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## Student Note

# Agribusiness and Antibiotics: A Market-Based Solution

ALLISON PARR\*

### INTRODUCTION

Justifiable concerns about the welfare of animals raised for food are on the rise in the United States.<sup>1</sup> The model of modern agribusiness aims at maximizing cost-efficiency, which has led to the overuse of antibiotics in food animals for growth promotion and disease prevention purposes. This overuse inextricably diminishes animal welfare and puts human health at alarming risk.

In Part I, I explain the relationship between modern agribusiness and the use of antibiotics and explore some of the ways in which the commodification of farm animals has necessitated the industry's reliance on antibiotics for disease prevention. In addition, I show how these antibiotics practices have made disease more dangerous on factory farms. In Part II, I analyze recent regulatory approaches by the U.S. Food and Drug Administration (FDA), and examine *NRDC v. FDA*, FDA's Guidance for Industry, and a recent citizen petition urging FDA to withdraw approval for the use of medically-important antibiotics in food animals. In Part III, I argue for a market-based approach as an alternative to regulation and discuss how the phenomenon of agency capture and the current political shift towards deregulation may impact the promulgation of rules addressing the overuse of antibiotics in food animals. Further, I critique other market-based approaches that have enjoyed moderate success. Finally, I propose an alternative model—a third-party certification system that prioritizes animal welfare.

I acknowledge that many third-party certification systems have attempted to curb antibiotic use on farms and improve animal welfare. However, my idea differs in three major ways. First, my model reaches a compromise between industry and advocacy groups, and advances standards that are both workable for industry and protect animal welfare. Second, my model prohibits the routine use of both human

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<sup>1</sup> See Email from Bob Meadow and Joshua Ulibarri, Lake Research Partners, to Am. Soc'y for the Prevention of Cruelty to Animals 1 (June 29, 2016), [https://www.aspc.org/sites/default/files/publicmemo\\_aspca\\_labeling\\_fi\\_rev1\\_0629716.pdf](https://www.aspc.org/sites/default/files/publicmemo_aspca_labeling_fi_rev1_0629716.pdf) [<https://perma.cc/NU5Z-WBWJ>] (noting that a recent survey of American consumers indicated that “74% of consumers say they are paying more attention to the labels that pertain to how an animal was raised than they were five years ago”).

and animal antibiotics for growth promotion and disease prevention, and vitiate arguments over the meaning of “antibiotic.” Third, my model prioritizes animal welfare by permitting the use of antibiotics in response to illness in individual animals.

## I. THE MODERN FACTORY FARM

Approximately 10 billion farm animals are raised for food annually in the United States alone.<sup>2</sup> This number includes animals bred for meat, milk, and eggs.<sup>3</sup> The majority of farm animals in the United States are confined in concentrated animal feeding operations (CAFOs) or factory farms.<sup>4</sup> The Environmental Protection Agency (EPA) defines CAFOs in part as “lot[s] or facilit[ies] where animals are kept, confined and fed or maintained for 45 or more days per year . . .” and “that contain at least a certain number of animals, or have a number of animals that fall within a range and have waste materials that come into contact with the water supply.”<sup>5</sup>

As with most industry in the United States, animal agriculture has become more mechanized and efficient over time. The price-fixing emergency measures of the Agricultural Adjustment Act provided incentives for practitioners of animal husbandry to invest in other aspects of the industry, including feed, hatcheries, and slaughterhouses.<sup>6</sup> This vertical integration led to the development of agricultural giants that are now household names.<sup>7</sup> Since the 1960s, animal agriculture has incorporated practices that have decreased the amount of time it takes to grow animals to a size appropriate for slaughter, and as a result, food production has increased.<sup>8</sup>

<sup>2</sup> AM. SOC’Y FOR THE PREVENTION OF CRUELTY TO ANIMALS, FARM ANIMALS NEED OUR HELP, <http://www.aspc.org/animal-cruelty/farm-animal-welfare> [<https://perma.cc/3JWU-VXST>] (last visited Nov. 7, 2017) [hereinafter *Farm Animal Welfare*].

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* (stating that “[o]ver 99% of farm animals in the U.S. are raised in factory farms”); Ronnie Cummins, *How Factory Farming Contributes to Global Warming*, ECOWATCH (Jan. 21, 2013), <http://www.ecowatch.com/how-factory-farming-contributes-to-global-warming-1881690535.html> [<https://perma.cc/LY4S-BWG9>] (“[N]early 95 percent of the meat, dairy and eggs sold in the U.S. come from CAFOs.”).

<sup>5</sup> See CARRIE HRIBAR, NAT’L ASSOC. OF LOCAL BD. OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES I (2010), [https://www.cdc.gov/nceh/ehs/docs/understanding\\_cafos\\_nalboh.pdf](https://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf) [<https://perma.cc/CN8F-A4VS>] (internal citation omitted); U.S. DEP’T OF AGRIC. & U.S. ENVT’L PROT. AGENCY, UNIFIED NATIONAL STRATEGY FOR ANIMAL FEEDING OPERATIONS I (Mar. 9, 1999), <https://www.epa.gov/sites/production/files/2015-10/documents/finafost.pdf> [<https://perma.cc/78LP-PUV2>].

<sup>6</sup> CHRISTOPHER LEONARD, THE MEAT RACKET: THE SECRET TAKEOVER OF AMERICA’S FOOD BUSINESS 57–62 (2014) (discussing the Agricultural Adjustment Act and Tyson’s successful expansion).

