THE FDA, ITS "GUIDANCES," AND THE INDUSTRIES IT IS SUPPOSED TO REGULATE

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INTRODUCTION

As an individual, what is your biggest fear as a food consumer, or how about as a parent of a food consumer? Would it be salmonella poisoning or perhaps high cholesterol? Maybe your biggest fear as a food consumer is sickness from *E. coli*, the result of a food service worker not properly washing his or her hands. For the less fortunate in society, these concerns may be foreign, and their biggest fear may simply be not having enough food to eat. What would you choose as your biggest fear if you learned that our livestock-based food supply contains enough antibiotic

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medication to jeopardize our ability to treat illness and infection, and its presence can be traced back to weak regulation by a federal agency? Before you address these questions and move on to others, you should pause for a moment and consider that this risk isn't a new development, it was acknowledged in the United Kingdom in 1969 and the United States in 1970; yet nothing concrete has been done about the problem by our federal government in the nearly fifty years which have followed.[1]

The unwelcome surprise of antibiotic medication in our food supply jeopardizes our ability to fight illness by opening the door to bacteria development, which has very dangerous consequences.[2] Where is this danger typically found you ask? In general, the locations in which antibiotics are most frequently found are "hospitals, farms, and child-care settings."[3] Regarding our food supply, the danger comes from the food-producing livestock industry itself. This risk has gone unaddressed, even though the agricultural industry has experienced big changes over the past twenty years—from the emergence of antimicrobial resistant bacteria to genetically-modified organisms—and is poised to experience even more as demand increases. These big changes are in part due to the agricultural industry anticipating and responding to pressure to produce enough food for an ever-increasing world population while maintaining profitability.[4]

This Note will discuss the guidances the FDA has issued to address this significant risk to public health, the demographic changes during that evolution and how they relate to the demands on the agricultural and pharmaceutical industries, and whether the federal government is doing enough to fulfill its duty. Next, this Note will discuss the technological developments in agriculture that have occurred in recent years and how those relate to antimicrobial resistant bacteria. Then, finally, the Note will discuss the history of food and drug regulation in the United States, recent regulatory action, challenges to future regulation, and what options are available to avoid the development of a superbug.

1. CTR. FOR VETERINARY MED., FDA, GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 5-6 (2012), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf [hereinafter GUIDANCE #209].

2. CHRISTOPHER T. WALSH ET AL., TREATING INFECTIOUS DISEASES IN A MICROBIAL WORLD 1 (National Academies Press, 2006).

3. *Id.* at 11.

4. Jared Green, *The Effects of Population Growth on Land Use*, THE DIRT (Nov. 9, 2009), https://dirt.asla.org/2009/11/09/the-effects-of-population-growth-on-land-use/.

II. FDA GUIDANCES

The Oxford Dictionary defines guidance as "[a]dvice or information aimed at resolving a problem or difficulty, especially as given by someone in authority."[5] Turning its attention to the problem of antimicrobial-resistant bacteria, the FDA has issued three guidances over the past thirteen years which aim to protect public health and reduce the chance that a superbug would develop.[6] These include: Guidance #152, which establishes guidelines for evaluating the safety of livestock antibiotics prior to their first administration;[7] Guidance #209, which suggests restricting antibiotic use to only treat illness or disease, and not to promote growth;[8] and Guidance #213, which modifies the practice of introducing antibiotics to livestock through feed and water.[9]

In these guidances the FDA acknowledges that using antibiotics in livestock without any analysis, scrutiny, or best practices could jeopardize the effectiveness of important antibiotics reserved for the treatment of serious illness in humans.[10] In this case the FDA's "advice or information" is aimed at preventing an outbreak of untreatable illness which could have been prevented by addressing risky agricultural practices, and it is directed at agricultural and pharmaceutical companies but is not mandatory. Each guidance clearly states in its introduction that regardless of what the guidance suggests, the guidances do not impose a legally enforceable responsibility on any party.[11]

Guidance #152 outlines a process by which drugs proposed for initial use in

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5. *Guidance*, OXFORDDICTIONARIES.COM, http://www.oxforddictionaries.com/us/definition/american_english/guidance (last visited Aug. 29, 2016).

6. *See, e.g.*, GUIDANCE #209, *supra* note 1, at 3; CTR. FOR VETERINARY MED., FDA, GUIDANCE FOR INDUSTRY #152: EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN CONCERN 8 (2003), http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm052519.pdf [hereinafter GUIDANCE #152]; CTR. FOR VETERINARY MED., FDA, 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, at 3 (2013), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf [hereinafter GUIDANCE #213].

7. *See* GUIDANCE #152, *supra* note 6, at 3.

8. GUIDANCE #209, *supra* note 1, at 22.

9. GUIDANCE #213, *supra* note 6, at 7.

10. GUIDANCE #152, *supra* note 6, at 8; GUIDANCE #209, *supra* note 1, at 4; GUIDANCE #213, *supra* note 6, at 3.

11. *E.g.*, GUIDANCE #152, *supra* note 6, at 2.

livestock are studied for any potential long-term jeopardy they might pose to our ability to fight infection in the future. The process is essentially a risk analysis that attempts to balance the chance of important antibiotics losing their effectiveness and jeopardizing human health, against an estimate of the probability that that risk will actually occur.[12] The FDA deems a new drug safe for the use in livestock if there is a reasonable certainty that it will not harm human health.[13] What this risk analysis also does, however, is balance those risks against the "benefits to agriculture."[14] The assessments discussed in the guidance are designed to estimate the chance, or lack thereof, that humans will be exposed to antimicrobial resistant bacteria through the consumption of "animal derived food commodities."[15]

Included with Guidance #152 is Appendix A, which ranks antibiotic medication based on public health importance.[16] These rankings are the FDA's statement to industry that the medications most important to treating infectious disease should be used sparingly, but also that some medications are less important to the treatment of illness and disease than others.[17] The primary reason some medications are ranked much lower than others is that bacterial resistance to those medications has already occurred.[18]

Guidance #152 discusses additional steps which can be implemented to protect the efficacy of these medications, including post-approval monitoring and advisory committee review of approval decisions.[19] These post-approval steps are important to the whole process in which drugs are approved because Appendix A does not represent all of the antibiotic drugs or drug classes, and the emergence of other disease and changes in prescribing practices can impact the rankings over time.[20] Also, the Federal Food, Drug, and Cosmetic Act allows withdrawal of an approved drug if later evidence reveals the drug to not be safe under certain use conditions, however this Note will explain later why that process is inefficient.[21]

Guidance #209 represents the FDA's thinking on how livestock and antibiotic administration practices might be modified to co-exist with Guidance #152's statement that some medications are important enough to not be used at all

12. *Id.* at 8-26.
13. GUIDANCE #209, *supra* note 1, at 18.
14. *Id.* at 9.
15. GUIDANCE #152, *supra* note 6, at 19.
16. *See id.* at 30 tbl.A1.
17. *Id.* at 20.
18. *Id.*
19. *Id.* at 23.
20. *See id.* at 28.
21. GUIDANCE #209, *supra* note 1, at 18.

or at least not for production or growth-enhancing purposes.[22] Production purposes, as a practice, maximize the economic return on livestock by increasing their physical size, reducing the amount of actual feed they need to achieve the same growth, or both.[23] This is what is referred to as an extra-judicious use of antibiotics in livestock, and such uses should be avoided because they are not used to treat any specific illness or disease. Section III of the guidance is a twelve-page discussion of the history of this issue by various governmental entities and professional scientific organizations.[24]

Guidance #209 recognizes that there are problems with using the risk analysis method for new drugs which have not previously been used on animals, and also on currently-approved drugs.[25] But on the other hand, to withdraw an already approved drug, the FDA would have to put forth evidence that the drug is no longer safe.[26] Therefore, Guidance #209 recommends two principles for the use of already-approved drugs until such time as the FDA can determine what steps the agency should take to identify whether those drugs, some of which have been used for over thirty years, should be restricted as well.[27] The first principle is that antibiotics should be restricted to uses necessary for maintaining animal health, and all production uses are not considered to be within that scope.[28] The second principle is that medically important medications should be used with oversight or consultation by a veterinarian.[29] These principles represent the FDA's thinking on how to address those medications which have already been approved, and they are positive principles, except for the word "should."[30] This word alone takes away any suggestion that these principles are what the industry must follow to protect public health, and when read in conjunction with the repeated header on each page that reads "Contains Nonbinding Recommendations," we can only speculate as to what might happen if these guidances are ignored.[31]

Guidance #213 was issued to give drug sponsors, veterinarians, and the livestock industry more direct recommendations on how to "voluntarily" align their practices with the two principles of judicious use discussed in Guidance

22. *Id.* at 4.
23. *See id.*
24. *See id.* at 5-17.
25. *Id.* at 19.
26. 21 U.S.C. § 360(b)(e)(1)(A) (2012); GUIDANCE #209, *supra* note 1, at 19.
27. GUIDANCE #209, *supra* note 1, at 20.
28. *Id.* at 21.
29. *Id.* at 22.
30. *Id.* at 21-22.
31. *See generally id.*

#209.[32]

What all three guides attempt to do is bring about positive change in the agricultural industry but do not actually require it or assign any penalties for the failure to so change. The FDA has stated it chose the guidance approach because it felt pursuing actual binding regulatory action would almost certainly be opposed, assumedly by farmers, pharmaceutical manufacturers, private interest groups, and legislatures, and this would be a faster way to bring about change. Due to the size of the industries involved and their individual motivations we should discuss the vested interests involved and how they may impact whether or not the FDA's guidance approach will work.

