Drug Administration (“FDA”) efforts to promote judicious use¹ of antibiotics in livestock, assesses its potential for effectiveness, and recommends additional steps that can be taken to combat antibiotic-resistant bacteria through diminished antibiotic use in food-producing animals.

As a background, this note will first explain how the business of farming relies on routine use of antibiotics in food-producing animals. Second, it will look at the emergence of antibiotic-resistant bacteria, associated health risks, and costs. Third, this note will highlight various failed attempts over the last four decades to reduce antibiotics used in food-producing animals. Fourth, it will examine two recent FDA efforts to increase judicious use of antibiotics in livestock with the stated goal of reducing antibiotic-resistant bacteria. Last, this note will point out the incongruity in the FDA’s stated intent, and the probable consequences of the industry guidance.

In the conflict section, the note will weigh both sides of the argument. Some believe recent FDA guidance is a necessary and meaningful step toward reducing antibiotic usage and antibiotic-resistant bacteria. The note will then examine how this current guidance and its language provide loopholes which critics believe will result in the guidance being largely ineffective.

The analysis will propose a resolution to the conflict. Congress should pass legislation to control antibiotic use. The FDA should promulgate rules that would close loopholes left open by voluntary suggestions and stop over the counter (“OTC”) use of antibiotics for

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1. The FDA describes judicious use as avoiding unnecessary or inappropriate use.

subtherapeutic use immediately. Should animals fall ill, farmers would be required to obtain prescriptions for antibiotics in medically necessary cases. Surveillance mechanisms need to be put in place to ensure compliance and if parties are found noncompliant, penalties should result. The FDA should have authority to monitor and enforce regulations and award fines for violations.

I. BACKGROUND

This note will discuss antibiotic resistance at length. Antibiotic resistance refers to bacteria that cause infections, which are resistant to antibiotics. When bacteria become resistant to antibiotics, standard treatments lose effectiveness.² As more and more bacteria develop resistance to antibiotics, a public health issue emerges. The Food and Drug Administration (“FDA”) has recently engaged the public health issue of antibiotic resistant bacteria. One of the FDA’s areas of concern is the widespread use of antibiotics with livestock.³

To respond to the public health issue of antibiotic resistance and to address the widespread use of antibiotics on farms, the FDA publishes guidance letters directed at the pharmaceutical industry. These letters are called Guidance for Industry. The first Guidance for Industry addressing antibiotic resistance is #209, entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals” (“GFI 209”) on April 13, 2012.⁴ GFI 209 articulated the agency’s current thinking regarding the judicious use of medically important antimicrobial drugs in food-producing animals. GFI 209 considered recommendations of dozens of scientific studies and reports produced over the past forty years. The FDA recognized the health crisis associated with overuse of antibiotics and called for judicious use.

2. *World Health Organization Fact Sheet*, <http://www.who.int/mediacentre/factsheets/fs194/en/>.

3. *Antibiotics and Antibiotic Resistance*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/antibioticsandantibioticresistance/default.htm>.

4. All FDA Guidance for Industry, available at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm>.

Then, in December 11, 2013, the supporting Guidance #213 (“GFI 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” was published.⁵ GFI 213 tells drug sponsors they may voluntarily change labels of antibiotics to comply with GFI 209 in the next three years.

*A. Agribusiness Relies on Routine Use of Antibiotics
in Food-Producing Animals*

Raising cattle today is a much different business than it was in 1953 when Don Tyson took a trip to the bank for Tyson Farms’ first loan.⁶ The family farm is nearly extinct today. In the past fifty years, the United States has lost more than one million farms.⁷ Instead, we have a lucrative industry of corporate meat producers. Presently, there exists a four-firm concentration in meat productions.⁸ Of the total U.S. market for poultry, pork, and beef, these four firms control 51 percent, 65 percent and 85 percent respectively.⁹ These firms produce animals in concentrated animal feeding operations (“CAFOs”).¹⁰ CAFOs produce millions of animals annually.

5. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #213, available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> [hereinafter GFI #213].

6. CHRISTOPHER LEONARD, THE MEAT RACKET 58 (2014) (I specifically mention Tyson Farms, because it was founded in 1935 and Tyson Foods Inc. is the largest meat producer in the world today).

7. Erin Williams, *How Corporate Control Squeezes Out Small Farms*, PEW CHARITABLE TRUSTS (July 18, 2012), <http://www.pewenvironment.org/newsroom/fact-sheets/how-corporate-control-squeezes-out-small-farms-8589942044>.

8. Roberto A. Ferdman, *Americans Have Never had So Few Options in Deciding What Company Makes Their Meat*, June 11, 2014, <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/06/11/americans-have-never-had-so-few-options-in-deciding-what-company-makes-their-meat/> (The four companies are Tyson Foods, JBS, Cargill, and Smithfield Foods. Another unrelated issue arising from a four firm concentration is the power to manipulate prices; in this case, of meat).

9. Williams, *supra* note 7.

10. Region 7 Concentrated Animal Feeding Operations (CAFOs), *What is a CAFO?*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/region7/water/caf/>. (Describing CAFOs as a type of Animal Feeding Operation (AFO) where

America has one of the highest meat consumption rates in the world.¹¹

1. CAFOs Create Deplorable Conditions for Livestock

Livestock raised on CAFOs do not typically have a lot of space to roam. A CAFO confines animals for more than 45 days of a growing season in an area that does not produce vegetation and meets certain size thresholds.¹² Pigs and chickens often live shoulder to shoulder and often do not see the light of day. Cows live confined in pens and stand in feet of their own feces. The close quarters in which animals are raised increases the animals' stress levels¹³ and creates an ever-present risk of disease.¹⁴ CAFOs also produce so much animal waste that the Environmental Protection Agency ("EPA") has categorized it as a pollutant.¹⁵ There is little legal protection controlling animal welfare. Many statutes exempt acceptable animal husbandry practices or exclude farm animals from their purview.¹⁶ Animal husbandry practices are set by the industry and profits are the guiding factor.¹⁷ While the manner in which animals are raised can and should be changed, animal welfare is beyond the scope of this note. Instead, this note will focus on the role antibiotics play on the industrial farm.

animals are confined for at least 45 days of a 12-month period. "AFOs congregate animals, feed, manure and urine, dead animals, and production operations on a small land area.")

11. Eliza Barclay, *A Nation of Meat Eaters: See How It All Adds Up*, NAT'L PUB. RADIO BLOG (June 27, 2012, 3:03 AM), <http://www.npr.org/blogs/thesalt/2012/06/27/155527365/visualizing-a-nation-of-meat-eaters>.

12. Robyn Mallon, *The Deplorable Standard of Living Faced by Farmed Animals in America's Meat Industry and How to Improve Conditions by Eliminating the Corporate Farm*, 9 MICH. ST. J. MED. & L. 389, 395 (2005).

13. *Id.* at 398-99.

14. Barbara O'Brian, *Animal Welfare Reform and the Magic Bullet: The Use and Abuse of Subtherapeutic Doses of Antibiotics in Livestock*, 67 U. COLO. L. REV. 407, 412 (1996).

15. Scott Jerger, *EPA's New CAFO Land Application Requirements: An Exercise in Unsupervised Self-Monitoring*, 23 STAN. ENVTL. L. J. 91, 99 (2004).

16. *See* O'Brian, *supra* note 14, at 408.

17. *See id.*

2. Antibiotics are Routinely Used to Promote Growth, Prevent Illness, and Treat Disease

Growing food is no longer referred to as farming or ranching. Instead, we now call the business of growing food “agribusiness.”¹⁸ Drugs are now used to make animals gain weight faster – known in the industry as “production,”¹⁹ and the animals that we eat are now described as “food-producers.”²⁰ Minimally funded federal agencies like the FDA, charged with guarding public health, are no match for wealthy pharmaceutical giants concerned mainly with shareholder profits.

The United States has a rich history of cases where the market takes an early lead with a new product as they scoop up unregulated profits.²¹ From cigarettes to asbestos, formaldehyde, and dichlorodiphenyltrichloroethane (“DDT”), each were sold and used in copious amounts.²² The public believed products were safe for use as advertised, and companies were quick to assure its consumers these products were free from unreasonable risks.²³ Public health again fails to garner appropriate attention in the marketplace despite study after study warning us of the risks. Meanwhile, legislative and judicial branches exhaust the weapons in their respective arsenals to combat antibiotic overuse.

The government is often slow to recognize and protect against dangers lurking in FDA-regulated products. Valerie Watnick, author of multiple articles on food quality and pesticide regulation, devoted an entire article to the FDA’s reluctance to step in where there is a disconnect between the public’s understanding of the dangerousness of pesticides and agency responsibility to protect public health.²⁴

18. See *Mirriam-Webster Dictionary*, agribusiness is defined as the business of industry of farming or agriculture: farming through of as a large business.

19. GUIDANCE FOR INDUSTRY #209, U.S. FOOD & DRUG ADMIN., available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf> [hereinafter GFI #209].

20. *Id.*

21. Valerie Watnick, *Pesticides and Children: Unwitting Participants in Experimentation*, 13 *CARDOZO J.L. & GENDER* 801, 804 (2008).

22. *Id.* at 804

23. *Id.* at 804

24. *See id.*

For these reasons, it often takes an outsider to point out a system is not working. The Federal Meat Inspection Act was enacted partially in response to Upton Sinclair's novel, *The Jungle*.²⁵ Currently, there is an information disconnect between the industrial farm setting and how diners believe their meat reaches the dinner plate. Environmental advocacy groups like Natural Resources Defense Council ("NRDC"), advocate for greater transparency regarding what drugs are in the meat that consumers are buying at the supermarket.²⁶

Current conditions and practices on CAFOs are not well known thanks to "Ag-gag laws," as they are colloquially called. These laws hide the reality of factory farming by making it a crime to report animal abuse. Eight states (Montana, North Dakota, Iowa, Missouri, Arkansas, Kansas, Utah, and South Carolina) have passed ag-gag provisions.²⁷ In some of these states, taking photos or videos of farms is a felony that is deemed a terrorist activity and places the offender on a "terrorist registry."²⁸ Without First Amendment rights to confront agricultural practices, reporters cannot gather information to report on the food industry,²⁹ and the public is effectively kept in the dark regarding the origin of their meat.

The FDA promulgates regulations regarding antibiotic use in livestock. A national program called Beef Quality Assurance offers guidelines to the beef industry for cattle production.³⁰ As seen from their guidelines on Feed Additive and Medications,³¹ they advise the beef industry to follow only FDA regulation and not to exercise

25. See Richard A. Merrill, *The Centennial of U.S. Food Safety Law: A Legal and Administrative History*, in *TOWARD SAFER FOOD* 23 (Sandra A. Hoffman & Michael R. Taylor eds., 2005).

26. *To Fight Superbug Crisis, Public Needs More Data on Farm Animal Drugs*, NAT. RES. DEFENSE COUNCIL (Mar. 20, 2013), <http://www.nrdc.org/media/2013/130320.asp>.

27. Ted Genoways, *Gagged by Big Ag*, MOTHER JONES, July/Aug. 2013, available at <http://www.motherjones.com/environment/2013/06/ag-gag-laws-mowmar-farms>.

28. *Id.* at 4.

29. Kristen Rasmussen, *Efforts to Restrict Recordings of Animal Abuse Could Impede Newsgathering*, 36 THE NEWS MEDIA AND THE LAW 4, 4 (2012).

30. See generally BEEF QUALITY ASSURANCE, <http://www.bqa.org/>.

31. *Feed Additives and Medications*, BEEF QUALITY ASSURANCE, <http://www.bqa.org/feedadditives.aspx>.

discretion to reduce use of antibiotics, so beef producers must adhere to FDA regulations regarding antibiotic use.

*B. Emergence of Antibiotic-Resistant Bacteria,
Associated Health Risks, and Related Costs*

Antibiotics are sold to farmers and ranchers not only to treat disease, but also to prevent animals from getting sick (preventative uses) and to increase the rate of weight gain or improve feed efficiency (production purposes).³² According to former FDA commissioner, David A. Kessler, 80 percent of the thirty million pounds of antibiotics sold in 2011 went to livestock.³³ As these antibiotics are being sold to meat suppliers, the dangers associated with sub-therapeutic uses of antibiotics are closely examined by the scientific community at home³⁴ and abroad.³⁵

32. See generally GFI #209 and GFI#213.

33. David A. Kessler, *Antibiotics and the Meat We Eat*, N.Y. TIMES, March 28, 2013, at A27.

34. See, e.g., COMM. ON THE SCIENTIFIC BASIS OF THE NATION'S MEAT AND POULTRY INSPECTION PROGRAM, FOOD & NUTRITION BD. COMM'N ON LIFE SCI. NAT'L RESEARCH COUNCIL, MEAT AND POULTRY INSPECTION: THE SCIENTIFIC BASIS OF THE NATION'S PROGRAM, (Nat'l Acad. Press, 1985) (explaining the inspection process for the safety of meat and poultry products for human consumption); Stuart B. Levy, *Playing Antibiotic Pool: Time to Tally the Score*, 311 N. ENGL. J. MED. 663-65 (1984); K.A. MEISTER & R. A. GREENBERG, AM. COUNCIL ON SCI. & HEALTH, ANTIBIOTICS IN ANIMAL FEEDS: A THREAT TO HUMAN HEALTH (1983) (The development of antibiotic-resistant bacteria resulting from feed additives and the transfer of resistant bacteria to humans are matters of public health concern.); Marc Linder, *I Gave My Employer a Chicken That Had No Bone: Joint Firm - State Responsibility for Line - Speed-Related Occupational Injuries*, 46 CASE W. RES. L. REV. 33, 41-42 (1995) (Unintended consequences of the sub-therapeutic doses of antibiotics added to chicken feed is resulting in bacteria that have become resistant to antibiotics, such as salmonella, E. coli, and campylobacter jejuni. These antibiotic resistant bacteria cause thousands of cases of diarrheal disease and deaths annually.).

35. EUROPEAN COMM'N., *Ban on Antibiotics as Growth Promoters in Animal Feed Enters into Effect* (Dec. 12, 2005), http://europa.eu/rapid/press-release_IP-05-1687_en.htm (In January 2006, the European Union banned the use of antibiotics as growth-promoters in feed and do not allow antibiotics to be used for non-medical purposes).

Further, the use of such antibiotics unsurprisingly resulted in the emergence of antibiotic-resistant pathogenic bacteria.³⁶

All animals normally have bacteria in and on their bodies. When an animal is treated with a drug, all the bacteria in and on that animal are also exposed to the drug. Some of the exposed bacteria may become resistant, meaning that the drug, and possibly similar drugs, will no longer work against those bacteria.³⁷

Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections. Many more people die from other conditions that were complicated by an antibiotic-resistant infection.³⁸

There are huge health costs associated with multi-drug resistant (“MDR”) bacteria that won’t react to antibiotics. Treating antibiotic resistant infections costs between \$16.6 and \$26 billion annually.³⁹

Emergence of the Superbug, or antibiotic-resistant bacteria, is a health crisis of global proportions recognized and monitored by the Food and Agriculture Organization of the United Nations and the

36. Robert Dorit, *Routes of Resistance*, 97 *AMERICAN SCIENTIST* 20, 20 (2009), available at <http://www.americanscientist.org/issues/pub/routes-of-resistance>. Dorit is a biology professor at Smith College who studies molecular evolution – specifically evolving antimicrobials that reduce antibiotic resistance.

37. ANIMAL HEALTH LITERACY, FROM AN IDEA TO THE MARKETPLACE: THE JOURNEY OF AN ANIMAL DRUG THROUGH THE APPROVAL PROCESS 5 (U.S. Food & Drug Admin., 2013), available at <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm>.

38. CENTER FOR DISEASE CONTROL, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES (U.S. Dept. of Health & Human Serv., 2013), available at <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>.

39. ALLIANCE FOR THE PRUDENT USE OF ANTIBIOTICS (“APUA”), ANTIBIOTIC-RESISTANT INFECTIONS COST THE U.S. HEALTHCARE SYSTEM IN EXCESS OF \$20 BILLION ANNUALLY (Biomérieux, 2009) available at http://www.tufts.edu/med/apua/news/aam_report.pdf.