III. IMPACT OF FARM OPERATIONS

Gone are the days of the small family farmer. The sobering reality is that large-scale commercial farming operations have replaced those family farms, and modern farmers operate an industrial model of production, much like any other production-oriented business.[33] How does this impact the agricultural industry, our food supply, and our health? This means commercial farmers focus on economies of scale, increased profitability through technology, production of a particular product, and they control the product from beginning to end.[34] The target of the commercial farmer is to increase production and maintain as low of a per product cost as possible.[35] This mentality and methodology has been beneficial to production and profitability, but it has its drawbacks. Of concern to us all, should be the effects of industrialization on the animals which are raised and processed for food. The industrialization trends for livestock mirror those of seed and grain agriculture, with commercial farms normally focusing on a single species.[36]

The USDA analyzed the impact of technological change on animal agriculture and noted that while commercial farming operations are able to maximize their profits by lowering their costs, there are drawbacks.[37] Such increased confinement of a single species of animal often results in less room for each animal, meaning there is significant crowding, stress, and inadequate ventilation, among other problems.[38] Also, small area confinement of a large

32. GUIDANCE #213, *supra* note 6, at 4.

33. SUSAN A. SCHNEIDER, FOOD, FARMING, AND SUSTAINABILITY: READINGS IN AGRICULTURAL LAW 3, 17 (Carolina Academic Press, 2011).

34. *Id.*

35. *Id.*

36. *Id.* at 3, 22.

37. *Id.*

38. *Id.*

number of animals leads to a high volume of excrement in a limited space, which contaminates the air and pollutes the water. To achieve the low-cost, high-return model of farming economics, each farmer must have a higher yield per food-producing animal. The USDA has noted large scale farming operations are likely to use antibiotics for pre-emption of illness and to accelerate animal growth as a means to drive up yield.[39]

There are questions which remain unanswered as to whether the benefits of commercial farming are shared by the farm operators, consumers, and the environment alike, or whether the farm operators benefit alone. The environment takes a very large hit when placed in a battle with large scale farming operations. While not an exhaustive list, the environment suffers from concentrated waste, water pollution, air pollution, and disruption of wildlife and aquaculture.[40] The loss and degradation of habitat, erosion of topsoil and sediment deposits in our waterways, depletion of water sources, increased salinity of the soil and water, and insecticides, herbicides, and fungicides, are just some of the other hidden costs as family-farming transitions to industrialized farming.[41] These aren't unrealized worries, they all occur on a daily basis and two examples can help illustrate the impact that unregulated farming practices can have on our shared environment.

The first example can be found at Lake Red Rock in Knoxville, Iowa. Lake Red Rock is Iowa's largest lake at 15,000 acres of water and 35,000 acres of land,[42] and its dam was constructed in 1969, to collect run-off from 12,320 square miles of Iowa and Southern Minnesota land, to protect agricultural lands downstream.[43] Concern has been growing for quite some time that the lake itself is filling in with sediment transported by run-off from this surrounding and contributing land. It is estimated that each day Lake Red Rock has enough sediment deposited in the lake to fill seven Olympic size swimming pools.[44] Because Lake Red Rock is a man-made lake with a dam, there is no flow through of the sediment, and approximately 90 percent of the suspended sediment simply sinks to the bottom, gradually filling up the lake a little each day.[45] This reduces the water depth available for aquatic

39. James M. MacDonald & William D. McBride, USDA, THE TRANSFORMATION OF U.S. LIVESTOCK AGRICULTURE: SCALE, EFFICIENCY, AND RISKS, 3 (2009), http://www.ers.usda.gov/media/184977/eib43.pdf.

40. SCHNEIDER, *supra* note 33, at 3, 25.

41. *Id.* at 3, 121.

42. *Welcome to Lake Red Rock*, U.S. ARMY CORPS OF ENGINEERS, http://www.mvr.usace.army.mil/Missions/Recreation/LakeRedRock.aspx (last visited Aug. 21, 2016).

43. *Id.*

44. Mark Thompson, *Red Rock's Dirty Secret*, GLADYS BLACK ENVTL. EDUC. PROJECT, http://www.gladysblackeagle.org/project-ideas/red-rock-s-dirty-secret (last visited , 2016).

45. *Id.*

life and recreation and is an example of a hidden cost of farming not absorbed by the farming operation itself but rather by consumers, outdoor enthusiasts, and the environment.

The second example of hidden farming costs is litigation proposed by the City of Des Moines against three neighboring counties for contaminating the water sources which feed the City of Des Moines. The City of Des Moines paid $900,000 in 2013 to remove nitrates from its water supply, nitrates that reached the City of Des Moines from fertilizer run-off in the Des Moines and Raccoon rivers.[46] Farmers spread fertilizer on their crops, which turns into nitrates and works its way into our water supply as run-off.[47] Nitrates are difficult to remove, pose a risk to young children, and have killed off aquatic life from the Midwest to the Gulf of Mexico.[48] Because of the problems this unregulated practice poses, the City of Des Moines sent notice to Buena Vista, Calhoun, and Sac county of its intent to sue for damages.[49] The point in discussing the fill-in of Lake Red Rock and the contamination of the City of Des Moines's water supply is to force consideration of the question of how much actual benefit consumers derive from industrialized farming; a question which can only be answered if all of the hidden costs of its operation are accounted for.

The City of Des Moines is a rare example of an entity having enough resources to try and force these costs back onto the agriculture industry or at least those responsible for its operation. For most everyone else, the list of problems, and the relative lack of bargaining power between consumers, outdoor enthusiasts, and the environment and commercial farmers, these latent costs of production are absorbed by us.[50] Just as the problem of antimicrobial resistant bacteria is a worldwide problem, so are the hidden costs of farming. This too is not a new development, while the numbers might be dated, an English researcher determined that the estimated hidden costs of commercial farming in Britain in the 1990s was $2.6 billion dollars.[51] Adjusted for inflation, that $2.6 billion dollar loss in Britain alone equates to roughly $4.9 billion dollars today.The problem is almost every

46. Dan Charles, *Iowa's Largest City Sues over Farm Fertilizer Runoff in Rivers*, NPR: THE SALT (Jan. 12, 2015, 3:26 AM), http://www.npr.org/blogs/thesalt/2015/01/12/376139473/iowas-largest-city-sues-over-farm-fertilizer-runoff-in-rivers.

47. *Id.*

48. *Id.*

49. *Id.*

50. SCHNEIDER, *supra* note 33, at 26; Doug O'Brien, *Policy Approaches to Address Problems Associated with Consolidation and Vertical Integration in Agriculture*, 9 DRAKE J. AGRIC. L. 33, 34 (2004).

51. SCHNEIDER, *supra* note 33, at 26.

law enacted to protect the environment has an exception for farming operations.[52] Many laws and regulations are, in fact, written or interpreted in a way that imposes the lowest financial burden on the agricultural industry.[53]

IV. DEMAND ON AGRICULTURAL AND PHARMACEUTICAL INDUSTRIES

Why does the use of antibiotics in livestock represent a serious concern which must be addressed now, compared to one our federal and state authorities can afford to address over time? Because at our current level of food demand, farmers already use these medications to promote growth. Which is concerning because the worldwide demand for food over the next forty-five years is projected to be greater than in the prior 10,000 years combined.[54]

In 1970, the total world-wide meat consumption was 29 million metric tons, and milk consumption was 74 million metric tons.[55] By 2003, the world's consumption rose to 143 million metric tons of meat and 240 million metric tons of milk.[56] In a span of thirty-three years meat consumption increased by 393 percent, which just outpaced a 224 percent increase in milk consumption.[57] Those leaps in demand correlated with a world-wide population level of which rose from 3.7 billion to just over 6.3 billion people - an increase of 2.6 billion lives worldwide.[58] These are not scientific figures, but looking at those figures reveals that a 70 percent increase in population triggered a 393 percent and 224 percent increase in meat and milk consumption, respectively.

Over the next thirty-five years the world population is estimated increase by another 50 percent, but compared to prior population increases, there is essentially no expansion land available to grow additional crops and increase livestock production, and, in fact, there could be less land available than we have now.[59]

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52. *Id.* at 138.

53. Susan A. Schneider, *A Reconsideration of Agricultural Law: A Call for the Law of Food, Farming, and Sustainability*, 34 WILLIAM & MARY ENVTL. L. & POL'Y REV. 935, 942 (2010).

54. Jacques Diouf, *Feeding a World of 9 Billion*, PEOPLE & THE PLANET (June 2008), http://www.peopleandtheplanet.com/index.html@lid=26107&section=34&topic=44.html.

55. Don Hofstrand, *Can the World Feed Nine Billion People by 2050?*, AGRIC. MARKETING RES. CTR., at tbl.4, http://www.agmrc.org/renewable_energy/renewable_energy/can-the-world-feed-nine-billion-people-by-2050/ (last visited Aug. 21, 2016).

56. *Id.*

57. *Id.*

58. *Id.*

59. Steve Connor, *2.4 Billion Extra People, No More Land: How Will We Feed the World in 2050?*, INDEP. (Jan. 21, 2011), http://www.independent.co.uk/news/science/24-billion-extra-people-no-more-land-how-will-we-feed-the-world-in-2050-2191260.html.

Even if that were not the case the United Nations Food and Agriculture Organization estimates that additional land would at best produce only 20 percent of the additional food we will need by that time.[60] These figures demonstrate that there are clear pressures looming that will require for further improvement and efficiency in agricultural production to meet the food demand of a growing planet. Just as their grain producer counterparts will be forced to identify ways to improve crop yield with the same amount of farm ground, livestock producers will experience both heightened demand and decreased expansion possibilities, which could incentivize producers to use risky production methodologies.

If livestock producers continue to utilize production purposes antibiotic administration, as demand for food increases it is safe to speculate that demand on the pharmaceutical industry will correspondingly increase. Ironically, in the nearly eleven-and-a-half years and three years, respectively, since Guidance #152 and Guidance #209 were issued, the animal pharmaceutical industry has not experienced a drop in the demand for its products. One report indicates that global animal health market revenue for the use of feed additives, pharmaceuticals, and vaccines is projected to grow at a rate of 5.43 percent through 2018.[61] That level of projected revenue growth was determined by comparing the current market size to the predicted sales of various animal health products.[62] The report indicates that the growth in revenue directly relates to increased demand for animal food and protein-rich nutrition, however regulatory difficulties which delay introduction of additional drugs into the marketplace will impact revenue growth.[63] It is not clear what those regulatory difficulties might be, considering the very entity capable of regulating them, the FDA, is expressly not doing so.[64] Somewhere, Dr. Wiley is turning over in his grave at the thought that this many years later the FDA has forgotten how and why it began; private economic interests jeopardized the health and safety of our nation.

60. JEFF SIMMONS, ELANCO ANIMAL HEALTH, FOOD ECONOMICS AND CONSUMER CHOICE: WHY AGRICULTURE NEEDS TECHNOLOGY TO HELP MEET A GROWING DEMAND FOR SAFE, NUTRITIOUS AND AFFORDABLE FOOD 1 (2010), http://www.thepoultryfederation.com/public/userfiles/files/2-8%20Wed%20-%20Jeff%20Simmons%20-%20Food%20Ecomonics%20and%20Choice.pdf.

61. *Global Animal Health Market 2014-2018: Key Vendors are Bayer, Elanco, Merck Animal Health, Merial and Zoetis*, PR NEWSWIRE (Sept. 12, 2014, 7:59 PM), http://www.prnewswire.com/news-releases/global-animal-health-market-2014-2018-key-vendors-are-bayer-elanco-merck-animal-health-merial-and-zoetis-274875481.html.

62. *Id.*

63. *Id.*

64. *E.g.*, GUIDANCE #152, *supra* note 6, at 15 (each Guidance has the same "Contains Nonbinding Recommendations" language).

V. TECHNOLOGICAL DEVELOPMENTS

Just like any industry, farmers continually seek ways to raise the efficiency of crop and animal production. For example, crop growers use high yield seed that is significantly more drought resistant than in decades past, and there is support for the use of genetically modified organisms - crop seed modified at the molecular level to include genes from other seed or grain, which would have been difficult for normal seed to obtain even through selective breeding.[65] Livestock producers face the same pressure to increase their output through genetic and chemical efficiency.[66] Although not molecular-level modification, antibiotics are "naturally occurring, semi-synthetic or synthetic compounds used to treat bacterial infections" in humans and livestock.[67]

Recently, former USDA commissioner, Donald Kennedy, stated the widespread and long-term use of pharmaceuticals in livestock has become routine and the evidence establishing this reality is "astonishing."[68] Statistically, 80 percent of all antibiotics manufactured in the United States is used on livestock such as cattle, hogs, and chickens.[69]

Under normal circumstances, animal pharmaceuticals are used by livestock producers to treat and prevent disease and infection, and are used in vaccine and antibiotic form.[70] The means by which antibiotics are introduced into livestock include pills, liquid, drenching an animal with liquid medication, and adding it to feed and water.[71] Veterinarians or owners administer these medications to treat

65. Julia M. Diaz & Judith L. Fridovich-Keil, *Genetically Modified Organism (GMO)*, ENCYCLOPEDIA BRITTANICA, http://www.britannica.com/science/genetically-modified-organism (last updated Apr. 28, 2016).

66. *See* James C. Greenwood, Opinion, *My Voice: Building a Better Animal*, ARGUS LEADER (Sept. 12, 2014, 9:19 AM), http://www.argusleader.com/story/opinion/2014/09/11/voice-building-better-animal/15494389/ (discussing genetically modified food animals).

67. Ravi PN Mishra et al., *Vaccines and Antibiotic Resistance*, 15 CURRENT OP. IN MICROBIOLOGY 596, 696 (2012).

68. Brian Grow et al., *Documents Reveal How Poultry Firms Systematically Feed Antibiotics to Flocks: Pervasive Use Fuels Concerns About Impact on Human Health, Emergence of Superbugs*, REUTERS INVESTIGATES (Sept. 15, 2014, 1:00 PM), http://www.reuters.com/investigates/special-report/farmaceuticals-the-drugs-fed-to-farm-animals-and-the-risks-posed-to-humans/.

69. Susan Brink, *Fatal Superbugs: Antibiotics Losing Effectiveness, WHO Says*, NAT'L GEOGRAPHIC (May 2, 2014), http://news.nationalgeographic.com/news/2014/05/140501-superbugs-antibiotics-resistance-disease-medicine/.

70. *Pharmaceuticals*, ANIMAL HEALTH INST., http://www.ahi.org/about-animal-medicines/pharmaceuticals/ (last visited Aug. 21, 2016).

71. *Id.*

parasites, inflammation, pain, illness, reproductive problems, and cardiovascular or metabolic conditions.[72] However, it's the extrajudicious uses that are the problem right now.

Not only is overuse of antibiotics a risk to us, it is to the environment as well. In 2013, the Environmental Protection Agency published a review of emerging contaminants in livestock manure and focused on antimicrobials and hormones used to promote growth, feed efficiency, meat quality, and increase milk production.[73] This extra judicious use of antibiotics in livestock rearing has already resulted in measurable emerging contaminants in the environment, which threaten grasslands, waterways, aquaculture, wildlife, and ecological biology.[74] As emerging contaminants pass from livestock into feces and from there into the ground and waterways, drug-resistant bacteria develops everywhere.[75]

Although difficult to properly assess due to a lack of reporting requirements, the estimated amount by which the pharmaceutical industry is leveraged on the livestock industry is 80 percent compared to 20 percent for human medicine, which equates to an estimated 28.8 million pounds of drugs distributed for food-producing animals, leaving only 7.2 million pounds for humans.[76] Which in a disturbing way makes sense, when you compare livestock populations to human. The total United States population in 2012 was an estimated 312.8 million residents.[77] The total estimated consumable livestock population for the same year was the following: cattle at 90 million;[78] hogs and pigs at 66 million;[79] sheep and lambs at 5.36 million;[80] goats at 2.6 million;[81] horses and mules at 3.9 million;[82] and various poultry at 2 billion;[83] which equals an estimated livestock population

72. *Id.*

73. Kelly Damewood, *Emerging Contaminants: Ag Runoff Poses Health Risks*, FOOD SAFETY NEWS (Oct. 24, 2013), http://www.foodsafetynews.com/2013/10/emerging-contaminants-potential-health-risks-from-agricultural-runoff/#.VCdQAPldU7Q.

74. *Id.*

75. *Id.*

76. Maryn McKenna, *News Break: FDA Estaimates US Livestock get 29 Million Pounds of Antibiotics per Year*, WIRED (Dec. 29, 2010), http://www.wired.com/2010/12/news-break-fda-estimate-us-livestock-get-29-million-pounds-of-antibiotics-per-year/.

77. *U.S. and World Population Clock*, U.S. CENSUS BUREAU, http://www.census.gov/popclock/ (last visited Aug. 21, 2016).

78. TOM VILSACK & CYNTHIA Z. F. CLARK, USDA, 2012 CENSUS OF AGRICULTURE 19, tbl.12 (2014).

79. *Id.* at 21, tbl.19.

80. *Id.* at 23, tbl.27.

81. *Id.* at 24, tbl.30.

82. *Id.* at 24, tbl.31.

83. *Id.* at 25, tbl.32.

estimate of 2.16 billion. These figures reveal that out of an estimated combined human and livestock population of 2.48 billion, humans represent roughly 14.5 percent of the total population and livestock represent 85.5 percent. These figures are admittedly rough and are subject to adjustment but are included to allow some comparison of markets the pharmaceutical industry targets.

To be fair, not all pharmaceuticals used on animals are considered a significant risk to human health,[84] but at this time, it is somewhat a guessing game for federal authorities as to how large or small the problem may be because under the current regulatory scheme, only twenty out of over 10,000 pharmaceutical manufacturers are required to file environmental assessments of medications they produce.[85] Which is strange, considering the FDA has stated animal-derived food represents the most significant opportunity for human exposure to antimicrobial resistant bacteria,[86] and medical treatments are slowly losing their efficacy as they become "ineffective owing to rapid and widespread emergence of multidrug resistant bacteria."[87] This could make every day medical procedures much riskier with dire consequences if hospital borne pathogens cannot be treated with antibiotics.[88]

To illustrate the weakness of the guidances, in 2007 the FDA—over objection of its own advisory board[89]—approved the drug, cefquinome, for treatment of illness in livestock.[90] This particular antibiotic is a member of a class of highly potent antibiotics that were reserved as the last line of defense against serious human infection.[91] The FDA defended itself by stating that it was required to approve the drug because of the way Guidance #152 is written, and because it cannot prove that cefquinome is linked to human mortality.[92] Edward Belongia, an epidemiologist, says it is unwise to approve medications for use simply because their risk cannot be proven conclusively, and points out that "[i]t's easy to open the barn door, but it's hard to close the door once it's open."[93] This is not a false

84. *See* GUIDANCE #152, *supra* note 6, at 20-21, tbl.6.