World Health Organization.⁴⁰ However, antibiotics continue to be used in tremendous quantities in spite of evidence that their overuse is compromising human health.⁴¹ Nothing seems to be able to stop the antibiotic use – not international warnings, not congressional action, not citizen petitions, not shareholder letters, and certainly not action by the one agency tasked with the mission of protecting public health, the FDA.⁴²

C. Failed Attempts to Reduce Use of Antibiotics in Food-Producing Animals

1. Regulatory - Balkanized State of Federal Food Safety

The responsibility to protect food safety falls on the shoulders of four different agencies, the United States Department of Agriculture (“USDA”), EPA, CDC, and FDA. In a regulatory system that is constantly shifting, reorganizing, and reassigning duties, it is no surprise that each agency is responsible for different segments of the same issue – chemicals, pesticides, or drugs.

The USDA’s Food Safety and Inspection Service (“FSIS”) regulates meat through continuous inspection of processing operations and review of product labels.⁴³ The USDA enforces EPA pesticide tolerances in meat. The USDA, therefore, has little power to control antibiotics in meat other than to ensure the proper labeling of meat that is has been treated with antibiotics and meat that is not treated with antibiotics.

The EPA controls the Office of Pesticide Programs (“OPP”), which registers pesticides and sets the pesticide tolerances that are

40. *Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (“JEMRA”), CODEX ALIMENTARIUS INT’L FOOD STANDARDS*, <http://www.codexalimentarius.org/scientific-basis-for-codex/jemra/en>.

41. Ron Gasbarro, *Combating Growing Antibiotic Resistance*, AMERICAN DRUGGIST, Feb. 1996, at 49 (There is a possible rise in cases of diseases that have nearly been eradicated such as: tuberculosis, malaria, and dysentery possibly due to antibiotic overuse).

42. *See, e.g., What We Do*, U.S. FOOD & DRUG ADMIN. (Aug. 5, 2014), <http://www.fda.gov/aboutfda/whatwedo/> (“FDA is responsible for protecting the public health by assuring the safety, efficacy and security of . . . our nation’s food supply . . .”).

43. 21 U.S.C. §§ 451 – 471, 601 – 695 (2012).

enforced by the FDA or FSIS.⁴⁴ It is outside the EPA’s mission to monitor antibiotic use.

The Centers for Disease Control and Prevention (“CDC”), is a federal agency under the Department of Health and Human Services (“HHS”). The CDC serves as the primary clearinghouse for disease surveillance data, and the chief resource for epidemiological investigations.⁴⁵ In exercising its role in epidemiological investigations, the CDC could potentially help monitor the health problems resulting from long-term exposure of the human population to meat with residual toxicity of antibiotics.⁴⁶

In 2013, the CDC released a comprehensive report entitled, “Antibiotic Resistance Threats in the United States.”⁴⁷ In that report, the CDC calls for a multifaceted approach and partnerships between federal, state, and local agencies and departments to prevent antibiotic-resistant foodborne infections – some with animal reservoirs and others human reservoirs.⁴⁸ The report highlights the link between antibiotic uses in food-producing animals and emphasizes the importance of limiting use to medically necessary as opposed to sub-therapeutic uses.⁴⁹

The FDA is responsible for the safety of foods including labels and additives, human prescription and over the counter drugs, and veterinary products – including feeds and drugs.⁵⁰ The FDA also regulates veterinary drugs.⁵¹ The FDA also looks at health risks posed by foodborne chemicals and microbiological contaminants.⁵² The Center for Veterinary Medicine (“CVM”) within the FDA is

44. 7 U.S.C. §§ 135 – 136y (2012); 21 U.S.C. § 342 (a)(2)(B) (2012).

45. *National Notifiable Diseases Surveillance System (“NNDSS”)*, CDC, www.cdc.gov/nndss/ (NNDSS home page outlines the surveillance system involving collection, analysis, and sharing infectious diseases).

46. TOWARD SAFER FOOD, *supra* note 25, at 29.

47. *See* Antibiotic Resistance Threats, *supra* note 36.

48. *Id.* at 36.

49. *Id.* at 37.

50. *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN. (Jun. 12, 2014), <http://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm>.

51. 21 U.S.C. § 393 (b)(2)(2012).

52. *Risk & Safety Assessment*, U.S. FOOD & DRUG ADMIN., www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ (Risk & Safety Assessment web page reflects the FDA’s mission of preventing contamination and illness via risk analysis of chemical and microbiological contaminants).

responsible for premarket approval of New Animal Drug Applications (“NADA”) and surveillance of animal drug use.⁵³

The FDA is concerned with threats of acute poisoning caused by harmful microorganisms and controlling toxic materials that enter food by human activity.⁵⁴ The FDA’s Center for Food Safety and Applied Nutrition (“CFSAN”) monitors the safety and labeling of most non-meat and processed foods, and licenses food-use chemicals other than pesticides.⁵⁵ Many scholars and food safety advocates call on the FDA to make critical changes that would answer this problem.

The FDA is responsible for enforcing the Food, Drug, and Cosmetic Act (“FDCA”). Section 401(a)(2)(C)(ii) of the FDCA defines adulterated food as one that bears or contains a new animal drug that is unsafe within the meaning of FDCA Section 512.⁵⁶ New animal drugs are deemed unsafe under Section 512 unless they are the subject of an approved New Animal Drug Application (“NADA”), and the substance, use, and labeling conform to the approved NADA.⁵⁷ Section 402 tells us that food is adulterated if it contains poisonous or deleterious substances that render it injurious to health. The caveat, however, is in its next clause, which provides an exception that excludes those substances if the quantity added would not ordinarily be injurious to health.⁵⁸

Aware of these antibiotic-resistant bacteria, or “multi-drug resistant superbugs,” as they are now called,⁵⁹ the government established National Antimicrobial Resistance Monitoring System for Enteric Bacteria (“NARMS”) in 1996.⁶⁰ NARMS required collaboration between state and local public health departments, the

53. NATIONAL RESEARCH COUNCIL, ANIMAL HEALTH AT THE CROSSROADS: PREVENTING, DETECTING, AND DIAGNOSING 244 (The Nat’l Academies Press, 2005).

54. TOWARD SAFER FOOD, *supra* note 25, at 31.

55. 21 U.S.C. §§301 – 397 (2012).

56. Martin J. Hahn, *FDA Has the Legal Authority to Adopt a Threshold of Toxicological Concern (TTC) for Substances in Food at Trace Levels*, 65 FOOD DRUG L.J. 217, 222 (2010).

57. *Id.*

58. *See* Hahn, *supra* note 56, at 217, 219.

59. Zosi Kmiotowicz, *Superbugs are Beating at the Gates*, NEW SCIENTIST, July 17, 1999, <http://www.newscientist.com/ns/19990717/newsstory12.html>.

60. *See National Antimicrobial Resistance Monitoring System for Enteric Bacteria*, CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/narms/>.

CDC, the FDA, and the USDA.⁶¹ The purpose of NARMS was to track antimicrobial susceptibility of intestinal bacteria in people (CDC), retail meats (FDA), and food animals (USDA).⁶²

Every year, respective NARMS committees publish Human Isolates, Retail Meat Isolates, and Animal Isolates Reports.⁶³ In 2011, the FDA NARMS Retail Meat Annual Report found antibiotic-resistant bacteria on 81 percent of ground turkey, 69 percent of pork chops, 55 percent of ground beef, and 39 percent of chicken breasts, wings, and thighs.⁶⁴ For all of the compilation and tracking of data, NARMS fails to collect data on the sources of contaminated meat,⁶⁵ and NARMS committees only meet once a year.⁶⁶ It is surprising that with such high rates of antibiotic-resistant bacteria present in retail meat, NARMS does not meet more frequently. Stuart Levy, President of the Alliance for Prudent Use of Antibiotics, Professor at Tufts University School of Medicine, points out that while drug residue is being monitored, retail meat still has a high contamination of organisms.⁶⁷ These organisms are not followed, and the drug might be present in small undetectable amounts.⁶⁸

61. *See id.*

62. *See id.*

63. *See* NARMS ANNUAL HUMAN ISOLATES REPORTS, CENTER FOR DISEASE CONTROL & PREVENTION, *available at* <http://www.cdc.gov/narms/reports/index.html> (last visited Nov. 21, 2014); NARMS RETAIL MEAT ANNUAL REPORTS, U.S. FOOD & DRUG ADMIN., *available at* <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059103.htm> (last visited Nov. 21, 2014); NARMS ANIMAL ISOLATES COMPREHENSIVE ANNUAL REPORTS, U.S. DEPT. OF AGRIC., *available at* <http://ars.usda.gov/Main/docs.htm?docid=6750&page=4> (last visited Nov. 21, 2014).

64. U.S. FOOD & DRUG ADMIN., NARMS RETAIL MEAT ANNUAL REPORT (2011), *available at* <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm334828.htm>.

65. *See* Maryn McKenna, *Drug-Resistant Bacteria on Chicken: It's Everywhere and the Government Can't Help*, WIRE MAGAZINE, Dec. 19, 2013, <http://www.wired.com/2013/12/chicken-cr-pew/>.

66. *See, e.g.*, NARMS MEETINGS LIST, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059135.htm>.

67. Video: *Farm Animals and Antibiotics: Highlight from Battling Drug-Resistant Superbugs: Can We Win?*, (The Forum at Harvard School of Public

21 CFR § 510.110 is entitled “Antibiotics Used in Food-Producing Animals.” It recognizes the concern around the extensive use of antibiotics with food-producing animals and looks at antibiotic residue found in the edible tissue, milk, or eggs of treated animals.⁶⁹ With the focus on reduction of antibiotic residue, attention is drawn away from the core issue of use on the farm and resulting MDR resistant bacteria.

2. Civil – Citizen Petitions and Shareholder Letters Failed

The FDA denied citizen petitions in 1999⁷⁰ and 2005.⁷¹ In 2012, NRDC plaintiffs filed complaints alleging that FDA denials of these petitions amounted to Administrative Procedure Act (“APA”) and FDCA violations.⁷² In the midst of these failed citizen petitions, President Clinton signed the Animal Drug Availability Act 1996 (“ADAA”).⁷³ The law was designed to increase the number of animal drugs on the market by relaxing requirements for effectiveness studies and eliminating the requirement for field studies. ADAA allows for flexible labeling for a range of doses rather than an optimum dose.⁷⁴

Health presented Feb. 5, 2014), available at http://www.youtube.com/watch?v=I3I_Bg-lqZM.

68. *Id.*

69. 21 C.F.R. § 510.110 (2014).

70. The 1999 Petition was to rescind approvals of subtherapeutic uses in livestock or antibiotics use in (or related to those used in human medicine) and is available at http://www.ucsus.org/sites/default/files/legacy/assets/documents/food_and_agriculture/1999-FDA-Petition.pdf.

71. In 2005 another petition was filed. This time, seeking withdrawal of approvals of certain herdwide/flockwide uses of critically and highly important antibiotics pursuant to guidance #152. The petition is available at http://www.ucsus.org/sites/default/files/legacy/assets/documents/food_and_agriculture/2005-FDA-Petition.pdf.

72. *Natural Res. Def. Council, Inc., v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012).

73. Animal Drug Availability Act of 1996, Pub. L. No. 104-250, 110 Stat. 3151 (codified in scattered sections of 21 §U.S.C. (2012)).

74. See U.S. FOOD & DRUG ADMIN., ANIMAL DRUG AVAILABILITY ACT OF 1996 GUIDANCE, available at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm105940.htm>.

Another tactic by which change may be sought in a corporate setting is via the shareholder relationship with a company. In 2009, disgruntled shareholders, Adrian Dominican Sisters and Trinity Health, attempted to correct antibiotic overuse by directly petitioning Tyson Foods, Inc. via a proposal letter. Giant pork producer Tyson Foods, Inc., was petitioned by shareholders to cease sub-therapeutic use of antibiotics in hog production, but Tyson's legal team ducked any accountability by claiming this request dealt with matters related to Tyson's business operations and were ordinary practice. Records of the letters between shareholders and Tyson's legal representatives can be viewed by the public on the SEC website.⁷⁵

The case *Animal Legal Def. Fund, Inc. v. Provimi Veal Corp.* discusses warnings or labeling of veal calves raised with growth hormones.⁷⁶ The Animal Legal Defense Fund ("ALDF") of Boston sued Provimi Veal Corp. claiming their right to know about the company's animal husbandry practices and drugs used in their meat production.⁷⁷ The court held that the complex federal regulatory scheme monitoring industry marketing, labeling, and packaging of meat preempted plaintiffs' claims.⁷⁸ The court further explained that the FDCA does not grant private rights of action.⁷⁹ The First Circuit reaffirmed this decision on appeal.⁸⁰ With a complex regulatory scheme that preempts private rights of action, seeking accountability via the judiciary is problematic.

3. Legislative – Congressional Actions Failed

Legislative measures to reform these practices have also failed in each of the last three Congressional sessions. Bills to preserve antibiotics for medical treatment were introduced in the 110th (H.R.

75. See Letter from Adrian Dominican Sisters to Tyson Foods (Aug. 31, 2009) (on file with the Sec. & Exch. Comm'n), available at <http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2009/adriandominicansisters112509-14a8.pdf>.

76. *Animal Legal Defense Fund-Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986).

77. *Id.*

78. Barbara O'Brien, *Animal Welfare Reform and the Magic Bullet*, 67 U. COLO. L. REV. 407, 436. (1996).

79. *Provimi*, 626 F. Supp. at 283.

80. *Animal Legal Defense Fund-Boston, Inc. v. Provimi Veal Corp.*, No. 86-1234, 1986 U.S. App. LEXIS 32019, at *1 (1st Cir. Aug. 12, 1986).

962), 111th (H.R. 1549), and 112th (H.R. 965) Congresses.⁸¹ The Bill's full title is "To amend the FDCA to preserve the effectiveness of medically important antibiotics in the treatment of human and animal disease."⁸² Not one of the bills advanced to the floor.

Rep. Louise Slaughter (D-NY) introduced the most recent bill, H.R. 965 on March 9, 2011, and it was referred to the Committee on Energy and Commerce on June 15, 2011. The bill died in committee.⁸³

Ms. Slaughter, a public-health microbiologist and longtime champion of protecting antibiotics for critical medical uses, released the following statement after the bill failed to advance.

How many more news reports, outbreaks or deaths must there be before we really crack down on the source of the antibiotic-resistance crisis: the overuse of antibiotics on the farm? [...] These studies draw a troubling conclusion: that the presence of antibiotic-resistant bacteria in meat is more widespread than we thought, and our federal regulatory agencies simply refuse to hold the industry accountable. The failure of our regulatory structure to protect public health is completely unacceptable.⁸⁴

In March 2013, the Senate Health, Education, Labor, and Pensions ("HELP") Committee failed to add new reporting requirements related to the use of antibiotics on livestock used for human food production.⁸⁵ Senators Diane Feinstein (CA) and Kristen Gillibrand (NY) offered a provision that would have required the FDA to disclose additional information about the marketing and sale of antibiotics, whether the sales were over the counter or prescription.⁸⁶ Pharma and livestock lobbyists successfully swayed the Committee to avoid discussion or consideration of the amendment. The

81. Preservation of Antibiotics for Medical Treatment Act of 2009, H.R. 1549, 111th Cong. (2009).

82. *Id.*

83. Preservation of Antibiotics for Medical Treatment Act of 2011, H.R. 965, 112th Cong. (2011).

84. McKenna, *supra* note 65.

85. *See* Kessler, *supra* note 33.

86. *See id.*

availability of antibiotics via OTC or prescription potentially impacts the use of the drug. OTC approval means farmers can obtain the drug more easily than by prescription and may administer in any quantity without veterinary oversight.