85. Sonia Shah, *As Pharmaceutical Use Soars, Drugs Taint Water and Wildlife*, YALE ENVT. 360 (Apr. 15, 2010), http://e360.yale.edu/content/print.msp?id=2263.

86. GUIDANCE #152, *supra* note 6, at 3.

87. Mishra et al., *supra* note 67, at 596.

88. *See id.* (discussing antibiotics used for surgical wounds, dental surgery, post-chemotherapy treatment, and pregnant women to prevent perinatal infection).

89. Rick Weiss, *FDA Rules Override Warnings About Drug*, WASH. POST (Mar. 4, 2007), http://www.washingtonpost.com/wp-dyn/content/article/2007/03/03/AR2007030301311_pf.html.

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

problem. The FDA has faced this issue in the past. In the 1990s, the FDA overrode the warnings of experts from the CDC and approved Baytril and SaraFlox for use in poultry, only to battle for nearly twenty years to claw back approval after discovering strains of campylobacter developed a resistance to it and was hospitalizing patients with severe diarrhea.[94] What is most distressing is not just that the FDA overrode its own advisory panel, but that there were already more than a dozen medications on the market to treat the same condition, and all were still effective.[95]

VI. WHAT IS DRUG RESISTANT BACTERIA – IS THIS A PROBLEM THE FEDERAL GOVERNMENT NEEDS TO ADDRESS?

The FDA defines "[a]ntimicrobial-resistant food-borne bacteria" as hazardous agents "that are in or on a food-producing animal."[96] The "hazard" is the "human illness, caused by an antimicrobial-resistant bacteria, [that is] attributable to an animal-derived food commodity."[97] The fact bacteria develops an immunity to antibiotics is no mystery, we live in an environment where microorganisms have evolved, coexisted, and competed against each other for millions of years - overcoming adversity is what they do.[98] In fact, several leading commissions on infectious diseases have stated most antibiotics we have now will become obsolete at some point, but it is wise to try and slow that obsolescence.[99] The simple reality is that the less a drug is used, the less resistance emerges.[100]

The development and spread of antimicrobial-resistant bacteria can result from a broad range of factors including: microbial adaptation and change; human vulnerability; climate and weather; changing ecosystems; economic development and land use; human demographics and behavior; technology and industry; international travel and commerce; breakdown of public health measures; poverty and social inequality; war and famine; lack of political action; and the act of nefarious bodies to intentionally harm.[101] Further complicating the challenge of identifying a risk and then its source is the fact that new bacteria can occur from the mixture of any or all of these factors.[102]

94. *Id.*
95. *Id.*
96. GUIDANCE #152, *supra* note 6, at 7.
97. *Id.* at 8.
98. WALSH ET AL., *supra* note 2, at 1-2.
99. *Id.* at 10.
100. Weiss, *supra* note 89.
101. Guidance #209, *supra* note 1, at 11 n.4.
102. *Id.* at 11.

Drug resistant bacteria are also known as antimicrobial resistant bacteria, antibiotic resistant bacteria, and superbugs. Drug resistant bacteria were, at one time, successfully managed with antibiotics, but over time and through gene mutations, they are no longer responsive to traditional antibiotics.[103] Bacterial immunity has a causal relationship to antibiotics that are overused and misused to treat common colds and viruses, ailments which, in the interest of decreasing the prevalence of drug-resistant bacteria, should simply run their course untreated.[104] This means the more antibiotics are used in humans and livestock, the faster bacteria develops genetic immunities to the effects of the medication.

Some common antibiotic-resistant bacteria include methicillin-resistant *Staphylococcus aureus* (MRSA is inflectional bacteria that can spread to bones, joints, and major organs),[105] *Klebsiella pneumonia* (bacteria that produces an enzyme prohibiting antibiotics from killing it), *Clostridium difficile* (intestinal bacteria that can cause severe diarrhea and severe colon inflammation), extensively drug-resistant tuberculosis (lung and organ infection), drug-resistant *Neisseria gonorrhoeae* (sexually transmitted disease), and Shiga toxin-producing *Escherichia coli* (*E. coli* found in guts of livestock that can cause diarrhea, urinary tract infections, respiratory illness, and pneumonia).[106] Others include a group of six common hospital-borne pathogens known as Enterococcus, Stapyhlococcus, Klebsiella, Acineobacter, Pseudomonas and Enterobacter, which health professionals have fought with for over two decades but which have developed a resistance to antibiotics.[107] To further illustrate the growing problem with antibiotic-resistant bacteria, the *E. coli* mentioned above developed a resistance to the antibiotic ciprofloxacin within ten hours of incubation.[108] As of 2006, 70 percent of nosocomial (hospital-acquired) infections were resistant to at least one of the most common antibiotics used to treat infection.[109]

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103. Brink, *supra* note 69.

104. *Stop the Spread of Superbugs: Help Fight Drug-Resistant Bacteria*, NEWS IN HEALTH (Feb. 2014), http://newsinhealth.nih.gov/issue/feb2014/feature1.

105. Maryn McKenna, *Bacterial Coinfections Boosting Child Flu Deaths*, UNIV. MINN.: CTR. FOR INFECTIOUS DISEASE RES. & POL'Y, BACTERIAL (Oct. 7, 2008), http:/www.cidrap.umn.edu/news-perspective/2008/10/bacterial-coinfections-boosting-child-flu-deaths; Linda Thrasybule, *6 Superbugs to Watch Out For*, LIVESCIENCE (Oct. 2, 2012, 8:51 AM), http://www.livescience.com/36674-superbugs-drug-resistant-bacteria-infections.html.

106. *See* Thrasybule, *supra* note 105.

107. Katie Moisse, *Antibiotic Resistance: The 5 Riskiest Superbugs*, ABC NEWS (Mar. 27, 2012), http://abcnews.go.com/Health/Wellness/antibiotic-resistance-riskiest-superbugs/story?id=15980356.

108. Mishra et al., *supra* note 67, at 597.

109. NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE PROBLEM OF ANTIMICROBIAL RESISTANCE (2006).

The healthcare industry's two lines of defense against illness and disease are antibiotics and vaccines. These two defenses are dissimilar, do not operate in the same manner, and at this time, vaccines do not increase the chance of a superbug.[110] Vaccines work when used before bacteria enter the body, as opposed to antibiotics which act after entrance. Vaccinations are presently viewed as one source of hope for reducing the impact of antimicrobial resistant bacteria, and as more vaccinations are created, we can inoculate humans and preempt bacterial infection.[111] Unfortunately, the process to develop new vaccinations is no faster that the process to develop new antibiotics. Second, not all antibiotic-resistant bacteria have mutated genetically to develop pure immunity, however resistance is just as problematic as immunity. For example, some bacteria have developed resistance through the addition of an enzyme known as New Dehli metallo-beta lactamase (NDM-1), which is resistant to "nearly every antibiotic currently in use,"[112] and the antibiotics remaining to address NDM-1 are not without high risk.[113] Antimicrobial-resistant bacteria can pass between humans and animals through physical contact and as food sources, but they have indirect paths as well.

Emerging contaminants are chemicals or materials which represent a "threat to human health or the environment"[114] and include hormones, antibiotics, steroids, nanomaterial, human pharmaceuticals, and other personal care products. In agriculture, emerging contaminants pass to the environment through livestock excrement. Once deposited, the organisms either degrade, attach to the soil, absorb into plant life, move into the groundwater system, or move across land through runoff and drainage.[115] Bacteria are not static organisms, they can move laterally from the same organism to the same organism, and across specie boundaries.[116]

Over 150 different human and veterinary medicines have been found in the environment, including in 80 percent of the streams in the United States.[117] Unfortunately, these same medications have reached our drinking water supply

110. *See* Mishra et al., *supra* note 67, at 597.

111. *Id.*

112. Jessica Kowalik, *The NDM-1 "Superbug": The Next Global Health Crisis?*, THE TRIPLE HELIX ONLINE (May 27, 2013), http://triplehelixblog.com/2013/05/the-ndm-1-superbug-the-next-global-health-crisis/.

113. *See id.* (noting one third of patients treated with the antibiotic colistin have suffered toxic side effects).

114. *Pesticide Registration Manual: Chapter 18 – Other Fed. Or State Agency Requirements*, EPA.GOV, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency#intro (last visited Aug. 21, 2016).

115. Damewood, *supra* note 73.

116. WALSH ET AL., *supra* note 2, at 11.

117. Shah, *supra* note 85 (animal and human medicines have been detected as far away as the Arctic).

and include antibiotics, anti-convulsants, mood stabilizers, sex hormones, heart medicine, estrogen, and tranquilizers.[118]

The impact of the existence of antibiotics in the environment, and their movement through it, has already resulted in large wildlife die-offs and has shown alarming results in case studies.[119] To illustrate, shrimp imported to the United States has tested positive for banned antibiotics, which is concerning because while we import 90 percent of our shrimp supply, the USDA physically inspects less than 2 percent of the imports.[120]

Thinking about this subject for the first time, it may be difficult to accept that personal or animal medications can have such an impact on our environment and water supply. It is true that we do not data to examine the full consequences of emerging contaminants, but federal agencies must make it a priority to study what those impacts will be and develop an action plan because they are expected to increase exponentially as our population increases by two-and-a-half billion people over the next thirty-five years.[121] To be clear, emerging contaminants are not a problem unique to the agricultural industry, they do exist in other forms. For example, researchers have started to study the impact of music festivals on the environment, specifically, the use of illicit narcotics.[122] One example is the Spring Scream music festival, which is well-known for drug abuse and addiction, and researchers wanted to survey the pre- and post-festival environment for signs of any chemical impact.[123] What researchers found was that five specific emerging contaminants: caffeine, acetaminophen, pseudoephedrine, ketamine, and MDMA, all spiked enormously during the concert festival.[124] The widespread occurrence of these emerging contaminants is thought to be a major problem, but as the researchers noted, even though some compounds have already been placed on regulatory prohibited lists, there is still "relatively little information on their

118. *Unsafe Disposal Affects Both You and the Environment*, DISPOSE MY MEDS, http://www.disposemymeds.org/index.php/environmental-impact (last visited Aug. 30, 2016).

119. Shah, *supra* note 85 (India's Gyps vultures, a scavenger animal, were resistant to livestock diseases, but after feeding on the carcasses of cows given the anti-inflammatory diclofenac, 95 percent of its population is extinct, and male minnow and water flea populations crash after coming in contact with certain mixtures of pharmaceuticals).

120. *See* Helena Bottemiller, *ABC Finds Illegal Antibiotics in Imported Shrimp*, FOOD SAFETY NEWS (May 21, 2012), http://www.foodsafetynews.com/2012/05/abc-finds-illegal-antibiotics-in-imported-shrimp/#.V0xaEZErLaE.

121. *See* Jheng-Jie Jiang et al., *Impacts of Emerging Contaminants on Surrounding Aquatic Environment from a Youth Festival*, 49 ENVTL. SCI. & TECH. 792, 792 (2014).

122. *Id.*

123. *Id.*

124. *Id.* at 796.

ecotoxicological effects . . . ."[125]

Studies such as these reveal that what we do in all forms of daily living, consumables production, and recreation has an impact on this planet, even though special interest groups would argue otherwise.[126]

VII. HISTORY OF FOOD AND DRUG REGULATION

Reports of concern over food safety date back as far as the fourth century BC, at which time Theophrastus wrote a ten-volume treatise concerned with the economically-motivated use of adulterants in food.[127] From that time to present, protections have been put in place to provide some food source stability, such as Roman law that provided for permanent exile in some instances of food adulteration, to trade guilds promoting higher food standards as a way of self-regulating and self-policing.[128]

The United States has regulated as well. In 1883, Dr. Harvey Wiley, chief chemist for the U.S. Bureau of Chemistry, conducted a study on live human subjects which, by today's standards, might be prohibited by law.[129] Dr. Wiley conducted research on the effects chemical preservatives have on the human body. His research group consisted of volunteers who willingly ingested chemicals which were, at that time, prevalent in food sources. These chemicals included sulfur, boric acid, and formaldehyde,[130] as well as other poisonous preservatives and dyes.[131] The public unveiling of their presence in food, and the educated examination of their impact on the human body, prompted public contempt and positioned the public against food producers.[132] Shortly thereafter, the Tea Importation Act passed which required customs inspections to prevent adulterated tea from entering the United States marketplace, and the Committee on Food Standards was established to incorporate Dr. Wiley's standards from his earlier research.[133] From this point forward the federal government assumed responsibility for the safety and purity of our food products. Yet, the public

125. *Id.* at 792.

126. *See* Weiss, *supra* note 89.

127. NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 4 (John Wiley & Sons, Inc., 2009).

128. *Id.*

129. *See* Richard Summers, *The Ethics of Human Experimentation*, HARVARD CRIMSON (Apr. 21, 1968), http://www.thecrimson.com/article/1968/4/21/the-ethics-of-human-experimentation-pbebxperimental/.

130. FORTIN, *supra* note 127, at 5.

131. *Id.* at 6.

132. *Id.* at 5.

133. *Id.*

outrage over the fraud, danger, and unsanitary methods, which pervaded the food system revealed in Dr. Wiley's study did not trigger an immediate reaction by the national government. It wasn't until nearly twenty years later when Upton Sinclair's 1905 novel, *The Jungle*, was published, that national concern over food safety was taken seriously enough for the federal government to take action.[134]

The first step Congress took to protect consumers of food and drug occurred in 1906, when Congress passed the Pure Food and Drug Act and the Meat Inspection Act.[135] These two congressional enactments were passed long before Congress established several other well-known consumer-protection federal agencies.[136] The act's establishment followed the creation of the United States Department of Agriculture (USDA) in 1862.[137] The USDA was empowered to employ chemists to conduct chemical analyses of food sources used to feed man and animal.[138] The first Agricultural Commissioner, Isaac Newton, created the Chemical Division of the USDA which, through several evolutions, eventually became the Food and Drug Administration (FDA) in 1930.[139] Ten years later the FDA was moved out of the USDA and, through several evolutions of its own, is now a separate entity within the Department of Health and Human Services.[140]

Soon after the Pure Food and Drug Act passed, the FDA, food industry interest groups, and Congress started pushing for greater control, authority, stringent product quality standards, better safety standards, and fair dealings.[141] Unfortunately, it took a disaster to bring about any actual revision to the act.[142] In 1937, a product called Sulfanilamide was released to treat strep throat and other bacterial diseases.[143] This product contained sulfa and diethylene glycol, and within weeks of its release patients started to die; it is estimated that at least 107 people agonizingly died from this product.[144] Not surprisingly, the very next year

134. *Id.* at 6.

135. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS (Robert C. Clark et al. eds., 3rd ed. 2007).

136. *Id.* (the Pure Foods and Drug Act and the Meat Inspection Act were passed long before the Federal Trade Commission, Environmental Protection Agency, and the Consumer Protection Agency were created).

137. Peter Barton Hutt, *A Historical Introduction*, 45 FOOD DRUG COSM. L. J. 17, 18 (1990).

138. *Id.*

139. *Id.* at 17-18.

140. *Id.*

141. FORTIN, *supra* note 127, at 6.

142. *Id.*

143. *Id.*

144. *Id.*

Congress enacted the Food, Drug, and Cosmetic Act.[145] Several other Congressional statutes were enacted in the years which followed. For example, in 1958, the Food Additives Amendment to the Food, Drug, and Cosmetic Act passed which required food additives to be evaluated for safety.[146] Later the Delaney Clause was enacted to prevent the use of any substance in the food supply found to cause cancer in laboratory testing.[147] Interestingly, though, there seems to be a recurring theme among all of these congressional protections. They all followed a severe threat to public safety. Take for example the Low-Acid Food Processing Regulations, which were passed after a public outbreak of botulism food poisoning, or the Tamper-Resistant Packaging Regulations, which passed after several deaths occurred from cyanide-laced Tylenol capsules.[148] More recently, in 1990, Congress passed the Nutritional Labeling and Education Act, which required nearly all packaged food be required to clearly reveal nutritional information.[149]

This recent act was passed eighty-four years after the first two food protection statutes and for almost the same reason – concern over whether our food is as safe for us as the producers say it is.[150] One difference between these historical changes and what the FDA is doing now is that the regulations issued by the FDA are non-binding.[151] This means there are no penalty provisions for non-compliance, which is concerning on a pragmatic level. The FDA has essentially asked private, for-profit corporations to voluntarily change long-standing practices which, arguably, have not been found to be unsafe, out of a sense of good will.

VIII. CURRENT REGULATION AUTHORITY

The FDA and the United States Department of Agriculture (USDA) split the bulk of the responsibility for regulating our food supply, with several other agencies involved depending on specific foods or activities.[152] The FDA regulates non-meat food, over the counter and prescription medications, seafood, wild game, and eggs in the shell.[153] The USDA is responsible for raw vegetables and fruit, meat, poultry, and the processing and grading of eggs.[154]

The FDA is the oldest consumer protection federal agency in the federal

145. *Id.*
146. *Id.* at 7.
147. *Id.*
148. *Id.* at 8.
149. *Id.*
150. *See id.*
151. *E.g.*, GUIDANCE #152, *supra* note 6, at 2.
152. FORTIN, *supra* note 127, at 23.
153. *Id.*
154. *Id.*

government.[155] It is responsible for securing the safety of many things for which we often take for granted their safety, such as the majority of our food, medications, invasive medical instruments and bodily fluids and tissues, cosmetics and medical and consumer products, among others.[156] An area of control under the FDA which may not immediately spring to the minds of non-agricultural citizens is the regulation and monitoring of all medications used on animals and their feed.[157]

The USDA was established in 1862, at a time when 50 percent of the United States population lived on farms, compared to 2 percent today.[158] The USDA's goal is to expand economic development in agriculture through innovation, provide enough food to meet the global demand, all while striving to preserve natural resources.[159] The USDA works to prevent foodborne illness by in-commerce monitoring of food and works to make sure products are properly packaged and correctly labelled.[160]

The Center for Disease Control and Prevention (CDC) is the national health protection agency, and it works to fight illness and disease, whether those risks originate from home or come from abroad.[161] The CDC began operation in 1946, and its first challenge was to stop the spread of malaria throughout the United States.[162] The CDC increased sanitation and hygiene, developed the process by which the global population attempts to eradicate a specific disease through coordinated vaccination, and researched and developed antibiotics and methods for testing for infectious disease.[163] The CDC has acknowledged the difficulty in containing and treating infectious illness and disease is due, at least in part, to complacency in the early 20th century, a complacency which occurred, ironically,

155. *See FSIS History*, USDA, http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/history/history (Mar. 24, 2015).