4. Judiciary – Judge Katz’s 2012 Order for FDA to Initiate
 Withdrawal of Antibiotic Approval

There was a recent victory in the court system regarding FDA withdrawal of antibiotic approval. In 2011, the NRDC brought suit against the FDA for its failure to follow through on the dormant NOOH from 1977 to withdraw approval for sub-therapeutic use of penicillin and tetracyclines.⁸⁷ It further alleged that FDA failure to withdraw approval was in violation of the APA, 5 U.S.C. § 706(1).⁸⁸

In 2012, Magistrate Judge Theodore Katz, S.D.N.Y. handed down a decision reversing agency inaction. Judge Katz granted summary judgment for NRDC with the following:

Defendants are hereby ordered to initiate withdrawal proceedings for the relevant NADAs/ANADAs. Specifically, the Commissioner of the FDA or the Director of the CVM must re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing. If, at the hearing, the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order.⁸⁹

Judge Katz concluded the FDA must initiate withdrawal proceedings for antibiotics called out in citizen petitions because reasons for not doing so were arbitrary and capricious.⁹⁰

87. See *Natural Res. Def. Council, Inc.*, 884 F. Supp. 2d at 137.

88. *Id.* at 130.

89. *Id.* at 151.

90. *Natural Res. Def. Council, Inc., v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 342 (S.D.N.Y. 2012).

In response to the order, the FDA said it believed it was legally obligated to conduct formal process with full notice and hearing period before it could initiate withdrawal approvals.⁹¹

5. International Perspective

In many areas of the law, it is helpful to gain an international perspective. Perhaps the issue is largely unsettled or international actors are facing similar dissention. When compared to the United States decades-long reluctance to address antibiotic use, other countries have already taken action. Europe took a number of steps to limit antibiotic use and to combat antibiotic-resistant bacteria. Laws restricting additives in animal feed were enacted in 1970.⁹² Sweden began phasing out antimicrobial growth promoters in food-producing animals in 1986.⁹³ In January 2006, the European Union (“EU”) banned the use of antibiotics both for non-medical purposes and as growth promoters in feed.⁹⁴ Ceasing non-therapeutic use of antibiotics yields fast results in combating antibiotic resistance. Denmark instituted a voluntary ban in 1998 and followed with a full ban in 2000.⁹⁵ Under the new law, all uses of antibiotics must be prescribed by a veterinarian in a valid veterinarian-client-patient relationship; veterinarians must report all sales of antibiotics and must not profit from their sale.⁹⁶ The ban has reduced human health

91. See Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1008 (2013).

92. See, e.g., Council Directive 70/524, 1970 J.O. (L 270) 1-17 (EC); Council Regulation 1831/2003, On Additives for Use in Animal Nutrition, 2003 O.J. (L 268) 29-43 (EC).

93. See Carol Cogliani, *Restricting Antimicrobial Use in Food Animals: Lessons from Europe*, 6 MICROBE 274 (2011).

94. See *Press Release: Ban on Antibiotics as Growth Promoters in Animal Feed Enters into Effect*, EUROPEAN COMMISSION (Dec. 22, 2005), http://europa.eu/rapid/press-release_IP-05-1687_en.htm.

95. See *Issue Brief: Avoiding Antibiotic Resistance: Denmark's Ban on Growth Promoting Antibiotics in Food Animals*, THE PEW CHARITABLE TRUSTS (Nov. 1, 2010), <http://www.pewhealth.org/reports-analysis/issue-briefs/avoiding-antibiotic-resistance-denmarks-ban-on-growth-promoting-antibiotics-in-food-animals-85899371053>.

96. See *id.*

risk, increased livestock and poultry production, and has cut antibiotic resistance on farms and in meats.⁹⁷

Frank Aarestrup, D.V.M., Ph.D., and head of the EU Reference Laboratory for Antimicrobial Resistance, authored a 2012 article on Denmark's antibiotic ban stating, "instead of eviscerating the nation's pork industry, those moves contributed to a 50 percent rise in pork production."⁹⁸ Denmark took a three-pronged approach to halt use of antibiotics for growth promotion.⁹⁹ First, it enacted laws banning improper use; second, it implemented a robust surveillance and enforcement system; and third, it barred veterinarians from antibiotic sales profits, thereby eliminating an incentive to overprescribe.¹⁰⁰ Aarestrup goes on to encourage wary American counterparts by saying, "Farmers and their livestock can thrive without the heavy use of antibiotics... With a little effort, I believe that other countries can and must help their farmers to do the same."¹⁰¹

*D. The FDA has not Withdrawn Approvals for
Sub-Therapeutic Use of Antibiotics in Livestock*

According to Mark Bittman, the FDA works with a shoestring budget (US \$3-4 billion FY 2011 and 2012),¹⁰² while the largest four meat companies' sales total nearly US\$100 billion.¹⁰³ There is ample

97. *Id.*

98. Frank Aarestrup, *Get Pigs off Antibiotics*, 486 *NATURE* 465, 465 (June 28, 2012).

99. *Id.* at 466.

100. *Id.*

101. *Id.*

102. U.S. FOOD & DRUG ADMIN., FY 2013 BUDGET OVERVIEW, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM301719.pdf> (last updated May 21, 2012).

103. See Monica Watrous, *Ranking the Meat and Poultry Industry's Top 10 Companies*, *FOOD BUSINESS NEWS*, Mar. 19, 2013, http://www.foodbusinessnews.net/articles/news_home/Business_News/2013/03/Ranking_the_meat_and_poultry_i.aspx?ID={E1E627B9-E4CE-40A0-A3E0-ED9B597FCBFE} (Tyson US\$33.3 billion, JBS US\$31.3 billion, Cargill US\$18 billion, and Smithfield US\$13.09 billion in sales).

financing available to fund SuperPACs¹⁰⁴ and agribusiness lobbyists (\$153 million in 2013)¹⁰⁵ who bend congressional ears.¹⁰⁶

1. 1977 – 2011 Notice of Opportunity for Hearing

Antibiotics came to be approved for purposes other than treating active infections because Congress granted the FDA authority to waive safety and efficacy requirements if it found doing so would be safe.¹⁰⁷ Farmers quickly discovered antibiotics helped animals gain weight faster, and the FDA approved its use in 1951.¹⁰⁸ Two years later, antibiotic use to prevent infection was approved.¹⁰⁹ “Shortly after the licensing and use in livestock of fluoroquinolone, a powerful new class of antimicrobials, fluoroquinolone-resistant *Salmonella* and *Campylobacter* isolations from animals, and humans increased.”¹¹⁰

By the 1960’s, the FDA became worried about the effects of sub-therapeutic antibiotic use so the FDA formed a Task Force to study it. The Task Force published a report in 1972 linking sub-therapeutic use of antibiotics in livestock and increased antibiotic-resistant bacteria in livestock and meat intended for human consumption.¹¹¹ Aware of risk of antibiotic resistance in humans, the FDA published a rule in the Code of Federal Regulations in 1973 asking drug companies to present evidence that sub-therapeutic use of antibiotics

104. *McCutcheon v. Federal Election Commission*, 2013 WL 2102847 (U.S. May 13, 2013).

105. Graph, *Annual Lobbying on Agribusiness*, OPENSECRETS.ORG, <https://www.opensecrets.org/lobby/indus.php?id=A&year=2013> (last visited Nov. 7, 2014).

106. Mark Bittman, *Bacteria 1, F.D.A. 0*, N.Y. TIMES OPINIONATOR (Dec. 27, 2011, 9:00 PM), <http://opinionator.blogs.nytimes.com/2011/12/27/bacteria-1-f-d-a-0/>.

107. Fed. Food, Drug, and Cosmetic Act of June 25, 1938, ch. 281, sec. 507, § 3, 59 Stat. 463 (1945) (repealed 1997).

108. Miscellaneous Amendments to Part 146, 21 C.F.R. § 146.61 (2014).

109. Exemption from Certification of Antibiotic Drugs for Use in Animal Feed, 18 Fed. Reg. 2335, 2335-36 (Apr. 22, 1953) (codified at 21 C.F.R. § 146.62).

110. See *Use of Antimicrobials Outside Human Medicine and Resultant Antimicrobial Resistance in Humans*: Fact Sheet No. 268, WORLD HEALTH ORG. (2002), available at http://whqlibdoc.who.int/fact_sheet/2002/FS_268.pdf.

111. *Natural Res. Def. Council, Inc., v. U.S. Food & Drug Admin.*, 760 F.3d 151, 154 (2d Cir. 2014).

did not violate FDCA.¹¹² And in 1977, the Director of BVM announced a notice of opportunity for a hearing under 21 U.S.C. § 360(b)(e)(1) regarding penicillin in animal feed to show its safety under 512(e)(1)(B) of FDCA.¹¹³

Twenty-one drug firms, organizations, and individuals requested hearings to prove relevant uses were safe, but the hearings were never scheduled.¹¹⁴ Both the FDA and CDC issued guidance and information related to the overuse of antibiotics. The guidance indicated that when antibiotics are overused, their efficacy becomes diminished when used in legitimate medically necessary situations.

In December 2011, FDA rescinded the 1977 notice of opportunity for hearings.¹¹⁵

However, due to agency capture,¹¹⁶ even the 2012 court order¹¹⁷ to immediately initiate withdrawal proceedings failed to cause FDA to close the loophole on the routine use of antibiotics on factory farms.

2. FDA Guidance for Industry 209 & 213 Aimed to Increase Judicious Use of Antibiotics in Food-Producing Animals

The FDA has taken action as a result of being ordered to withdraw approval of antibiotics used sub-therapeutically in livestock. First, it issued Guidance for Industry #209 (“GFI 209”) entitled, “Judicious Use of Antimicrobials.”¹¹⁸ The second, and more powerful, Guidance for Industry #213 (“GFI 213”) was published on December 11, 2013.¹¹⁹ It is called, “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: recommendations for

112. Antibiotics and Sulfonamide Drugs in the Feed of Animals, 21 C.F.R. § 135.109 (2014).

113. Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977).

114. *See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 127, 131 (S.D.N.Y. 2012).

115. Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79697, 79697 (Dec. 22, 2011).

116. *See Brian Daluiso, “Is the Meat Here Safe?” How Strict Liability for Retailers Can Lead to Safer Meat*, 92 B.U. L. REV. 1081, 1097-98 (May 2012).

117. *Nat. Res. Def. Council, Inc.*, 884 F. Supp. 2d at 151.

118. GFI #209.

119. GFI #213.

Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209.”

GFI 209 laid out what judicious use of antibiotics is, and what types of uses are not deemed “judicious.”

The focus of this document is on the use of medically important antimicrobial drugs in food-producing animals. Based on a consideration of the available scientific information, FDA is providing a framework for the voluntary adoption of practices to ensure the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. This framework includes the principles of phasing in such measures as 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation.¹²⁰

GFI 213 explained that drug sponsors could voluntarily withdraw uses for growth promotion and feed optimization in the next three years. If drug sponsors fail to withdraw uses, the FDA would be compelled to develop a new approach to reduce the use of antibiotics on factory farms. Here is the 213’s introduction:

This guidance is intended for sponsors of approved applications for new animal drugs and new animal drug combination products containing medically important antimicrobial new animal drugs for use in or on medicated feed or water of food-producing animals. The guidance contains information for sponsors of such new animal drugs and combination products to facilitate voluntary changes to the conditions of use for such new animal drugs and combination products consistent with FDA’s recommendations included in the guidance document entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”

120. GFI #209.

(Judicious Use Guidance, GFI #209). In particular, the purpose of this guidance is to provide sponsors with specific recommendations on how to supplement their approved new animal drug applications to align with FDA's GFI #209.¹²¹

GFI 213 targets medically important antimicrobials used in the feed and water of food-producing animals. The guidance's purpose is to encourage drug sponsors to align use conditions with GFI 209 and to phase out the use of antimicrobials merely for production purposes (e.g., growth promotion and feed efficiency).¹²² GFI 209 provided two recommended principles on the appropriate or judicious use of medically important antimicrobial drugs: limiting antimicrobials to uses 1) necessary to assuring animal health, and that 2) includes veterinary oversight or consultation. The FDA considers prevention of specific diseases to be a valid therapeutic use.¹²³

While some might see GFI 209 and 213 as triumphant steps in the right direction, others could view the guidelines as a complete failure to close the loophole of antibiotics routinely administered in a preventative fashion.

II. CONFLICT: FDA GFI 209 AND 213 STRENGTHS AND WEAKNESSES

Forty years of agency intransigence have finally given way to guidance for industry related to judicious use of antibiotics and voluntary withdraw of antibiotic use for growth promotion. The guidance has caused supporters and critics to raise a myriad of questions that can only be answered with time. Many public health experts and industry journalists believe the guidance is just a media distraction while the FDA helps drug companies re-label antibiotics to qualify under other medical uses.¹²⁴

121. GFI #213.

122. *Id.*

123. GFI #209.

124. See e.g., Beth Hoffman, *New FDA 'Rules' Not Likely to Reduce Antibiotic Use on Farm*, FORBES, Dec. 13, 2013, <http://www.forbes.com/sites/bethhoffman/2013/12/13/new-fda-rules-will-not-reduce-antibiotic-use-on-farm/>.

The FDA's nonbinding recommendation that drug sponsors voluntarily align their product use conditions with judicious use guidelines is insufficient to achieve the kind of results for which world health organizations, scientific associations, shareholders, and citizens have long advocated. The FDA is charged with protecting public health. Antibiotic resistance has been a major health issue for decades. When there is a court order mandating FDA to take action on antibiotic use, the agency's guidance should not be voluntary. If the FDA is really aiming for judicious use, then the restrictions on antibiotics use for non-medical purposes should be clear and firm.

But the actual impact of the guidelines seems insignificant. According to industry insiders and pharma companies, antibiotics used for growth promotion represents such a small share of all antibiotics used in livestock, there will not be a substantial impact on their sales revenues.¹²⁵

A. FDA Guidance is a Meaningful Step Toward Reducing Antibiotic Usage and Antibiotic-Resistant Bacteria

The FDA believes it is taking a meaningful step toward encouraging judicious use of antibiotics in livestock. As GFI 213 was published, the FDA news release¹²⁶ heralded the guidance by characterizing it in the following way, "Agency implementing plan to ensure judicious use of antibiotics in food animals."¹²⁷ Bernadette Dunham, DVM, Ph.D., director of the FDA's Center for Veterinary Medicine, explained that the GFI "promotes the judicious use of important antimicrobials to protect public health while ensuring that sick and at-risk animals receive the therapy they need."¹²⁸

1. Drug Sponsor and Industry Compliance

The FDA has reason to believe their guidance will yield results. The Administration has previously successfully withdrawn approval

125. *Id.*

126. See *FDA Takes Significant Steps to Address Antimicrobial Resistance*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm378193.htm>.

127. *Id.*

128. *Id.*

for antibiotics. GFI 213 comes at the heels of the 2005 FDA decision to withdraw of approval for livestock antibiotic, Baytril®.¹²⁹ Drug sponsor Bayer did not fight the decision. This could be indication that other drug sponsors might react similarly.

Further, industry groups have reacted with vigor. Iowa Pork Producer Headlines (“The Headlines”), a publication of the Iowa Pork Producers Association, reviewed GFI 209,¹³⁰ and acknowledged that although GFI 209 is only guidance and not law, it indicates the FDA’s future plans and will be adhered to as though it were mandatory.¹³¹ If the Association is indicating it will follow the guidance, it will probably influence pork producers to follow guidelines or begin implementing processes and procedures that would anticipate formal rules or regulations around antibiotic use.

The Headlines presented economic predictions warning farmers that the new FDA guidance could potentially increase the cost of raising a pig in its first year by as much as \$4.50.¹³² As most businesses are profit-driven, cost-production increases are typically dreaded. Farmers might read this economic prediction of increased costs and begin to think about how they can maintain current costs. The Headlines also provides practical recommendations such as keeping buildings clean, treating sick pigs with medicine, and changing antibiotics to non-medically important ones.¹³³ These recommendations appear to be in line with good animal husbandry practices and hopefully are simply re-emphasizing existing practices.

The FDA also has open support from groups who advocate for decreased antibiotic use. The Alliance for the Prudent Use of

129. See Vanessa K.S. Briceño, Recent Developments, *Superbug Me: The FDA’s Role in the Fight Against Antibiotic Resistance*, 9 N.Y.U. J. LEGIS. & PUB. POL’Y 521, 521-522 (2005-2006).

130. See IOWA PORK PRODUCERS ASS’N, *The Future of Antibiotics - A Review of FDA Guidance 209*, 11 HEADLINES NEWSLETTER, no. 1, 2012, available at <http://iowapork.org/FileLibrary/States/IA/News/Headlines%20Newsletter/Headlines%20Summer%2012.pdf>.