156. *Legislation*, FDA, (July 2, 2015) http://www.fda.gov/RegulatoryInformation/Legislation/ (stating the USDA regulates "all food except meat, poultry, and some egg products").

157. *Id.*

158. *USDA Celebrates 150 Years*, USDA, http://www.usda.gov/wps/portal/usda/usdahome?navid=USDA150 (Dec. 31, 2012).

159. *See id.*

160. THOMAS J. VILSACK, USDA, STRATEGIC PLAN FY 2014-2018 28 (2014), http://www.usda.gov/documents/usda-strategic-plan-fy-2014-2018.pdf.

161. *Mission, Role & Pledge*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/about/organization/mission.htm (last updated Apr. 14, 2014).

162. *Our History – Our Story*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/about/history/ourstory.htm (last updated July 22, 2015).

163. *See generally, Mission, Role & Pledge*, *supra* note 161.

because of success in reducing morbidity and mortality.[164] The CDC is presently challenged by new infectious diseases, foodborne illness, bioterrorism, and the reemergence of once-dormant infectious disease now in a drug-resistant form.[165] The CDC works in conjunction with all levels of government to investigate the sources of foodborne disease and conducts research to limit such outbreaks.[166]

The Center for Veterinary Medicine (CVM) is responsible for protecting human and animal health in many ways. For example, CVM is obligated to make sure animal drugs are safe and effective before approving them for use, and if the animals are food-producing, it makes sure the food products made from the treated animals are safe for consumption. CVM is also responsible for monitoring the safety and effectiveness of drugs which have already been approved. One duty of the CVM of particular interest to the animal pharmaceutical problem, is CVM's responsibility to ensure animal feed is safe, sanitary, and properly labeled. This particular duty is an important link in the chain between pharmaceuticals and their ultimate impact by the time the food-producing animal is sent for processing because these pharmaceuticals are often introduced in the animal feed.[167] This is a important duty, and one which requires vigilance. For example, within our own borders, feather meal, a feed additive for chickens, hogs, cattle, and fish, has tested positive for antibiotics specifically banned by the FDA.[168]

The USDA Food Safety and Inspection Service (FSIS) carries out the Federal Meat Inspection Act, and among several other very important roles, it collects and analyzes food products for microbial and chemical contaminants and infectious and toxic agents.[169] The U.S. Environmental Protection Agency polices our drinking water and pesticide used to prevent toxic substances and waste from entering our environment and food supply.[170] The entities covered in this section do not represent a comprehensive list of all of the agencies which have a role in protecting our food supply,[171] however, these agencies are the most relevant to a discussion of the impact of introducing pharmaceutical medications into livestock

164. *See generally, Ten Great Public Health Achievements in the 20th Century*, CTR. FOR DISEASE CONTROL, http://www.cdc.gov/about/history/tengpha.htm (last updated Apr. 26, 2013).

165. *Our History - Our Story*, *supra* note 162.

166. FORTIN, *supra* note 127, at 24-25.

167. GUIDANCE #209, *supra* note 1, at 6.

168. *Researchers Find Evidence of Banned Antibiotics in Poultry Products*, JOHN HOPKINS (Apr. 5, 2012), http://www.jhsph.edu/news/news-releases/2012/feather-meal-clf.html.

169. FORTIN, *supra* note 127, at 25.

170. *Id.*

171. *Id.* at 26 (such as the National Marine Fisheries Service, Alcohol and Tobacco Tax and Trade Bureau, and the U.S. Customs Service).

and subsequently, our food supply, water supply, and environment.

These agencies were deemed by our federal government as critical to the protection of public health and the safety of our food supply, but they are not above scrutiny over very liberal approvals of questionable food sources. For example, even though China has a horrible reputation for food safety and amidst strong opposition in our country, in 2013, the USDA green-lighted four companies located in China to ship meat to the United States.[172] The USDA's approval shifts the burden of protecting citizens from unsafe food sources on to the U.S. Customs Service agents to methodically inspect foods imported from China.[173] The problem is that our customs inspections are very low.[174] For example, in 2009, "the FDA tested only .1 percent of all imported seafood products . . . ."[175] This burden shifting mentality, coupled with low oversight, creates gaping holes in the net within which we hope our federal agencies will catch these risks.

The lack of action could be attributed to many different things. The debate over whether or not antibiotic use actually represents a risk to our livestock population, our food supply, and the citizens of this country, parallels the dynamics of the public debate over whether global warming is real or not. There might be inaction because the general population exhibits apathy on a subject until such time as a problem arises, and then after addressing the problem they return to apathy. Or it is possible this lack of action is due in part because from the time of the creation of the federal statutes and agencies in 1906, until the 1980s, very few law schools offered food and drug law as an academic course, and there were even less academic scholarships on the topic overall.[176] The lack of non-scientific academic and professional scrutiny decreases the opportunity for critical analysis of what these agencies are doing. The effectiveness of the federal congressional or agency action can only be measured by results, or tested by judicial scrutiny. It is impossible however to test agency action that is merely suggested or recommended.

This isn't the first time our federal government was warned of the risks antibiotics pose to public health. The FDA was told by the National Academy of Sciences in 1980, that, even though there was limited data available to properly study the effects these medications could have on human health, "[t]he lack of data

172. Stephanie Strom, *Chinese Chicken Processors are Cleared to Ship to U.S.*, N.Y. TIMES (Aug. 30, 2013), http://www.nytimes.com/2013/08/31/business/chinese-chicken-processors-are-cleared-to-ship-to-us.html?_r=0 (numerous examples of avian influenza outbreaks, salmonella in imported spices, and animal deaths from imported jerky treats).

173. *See* FORTIN, *supra* note 127, at 26.

174. *See* Bottemiller, *supra* note 120.

175. *Id.*

176. HUTT ET AL., *supra* note 135, at v.

linking human illness with subtherapeutic levels of antimicrobials must not be equated with proof that the proposed hazards do not exist."[177] This is a reality many international entities have already accepted, such as the WHO which stated nearly twenty years ago that "all uses of antimicrobials lead to the selection of resistant forms of bacteria,"[178] but the FDA still struggles with how to protect public health without engendering the financial interests of the livestock industry.

Eventually these federal agencies will have to start to read and apply the statutes we have in place already not restrictively but consistent with the original purpose for which they were drafted, which was to impact the "lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-regulation."[179]

One of the primary purposes of these acts is to ensure consumers get the product they pay for and that the product is safe,[180] otherwise the consumer is a victim of an adulterated or misbranded product.[181] Food safety law strictly defines adulterated or misbranded products. Adulteration of a product occurs as the result of "mixing something impure or spurious with something pure or genuine."[182] Unfortunately, at this time, unnecessary use of pharmaceuticals in livestock does not fall within this category. Misbranding products occurs when labeling, marketing, or promotion lead a consumer to believe a food product is something different than it actually is.[183] The FDA and USDA prohibit such acts,[184] but at this time, much like the debate over whether a GMO food should be specifically identified as such, there is no labeling or marketing requirement to let consumers know if their food source was given unnecessary antibiotics.

The Federal Food, Drug and Cosmetic Act regulates more products used in our daily lives than any other statute. The Act specifically defines two of the primary products it covers: food and pharmaceuticals. A food is an "article[] used for food or drink for man or other animals . . . and articles used for components of any other such article."[185] This definition is simple enough to understand, but just as you'll see from the definition of what constitutes a drug, the direct use of pharmaceutical medication in livestock for purposes other than treating present

177. GUIDANCE #209, *supra* note 1, at 7.

178. *Id.* at 8.

179. United States v. Dotterweich, 320 U.S. 277, 280 (1943).

180. *See* PATRICIA A. CURTIS ET AL., GUIDE TO US FOOD LAWS AND REGULATIONS 1, 25 (Patricia A. Curtis ed., Wiley Blackwell 2nd ed. 2013).

181. *Id.* at 24.

182. *Id.*

183. *Id.* at 25.

184. *Id.* at 24.

185. 21 U.S.C. §§ 321(f)(1), (3) (2012).

illness or disease doesn't fit neatly into either definition. A drug is defined as an "article[] intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" and an "article[] (other than food) intended to affect the structure or any function of the body of man or other animals."[186] The use of pharmaceuticals to promote growth or reduce feed requirements per animal doesn't exactly fall within the statutory definition of a regulated drug. Also, the definition is overbroad because prevention can be interpreted as giving an antibiotic to a whole herd if one animal is ill. Imagine if every time a co-worker or fellow student caught a cold, the whole employee or student population was given an antibiotic. Each unnecessary use multiplies the chance that an antimicrobial resistant bacteria can develop.

The closest on-point definition which would apply to the indiscriminate the use of pharmaceutical medication is in the term "food additive." The definition of food additive is "any substance the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" and includes "a new animal drug."[187] This is, not surprisingly, a common method of forcing ingestion of pharmaceuticals.

IX. RECENT FEDERAL REGULATION & OVERSIGHT

Determining whether the FDA and USDA are adequately policing food, pharmaceuticals, and animal livestock depends on your perspective. For example, in 2013, the FDA banned three animal feed drugs which contained arsenic compounds, a component of 101 drugs used to prevent illness, increase feed efficiency, and promote growth in chickens, turkeys and pigs.[188] This looks very much like the FDA exercising its authority, as we hope it would, but in reality the FDA was only reversing its prior approval of those substances and did so based on litigation filed by a food safety advocate.[189] As previously stated in this Note, this is an example of an agency action that is reactive in nature. The Natural Resources Defense Counsel has brought two suits against the FDA for the agency's failure to prohibit the use of non-therapeutic antibiotics in the use of livestock production, based on the FDA's position thirty years ago that the use of antibiotics without restriction will pose health risks.[190] This decade old acknowledgement of the risks

186. *Id.* §§ 321(g)(1)(b)-(c).

187. *Id.* § 321(s)(5).

188. Stephanie Strom, *F.D.A. Bans Three Arsenic Drugs for Poultry and Pig Feed*, N.Y. TIMES (Oct. 1, 2013), http://www.nytimes.com/2013/10/02/business/fda-bans-three-arsenic-drugs-used-in-poultry-and-pig-feeds.html.

189. *Id.*

190. Damewood, *supra* note 73.

antibiotics pose was restated in Guidance #152,[191] and even still the policies and recommendations are only voluntary in nature.[192] The FDA's hollow sense of urgency on these matters follows closely with the trend of federal agencies taking very little action until having their hand forced, and it puts private economic profit above public health.

X. CHALLENGES TO FURTHER REGULATION AND OVERSIGHT

Livestock producers are not required to provide information about the location, number of animals, and type of animals contained in concentrated animal feeding operations (CAFO'S), nor are the producers required to disclose what medications they administer to their livestock population.[193] Another problem that stands against regulation of the industry is that major livestock operations have been fortunate that the FDA and USDA still do not have a complete picture of the extent of extra judicious pharmaceutical use, which is "far more pervasive[]" than our federal agencies realize.[194] Failure to properly survey the industry obviously benefits the livestock and pharmaceutical companies and is directly tied to the FDA's election to weigh the risks to public health under a risk analysis approach. But how do you explain to the cancer patient who is weakened by chemotherapy or the parents of a newborn child who has a vulnerable immune system that the last line of defenses against infection do not work anymore because the risk analysis failed in their case?

The pharmaceutical and agriculture commercial industries are smart, and they mutually benefit from each other's efforts to reduce the public concern over livestock pharmaceutical use. For example, the Animal Health Institute, a trade organization that represents animal pharmaceutical manufacturers, hired a former Deputy Director for the Office of New Animal Drug Evaluation for the FDA, Dr. Richard Carnevale, who was also a former Assistant Deputy Administrator for the Office of Science at the USDA Food Safety & Inspection Service.[195] Dr. Carnevale testified before the Committee on Energy & Commerce regarding the fact rash action on pharmaceuticals and livestock should be avoided because the global

191. GUIDANCE #152, *supra* note 6, at 3.

192. GUIDANCE #209, *supra* note 1, at 3.

193. Damewood, *supra* note 73.

194. Grow, *supra* note 68; *see also* GUIDANCE #152, *supra* note 6, at 7.

195. *Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture: Testimony Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 77-229 (July 14, 2010) (testimony of Dr. Richard Carnevale, Vice President of Scientific, Regulatory, and International Affairs for Animal Health Institute), http://congressional.proquest.com/congressional/result/congressional/pqpdcoumentview?accountid=10555&groupid=105686&pgId=9876c75a-5fcd-4d31-9c99-0fa68d771a5b.

demand for food requires protection of food supply and efficiency, and because the perceived risk of antimicrobial resistance is greater than any actual risk.[196] He also characterized the FDA's guidances as "recent initiatives" which demonstrate the FDA's power and "authority to regulate."[197] He is clearly referring to the fact the FDA has not yet acted and gives deference to their election to not regulate at this time by suggesting that the private interests will carry out their wishes.[198] These industries also have external support as well. Dr. Hurd, a senior epidemiologist for Iowa State University's College of Veterinary Medicine and former USDA Deputy Under Secretary for Food Safety, does not believe that the use of antibiotics in livestock poses any risk, much less a significant one.[199] Dr. Hurd finds no evidence to support the transmission of antibiotic-resistant bacteria, or that illnesses between humans and livestock are very weak.[200] Dr. Hurd criticized as being very small a sample size of under 300 pigs that were studied to determine transmission capabilities of MRSA between livestock and humans - a study that did produce evidence of such transmission capabilities - by implying that specific animal-to-human transmissions of antibiotic-resistant bacteria are rare.[201]

The problem is Dr. Hurd's statement presumed the study was flawed solely because of a small sample size, without acknowledging that the size of the pool from which the studies were drawn is not a conclusive error, and in reality the sample could be representative of the larger population. To demonstrate sound objectivity, Dr. Hurd should make such a criticism only after comparable studies show differing results. To put Dr. Hurd's immediate dismissal of the study's relevance in proper perspective, Dr. Wiley's sample size of twelve men was miniature when compared to that of even the study of 200 pigs, yet Dr. Wiley's study of the "Poison Squad" prompted a national push for more information about how adulterants came to be in the food supply and what harm they posed.[202] In fact, the most interesting aspect of comparing Dr. Hurd's denouncement of a study of fewer than 300 pigs to Dr. Wiley's study of twelve men is that the country and its representatives took the concern seriously enough to enact the Pure Food and Drug Act of 1906.[203] However, a hundred years later our federal agencies issue

196. *Id.*

197. Chris Raines, *A Response to the CBS News Segment About Antibiotics*, PENN STATE (Feb. 16, 2010), http://meatisneat.wordpress.com/2010/02/16/a-response-to-the-cbs-news-segment-about-antibiotics.

198. *See id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. *See* CURTIS ET AL., *supra* note 180, at 23, 28-29, 31.

203. *Id.* at 23, 29, 31.

only non-binding recommendations.[204]

Just as Dr. Wiley had a healthy dose of skepticism for the food market in the early 1900s, Robert Lawrence, Professor of Medicine at Johns Hopkins School of Medicine and Professor of Environmental Health at Bloomberg School of Public Health, also flatly disagrees with the blanket assumptions that animal pharmaceuticals are safe.[205] Dr. Lawrence states that even though "[t]he pharmaceutical and animal industries" refuse to accept reality, "[t]he science is so clear that the political pressure on the FDA" from interest groups will not prevent the push for legislative changes to limit "routine, subtherapeutic antibiotic use."[206]

XI. WHAT ARE OUT OPTIONS?

If we assume for the purposes of this particular argument that there is a problem, the question then becomes, what do we do about it? Overreaction at this point could put our food supply at risk from an illness outbreak if we remove the use of antibiotics in their entirety, but continued use at the current rate could jeopardize our food supply but for a different reason. And, admittedly, personal misuse and professional overprescribing are not helping the matter, but we must remember the human market for pharmaceuticals is less than 20 percent. This section discusses what options are possible at this point, although many more may be revealed if more attention is given to this problem.

A. Make the Guidances Binding and Heavily Laden with Sanctions for Violations

The guides drafted by the FDA do lay out an initial framework upon which actual regulations and penalties could be developed. The guides require the following: all new drugs undergo a heightened screening process, drug manufacturers change their labeling practices to restrict all sensitive medications to veterinarian administration, antibiotics cannot be used for production purposes, and the list of restricted medications be revisited as often as necessary.[207] All this requires is to take those initial materials and redraft-them to reduce ambiguity and loop-holes and then to assign penalties or sanctions for violations of them, willful or not.

204. *E.g.*, GUIDANCE #209, *supra* note 1, at 2.

205. Helena Bottemiller, *Health Advocates: Science on Antibiotic Resistance is Clear*, FOOD SAFETY NEWS (Mar. 13, 2012), http://www.foodsafetynews.com/2012/03/health-advocates-science-on-antibiotic-resistance-is-clear/#.VH9LoTHF-Ds.

206. *Id.*

207. Raines, *supra* note 197.

b.. Precautionary Principle

The Precautionary Principle mandates that when there is a possible threat to human health or the environment, precautionary measures should be taken even if a specific cause and effect relationship has not been proven.[208] The premise behind the precautionary principle is that the burden and risk should be shouldered by the "proponent of the activity, rather than the public . . . ."[209] Dr. Wiley himself, as founding father of the FDA, felt the burden of proving a product's safety should fall on the manufacturers who want to introduce a product into the general population, not the other way around.[210] This principle may be the best approach when faced with problems which are subtler and less quantifiable.[211] The reason being that while engineering-type studies have guided us since the late seventies, they haven't done a very good job predicting the ecological and health impact of new technologies.[212] This is where the precautionary principle really starts to look attractive because in time of scientific uncertainty, such as whether using antibiotics indiscriminately in livestock increases the chance of antibiotic resistant bacteria and a corresponding superbug - the principle requires action be taken to prevent harm to the environment and public health.[213] In a twist of irony, based on the precautionary principle, the European Union has banned American beef treated with hormones, and yet because there is not yet a documented health risk from eating hormone-treated beef, the World Trade Organization declared the ban illegal.[214] This declaration is based on the precautionary principle's chief opponent, risk analysis[215]- the very analysis used in Guidance #152, and the very guidance which allowed the approval of important antibiotics over the objection of the advisory panel.

What is most interesting about this struggle is how I am reminded of my first year torts professor who, when discussing risk analysis, told us the question is not whether we, as an industrial and technological society, have the ability to render all products safe because theoretically we do, the true question is whether we, as a collective society, want to bear that cost. The precautionary principle also sounds

208. *Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK, http://www.sehn.org/precaution.html (last visited Aug. 21, 2016).

209. *Id.*

210. Carol Lewis, *The "Poison Squad" and the Advent of Food and Drug Regulation*, USFDA CONSUMER MAG. 1 (Nov. – Dec. 2002), http://esq.h-cdn.co/assets/cm/15/06/54d3fdf754244_-_21_PoisonSquadFDA.pdf.