131. *Id.* at 2.

132. *Id.* at 3.

133. *Id.*

Antibiotics (“APUA”) calls it a step in the right direction and believes GFI 213 will help the U.S. catch up to the EU.¹³⁴

2. Stakeholder Buy-In

Another factor that makes the guidance likely to succeed is that the FDA consulted with affected parties, drug companies, veterinarians and relevant stakeholders to obtain buy-in before putting forth GFI 209 and 213.¹³⁵ There is a generous, three-year timeline for voluntary changes, so sponsors will have ample opportunity to make changes. Now that a few months have passed since GFI 213 was announced, we can see the buy-in was productive. Nearly all drug companies who make antibiotics used in animal feed agree to go along with the guidance.¹³⁶ They will voluntarily withdraw the claim from labels in accordance with agency nonbinding recommendations. Skeptical public health experts point out the industry could continue to use antibiotics, but under other pretenses.¹³⁷

B. The Guidance will be Largely Ineffective Due to the Mode and Language used by the FDA

1. The FDA’s Use of Guidelines Instead of Rulemaking or Mandatory Claims Withdrawal Reduces the Probability the Agency will Achieve the Desired Result

Claim switching threatens the effectiveness of industry guidance. When a drug sponsor loses the ability to sell a product with one claim on the label, it switches to a different approved claim to maintain market share.

The FDA press release focuses on private party interests.¹³⁸ It looks to possible harms to the pharmaceutical industry or

134. *FDA Releases Two Guidelines to Limit Use of Antibiotics in Meat Production*, ALLIANCE FOR THE PRUDENT USE OF ANTIBIOTICS, http://www.tufts.edu/med/apua/policy/policy_antibiotic_food_animals.shtml.

135. GFI #209.

136. See Sabrina Tavernise, *F.D.A. Unveils Deal to Limit Antibiotic Use in Animal Feed*, N.Y. TIMES, Mar. 27, 2014, at B2.

137. See *id.*

138. *FDA Takes Significant Steps to Address Antimicrobial Resistance*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm378193.htm>.

agribusiness. It is not focused on the positive health effects or benefits to public health. The FDA's GFI 213 press announcement described the guidance as a "road map for animal pharmaceutical companies to voluntarily revise the FDA-approved use conditions on the labels of these products to remove production indications."¹³⁹ Ms. Dunham, Director of CVM, also said, "We realize that these steps represent changes for veterinarians and animal producers, and we have been working – and will continue to work – to make this transition as seamless as possible."¹⁴⁰

The guidance targets a narrow category of use. Growth promotion is not believed to account for the bulk of sub-therapeutic use on modern farms. Although it is difficult to obtain information about actual usage, some believe only 10-15 percent of antibiotics used in livestock is for growth promotion.¹⁴¹ If growth promotion is not currently a significant use and drug companies do not anticipate the guidance to affect sales, is the guidance merely lip service?¹⁴²

The mode of "industry guidance" is not a solution for a serious problem that requires radical change. The way the guidance is written, it hardly seems like a recommendation. On the top of every page are the words "Contains Nonbinding Recommendations." The document makes clear that guidance represents the agency's current position and is nonbinding. At the Introduction, the guidance reminds the reader it describes the FDA's current thinking, and use of the word "should" is a suggestion, not a requirement. The guidance also makes it clear that should a company decide to disregard the agency's position entirely, there will be no repercussions. It raises suspicion that drug companies are largely on board with guidance,¹⁴³ that, if taken on its face, would radically change industrial farming.

139. *Id.*

140. *Id.*

141. Beth Hoffman, *New Animal 'Rules' Not Likely to Reduce Antibiotic Use on Farm*, FORBES, Dec. 13, 2013, <http://www.forbes.com/sites/bethhoffman/2013/12/13/new-fda-rules-will-not-reduce-antibiotic-use-on-farm>.

142. *Id.*

143. Rebecca Thistlethwaite, *Subterfuge: FDA's Phase Out of Antibiotics for Animal Growth Purposes Ineffective – Will Disadvantage Small Farmers*, THE CORNUCOPIA INSTITUTE, Jan. 31, 2014, <http://www.cornucopia.org/2014/02/subterfuge-fdas-phase-antibiotics-animal-growth-purposes-ineffective-will-disadvantage-small-farmers-2/a>.

Industry insiders fail to hide their true intentions or beliefs about what the guidance will mean on the farm. We peer behind the veil on the American Association of Swine Veterinarians' ("AASV") website where Henry Snelson, DVM, AASV Director of Communications assures the industry that the FDA has indicated they will work with drug sponsors to add medically valid indications to claim labels.¹⁴⁴ So as drug companies voluntarily withdraw one claim from a label, another claim will be approved so the drug may still be administered within new guidelines.

2. Failure to Define Words Like Sub-Therapeutic or Explain When Preventative Uses are Allowed will Result in Continued Usage Under Different Auspices

Conducting a textual analysis of the guidance for industry reveals the language, word choice, and phrasing is vague. PEW Campaign on Human Health and Industrial Farming Project Director, Laura Rogers penned an eloquent letter to the FDA during the comment period for Guidance 209.¹⁴⁵ Ms. Rogers applauds the FDA for openly acknowledging the dangers associated with antibiotics used for growth promoting purposes.¹⁴⁶ She goes on to point out that the guidelines fail to define several key phrases, namely disease prevention and legitimate therapeutic use. Working with loosely defined terms, drug companies may be able to alter labels of existing pharmaceuticals resulting in little actual change in usage.¹⁴⁷ PEW pushes further, contending that disease prevention is also an inappropriate use.¹⁴⁸ This harkens back to the first regulatory

144. Harry Snelson, *Advocacy in Action; Guidance #209 and you*, AMERICAN ASSOCIATION OF SWINE VETERINARIANS, <http://www.aasv.org/shap/issues/v20n4/v20n4advocacy.html>.

145. Joshua Wenderoff, *Pew Asks FDA to Strengthen Guidelines on Antibiotic Use in Food Animals*, PEW CHARITABLE TRUSTS (July 20, 2012), <http://www.pewhealth.org/reports-analysis/issue-briefs/pew-asks-fda-to-strengthen-guidelines-on-antibiotic-use-in-food-animals-85899406584>.

146. *Id.*

147. *Id.*

148. *Id.*

rollbacks of the 1950's when disease prevention was first allowed as a use.¹⁴⁹

Recent FDA inaction on the issue of sub-therapeutic use of antibiotics is a clear illustration of what is known as “agency capture.” For the FDA to effectively regulate animal drugs, it must act independently.¹⁵⁰ Agency capture is often achieved through lobbying and results in the agency serving private interests instead of the public good.¹⁵¹ When discussing the transition from OTC to Veterinary Feed Directive status, the FDA is concerned with the impact on veterinarians, the animal feed industry, and animal producers, i.e. private interests. It does not focus on public good.

Now that a few months have passed since GFI 213 was announced, nearly all drug companies who make antibiotics used in animal feed have indicated they intend to comply with the guidance.¹⁵² Almost surprisingly, they voluntarily withdrew production claims from labels in accordance with agency nonbinding recommendations. Public health experts point out that the industry could continue to use antibiotics, but under new therapeutic pretenses.¹⁵³

Some students of this area of regulation doubt readiness to separate food from drugs.¹⁵⁴ The way GFI 213 is worded, antibiotics are banned from use as growth promoters, but they may be used to prevent disease.¹⁵⁵ Using antibiotics to prevent disease has been named the “preventative use” loophole. The “preventative use” loophole¹⁵⁶ explains why pharmaceutical executives feel secure enough to make statements on record reassuring shareholders that the new FDA guidance will not affect their pharmaceutical company's

149. Certification of Batches of Antibiotic-Containing Drugs, 16 Fed. Reg. 3647, 3648 (Apr. 28, 1951).

150. Daluiso, *supra* note 116.

151. *Id.*

152. Tavernise, *supra* note 136.

153. *Id.*

154. Marguax Birdsall, *Biopharming, Bananas and Bureaucracy: The Banana Vaccine as a Case Study for Products that Straddle the Food/Drug Divide*, 66 FOOD DRUG L.J. 265, 282 (2011).

155. GFI #213.

156. Ben Elgin & Andrew Martin, *FDA Crackdown on Antibiotics Relies on Unproven Steps*, BLOOMBERG, Jan. 2, 2014, <http://www.bloomberg.com/news/2014-01-03/fda-crackdown-on-antibiotics-relies-on-unproven-steps.html>.

bottom line.¹⁵⁷ The leading animal antibiotic manufacturer, Zoetis CEO Juan Alaix, said the guidance would not have a significant impact on their revenues and little effect on the usage of antibiotics in livestock.¹⁵⁸ A spokesman for Eli Lilly's animal health division, Elanco, said the new industry guidelines will not have a material or significant impact.¹⁵⁹

The FDA provides three years to implement changes. Because this is industry guidance and not a rule and it does not create or confer any rights to anyone, it is unclear what will happen at the end of three years. Will there be any action if sponsors who submitted notice to voluntarily withdraw fail to do so?

3. FDA has Assured Drug Companies It will Work with Them to Re-label Antibiotics Under Medically Acceptable Uses

The FDA promises to coordinate with drug sponsors to help them implement changes.¹⁶⁰ If a drug had previously been used for production purposes but also has a therapeutic benefits supported by scientific evidence, sponsors can seek new therapeutic indications. Drug sponsors are encouraged to voluntarily revise conditions to reflect the need for veterinary oversight. The timeline for implementation is quite generous. Drug sponsors are to notify the FDA within three months of intentions to modify their products. The FDA believes sponsors should be able to make changes within three years.¹⁶¹

Thomas G. Slama, MD, President of the Infectious Diseases Society of America ("IDSA"), also submitted a letter during the comment period for GFI 209.¹⁶² The tone is stern. IDSA rests on

157. Thistlethwaite, *supra* note 143.

158. *Id.*

159. Elgin & Martin, *supra* note 156.

160. GFI #213.

161. *Id.*

162. See Thomas G. Slama, *Comments on FDA Animal Antibiotic Use Documents*, INFECTIOUS DISEASES SOCIETY OF AMERICA (July 11, 2012), available at http://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Antimicrobial_Resistance/Agriculture/Letters/Test/IDSA%20Comments%20on%20FDA%20GFI%20209%20213%20and%20VFD%20PR%20071112.pdf.

scientific evidence commanding a radical change in the way antibiotics are used – bidding us enter a post-antibiotic era.¹⁶³ IDSA also brings up the worry that drug makers will simply re-label the same antibiotics and sell them under different uses. He reminds the FDA of the ultimate goal of significantly decreasing overall antimicrobial use in food animals.¹⁶⁴

III. RECOMMENDATIONS:
FDA SHOULD CLOSE THE LOOPHOLES NOW WITH
RULES, SURVEILLANCE, AND PENALTIES

While some believe FDA GFI 213 is a step towards reducing antibiotic overuse in livestock, this note will explain it is completely inadequate. Unregulated antibiotic use on the modern farm is resulting in multi-drug resistant bacteria. A false image of security is more dangerous than an enemy in the open.

There are four agencies involved in ensuring the safety of the food that reaches your dinner table. Over the past forty years, civil, legislative, and judicial actions based on scientific evidence demanded a change in the way antibiotics are routinely used in agribusiness. Neither the regulating agencies nor the other actions have been able to tackle antibiotic overuse in food-producing animals.

From 1977 to 2011, the FDA left a NOOH open and declined to investigate the safety of antibiotics. Recently, the FDA published GFI 213, which tells drug companies they may voluntarily align use claims to be more judicious. There is little belief that a voluntary, nonbinding mechanism would be an effective means to create meaningful change in either the agricultural or pharmaceutical industries. On the contrary, beef lobbyists have petitioned for fewer checkpoints between their beef and the dinner table.¹⁶⁵

163. *See id.*

164. *See id.*

165. ELANOR STARMER, *THE AGRIBUSINESS ACCOUNTABILITY INITIATIVE, HOGGING THE MARKET: HOW POWERFUL MEAT PACKERS ARE CHANGING OUR FOOD SYSTEM AND WHAT WE CAN DO ABOUT IT*, available at http://www.ase.tufts.edu/gdae/Pubs/rp/AAI_Issue_Brief_4.pdf (explaining there are no meat processing facilities in Wyoming that require federal inspection).

Pharmaceutical companies are notorious for finding loopholes in each step from safety and effectiveness to false claims to marketing.

FDA guidance is an insufficient measure to reduce use of antibiotics used in food-producing animals. The mode of recommendation - Guidance for Industry - is not designed to create change. The language is undefined and creates loopholes. Agency capture means that the FDA is erroneously focused on the industry instead of public health.¹⁶⁶

The FDA has failed to close address routine prevention uses.¹⁶⁷ Pew and Consumer Reports recommendations posit we could patch the many food safety issues around antibiotic resistance bacteria found on meat by reducing overuse of farm antibiotics, declaring Salmonella an adulterant, revising the data standards for the organism, and giving FSIS authority to enforce U.S. food safety regulations.¹⁶⁸

To close these loopholes and create a regulatory environment where antibiotics are used for their originally intended purpose of treating diseased animals, Congress should pass H.R. 1150: Preservation of Antibiotics for Medical Treatment Act of 2013 (“PAMTA”)¹⁶⁹ and stop OTC use of antibiotics for sub-therapeutic use immediately. PAMTA is aimed at ending the routine use of antibiotics on healthy livestock and reducing the threat of superbugs.¹⁷⁰ The FDA should require prescriptions for antibiotics only for therapeutic uses. This means redefining therapeutic to narrowly capture only medically necessary uses and exclude broad-brush preventative use. The industry understanding of “prevention” would no longer be a qualified therapeutic use. Also, herd-wide prescriptions would be permitted only in exceptional circumstances. Should drug companies use false claims, veterinarians prescribe off label, or farm owners misrepresent disease, the FDA would be able to pursue criminal charges and fines.

After initial rules have been established, the government can look to take secondary steps to ensure a successful follow through.

166. Daluiso, *supra* note 116.

167. *See* Elgin & Martin, *supra* note 156.

168. *See* McKenna, *supra* note 65.

169. *See* Preservation of Antibiotics for Medical Treatment Act of 2013, H.R. 1150, 113th Cong. (2013).

170. *See id.*

Surveillance of the regulations through industry reporting would provide information necessary for enforcement. Civil or criminal action and accompanying penalties would reinforce the importance of adhering to guidelines.

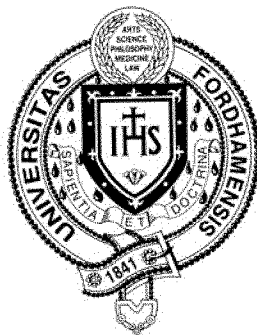
For example, veterinarians would report prescriptions and pharmaceutical companies will report sales figures to FDA. The USDA could classify strains of bacteria like salmonella that are resistant to multiple antibiotics and known to have caused disease as “adulterants” so tainted meat couldn’t be brought to market. FSIS would be empowered to monitor compliance with regulatory requirements through existing product control actions. The burden should be shifted back to processors in a strict-liability fashion to encourage the appropriate level of attention.

Although the FDA’s recent guidance might not be the change public health advocates are looking for, its failure might provide a backdrop for more effective steps.

IV. CONCLUSION

To address antibiotic overuse and prevent the emergence of a Superbug, the United States should take the following immediate steps. Congress should pass the Preservation of Antibiotics for Medical Treatment Act to stop OTC use of antibiotics for sub-therapeutic use. The FDA should only permit prescriptions for antibiotics for therapeutic uses. Herd-wide prescriptions would be permitted only in exceptional circumstances. Should drug companies use false claims, veterinarians prescribe off label, or farm owners misrepresent disease, the FDA would be able to pursue criminal charges and fines. It is the farmer’s responsibility to raise livestock in a healthy environment without antibiotic overuse. We ought to shift the burden of regulatory compliance back to food processors in a strict-liability fashion.

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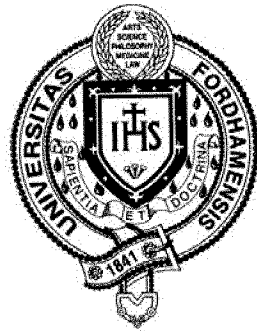
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