211. Michael Pollan, *Precautionary Principle*, N.Y. TIMES (Dec. 9, 2001), http://www.nytimes.com/2001/12/09/magazine/09PRINCIPLE.html.

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

very much like the Court's sentiment in the case of *United States v. Nova Scotia Food Products Corporation*, where the defendants were charged with preparing whitefish in contravention to FDA guidelines regarding the time, temperature, and salinity of the cooking conditions. [216] In *Nova Scotia Food Products*, the FDA sought to enforce a statute designed to prevent the growth of Clostridium botulinum, which was posted years earlier in the form of a guideline, much like the FDA's present guides, and when those guidelines were given the effect of law, the Defendant's challenged their constitutionality.[217] In *Nova Scotia Food Products*, the Court stated that legislative acts which impact public health should not be read restrictively but read consistent with Congress's purpose behind the act - to protect public health.[218] The precautionary principle combined with the judicial interpretation of the analyses which should be employed when reading a statute designed to protect public health all lead to one conclusion: the FDA, USDA, pharmaceutical industry, and veterinary industry must work together to restrict the use of antibiotics in livestock to the lowest level possible, at least until such time as further research could be done to determine the extent of the potential risk to human health these pharmaceuticals posed.[219] This is what the spirit of the guidances propose but fail to deliver.

c.. Research

Research efforts studying the impact of pharmaceutical drugs on the potential to trigger an antibiotic-resistant superbug are emerging at this point, but while the impacts of several chemical compounds used on livestock are known, there are many more substances which have not been tested.[220] The research efforts are also hampered because some compounds can affect bacteria and animals at a lower level than is protected under current regulations.[221] This is important to remember because while one particular instance of a compound may not constitute a threat to the environment or bacteria, the aggregated effect can be considerable. Take for example the fact that oral contraceptives, through normal excretory functions, find their way into our environment and waterways.[222] The same applies

216. Raines, *supra* note 197.

217. *See* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 243 (2d Cir. 1977).

218. *Id.* at 246.

219. Alistair B.A. Boxall, *The Environmental Side Effects of Medication*, 5 EMBO REP. 1110, 1110 (2004), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1299201/pdf/5-400307.pdf.

220. *Id.*

221. *Id.*

222. *Id.*

to veterinary medicines used on livestock.[223] Depending on the method by which the medication is introduced to the animal, it can reach the environment immediately in a less diluted fashion or later through the excretory process.[224] The point is that these risks must be assessed on a global scale, not just whether an individual case could lead to an illness or worse.[225]

Before we can identify other possible alternatives to antibiotics, we must first determine why and how they are being overused, define the unintended consequences of that overuse, and then identify alternatives.[226] Some of the questions researchers should consider in determining whether animal pharmaceuticals are within safe limits are: (1) what are the substances of which we do and don't know the health risks; (2) whether our methods of examining the risks pharmaceuticals are adequate; (3) whether the methods of examining these substances, and the data derived from these studies are relevant in the real world; and (4) if these substances increase the risk of antibacterial resistance?[227] The answer to these questions may lead us to the conclusion that the federal oversight on this issue must be increased, and we should begin to intensify our efforts to identify adequate alternatives to pharmaceuticals.

d. Alternatives to Antibiotics

As previously stated, vaccines have helped eradicate some of the deadliest infection agents in history, and they are proving useful in the battle against drug-resistant bacteria.[228] Thus, there are no cases of vaccine-resistant bacteria; therefore, their use can reduce the accumulation of drug-resistant bacteria by decreasing the use of antibiotics and correspondingly increasing the use of vaccines.[229] Also, vaccines have success in reducing reliance upon antibiotics by increasing herd immunity, a strategy which is especially beneficial in socioeconomically depressed areas.[230]

The most obvious approach to slow this risk of creating antibiotic-resistant bacteria is prudent and judicious use of the antibiotics we are currently using. The difficulty in this approach however, is defining appropriate guidelines which satisfy public health needs, protect of our food supply, and protect human health against the development of a superbug. To do this properly, however, we must

223. *See* Raines, *supra* note 197.
224. Boxall, *supra* note 219.
225. GUIDANCE #209, *supra* note 1, at 4.
226. *See* Raines, *supra* note 197.
227. Boxall, *supra* note 219.
228. Mishra et al., *supra* note 67, at 596.
229. *See id.*
230. *Id.* at 597.

take out of the hands of farm operators the authority and ability to administer these medications and place it where it has belonged all along, in the hands of state-licensed veterinarians.[231] Even that has its risks though because veterinarians can exercise discretion on use purposes, and absent of some clear evidence that a particular use is causing harm, they can use antibiotics in whatever manner they see fit.[232] Bear in mind that veterinarians have the proper diagnostic equipment to identify what specific bacteria is present in the majority of animal illnesses[233] and are subject to the scrutiny of a separate licensing body.

e. Judicious Use

Because pharmaceuticals, when used properly, are designed to target a specific bacterial infection, other natural compounds that similarly inhibit bacteria could be developed, such as bacteriophages, bacteriocins, and predatory bacteria.[234] This approach is attractive because it limits the scope of any particular treatment to the specific bacteria involved, thereby, eliminating any chance of over-treating bacteria which aren't present.[235] Also, this narrow scope of use is to actually treat a particular illness, opposed to uses to prevent illness.[236]

Narrowing the scope of the animals treated is a judicious and prudent strategy to reduce the overall dependency on pharmaceuticals as a whole.[237] Simply lowering the load on livestock by 40 percent would give researchers breathing room and an opportunity to search for long-range solutions. Unfortunately, the federal agencies who should lead this charge have drafted guidances and then stepped aside leaving the decisions up to the agricultural and pharmaceutical industries, both of which have a vested economic interest in taking a wait-and-see approach.

XII. CONCLUSION

We must be optimistic the FDA will seek out further research on this question and act to transform the guidance into enforceable regulations that restrict the use of pharmaceuticals. The federal agencies should impose severe penalties on violators who attempt to skirt the restrictions and on those who liberally use antibiotics without a demonstrated need. The birth of the FDA and USDA were

231. *See* Heather K. Allen et al., *Finding Alternatives to Antibiotics*, 1323 ANNALS N.Y. ACAD. SCI. 91, 93 (2014), http://onlinelibrary.wiley.com/doi/10.1111/nyas.12468/pdf.

232. Weiss, *supra* note 89.

233. Allen et al., *supra* note 231, at 97.

234. *Id.* at 91, 93.

235. *Id.*

236. *Id.*

237. GUIDANCE #213, *supra* note 6, at 7.

the federal government's response to social, cultural, political, and economic changes in the food and drug marketplace.[238] We must push these agencies to stop responding only after a crisis and to adopt a proactive approach of identifying what risk pharmaceuticals pose to our food supply and human health and establish clear policies, procedures, discipline, and sanctions for their improper use. If we do not hold the FDA accountable to carry out its duty to protect the citizens of this country, we may look back one day in the future and say, "[t]hen, too, the law proved not wholly adequate to meet the problems posed by changing economic and social conditions."[239] The growing antibiotic resistance problem involves many different stakeholders, yet with an 80 percent market share, the agricultural industry must help lead the charge to reduce reliance on antibiotics, to do otherwise jeopardizes our food supply, its target market, or both.[240] The remaining allies are impacted by narrower interests. The pharmaceutical industry itself is almost a $400 billion dollar industry, and one that is projected to grow as drug manufacturers attempt to account for a negative gain in human health products by increasing their market share in animal health products.[241] Because bacteria has existed for billions of years and has developed an ability to cope under harsh and toxic conditions, resistance capabilities are difficult to predict, and there is no one single drug which can protect against resistant bacteria.[242] Much discussion has taken place on the fear the superbug could lead to unstoppable human illness, but if you stop and pause for just a moment you will realize that our feed and dairy livestock are just as vulnerable. Even the accepted use of antibiotics, for illness, infection, and pain relief, can create a situation in which immunity can develop. If such bacteria does develop, our national food supply is in jeopardy because just like humans would have difficulty combating an antibiotic-resistant superbug, so would our livestock.

The FDA has already expressed some acknowledgement that their guides may not achieve the goal of reducing the non-judicious use of antibiotics, and the concept of seeking voluntary compliance is unreliable. The FDA has also hinted that regulatory action might be necessary if the private interests don't voluntarily adopt the principles detailed in the guidances. Instead of waiting for that compliance to occur, the FDA should voluntarily choose to take action now. The

238. *FSIS History*, *supra* note 155.

239. Bernard Schwartz, *The Administrative Agency in Historical Perspective*, 36 IND. L.J. 263, 263 (1961).

240. McKenna, *supra* note 76.

241. *US Pharmaceutical Market Value will Approach $550 Billion by 2020, says GlabalData*, GLOBALDATA (Mar. 17, 2015) http://healthcare.globaldata.com/media-center/press-release/pharmaceuticals/us-pharmaceutical-market-value-will-approach-550-billion-by-2020-says-glbaldata..

242. WALSH ET AL., *supra* note 2.

research over the past fifty years has consistently identified as risky the extra-judicious use of pharmaceuticals in humans and animals, even if the direct link between humans and animals is difficult to establish. Comparatively, other countries have already taken precautionary steps to limit any danger that his unquantifiable risk might pose, while the United States waits. The United States federal government should join with their international peers and push back on the private economic interests and force companies to prove the safety of their products instead of allowing the agricultural and pharmaceutical industries to force us to prove that their practices are unsafe.