<sup>7</sup> See e.g. Dale Keiger, *Farmacology: Johns Hopkins Researchers Are Investigating a Troubling Potential Source of Resistant Pathogens: The American Farm*, Johns Hopkins Magazine, June 2009, <http://pages.jh.edu/jhumag/0609web/farm.html> [<https://perma.cc/6A37-363R>] (discussing Perdue’s use of vertical integration in transforming from a small broiler chicken company to a “very large company with control of a significant share of the market.”).

<sup>8</sup> HRIBAR, *supra* note 5, at 1; THE HUMANE SOC’Y OF THE U.S., AN HSUS REPORT: THE WELFARE OF ANIMALS IN THE CHICKEN INDUSTRY I (Dec. 2013), [http://www.humanesociety.org/assets/pdfs/farm/welfare\\_broiler.pdf](http://www.humanesociety.org/assets/pdfs/farm/welfare_broiler.pdf) [<https://perma.cc/XS36-2QWB>] [hereinafter *The Welfare of Animals in the*

Agribusiness, looking to cut costs and inefficiencies, holds farm animals in extreme confinement. The industry justifies such confinement by arguing that it serves the purpose of efficiency by permitting farmers to raise more animals on less land,<sup>9</sup> and by creating an environment that is easier for farm workers to control.<sup>10</sup> Greater efficiency reduces costs, but the undesirable effects of extreme confinement present countervailing problems for industry.

The industrialization of animal agriculture has led to terrible living conditions for farm animals. The conditions of confinement for farm animals are directly related to the development and rapid spread of infections.<sup>11</sup> The confinement itself leads to injury, psychological distress, and disease. The physical and psychological health of farm animals is impacted further by other common practices on factory farms, including painful physical modifications.

### A. *Psychological Effects of Confinement*

Although industry standards vary depending on the type of animal,<sup>12</sup> most farm animals are given too little space to engage in natural behaviors,<sup>13</sup> which can result in abnormal behavior, including increased aggression.<sup>14,15</sup> For example, the U.S. pork industry<sup>16</sup> houses pregnant pigs in so-called “gestation crates” throughout their 112–

*Chicken Industry*] (noting that daily growth rates for broiler chickens have increased by more than 300 percent in the last 50 years).

<sup>9</sup> HRIBAR, *supra* note 5, at 1.

<sup>10</sup> See David Jackson & Gary Marx, *Pork Producers Defend Gestation Crates, but Consumers Demand Change*, CHI. TRIB. (Aug. 3, 2016), <http://www.chicagotribune.com/news/watchdog/pork/ct-pig-farms-gestation-crates-met-20160802-story.html> [<https://perma.cc/4KZY-EAVB>]; Neb. Farmer Goes to Mkt., *Translating Food Technology: Why Would Pig Farmers Insist on Using ‘Gestation Crates?’*, <http://nebraska.farmergoestomarket.com/index.php/recent-stories/13-technology/69-translating-food-technology-why-would-pig-farmers-insist-on-using-gestation-crates> [<https://perma.cc/39M8-QKMN>] (last visited Apr. 23, 2017).

<sup>11</sup> PEW COMM’N ON INDUS. FARM ANIMAL PROD., PUTTING MEAT ON THE TABLE: INDUSTRIAL FARM ANIMAL PRODUCTION IN AMERICA 33 (Apr. 29, 2008), <http://www.pewtrusts.org/~media/legacy/uploadedfiles/peg/publications/report/pcifapfinalpdf.pdf> [<https://perma.cc/KLS6-L4M5>]; see also Amanda Belanger, *A Holistic Solution for Antibiotic Resistance: Phasing Out Factory Farms in Order to Protect Human Health*, 11 J. HEALTH & BIOMED. L. 145, 151–57 (2015) (internal citations omitted).

<sup>12</sup> Belanger, *supra* note 11, at 151.

<sup>13</sup> Gaverick Matheny & Cheryl Leahy, *Farm-Animal Welfare, Legislation, and Trade*, 70 LAW & CONTEMP. PROBS. 325, 329 (Winter 2007) (“Most farm animals cannot engage in natural behaviors such as foraging, perching, nesting, rooting, and mating, and many are not even able to turn around or fully stretch their limbs.”).

<sup>14</sup> See THE HUMANE SOC’Y OF THE U.S., AN HSUS REPORT: THE WELFARE OF COWS IN THE DAIRY INDUSTRY 5, <http://www.humanesociety.org/assets/pdfs/farm/hsus-the-welfare-of-cows-in-the-dairy-industry.pdf> [<https://perma.cc/ATA7-5DKF>] [hereinafter *The Welfare of Cows in the Dairy Industry*] (noting that production cycles on factory farms may lead to aggressive behavior in dairy cows) (last visited Nov. 7, 2017).

<sup>15</sup> See THE HUMANE SOC’Y OF THE U.S., AN HSUS REPORT: WELFARE ISSUES WITH GESTATION CRATES FOR PREGNANT SOWS 6 (Feb. 2013), <http://www.humanesociety.org/assets/pdfs/farm/HSUS-Report-on-Gestation-Crates-for-Pregnant-Sows.pdf> [<https://perma.cc/L7XL-NP8B>] [hereinafter *Welfare Issues with Gestation Crates*] (discussing scientific studies showing that pigs housed in gestation crates become more aggressive than pigs in group housing).

<sup>16</sup> *But see* Farm Sanctuary, *State Legislation*, <https://www.farmsanctuary.org/get-involved/federal-legislation/state-legislation/> [<https://perma.cc/FFJ5-HKZT>] (“As of early 2016, nine states no longer allow or are phasing out the use of gestation crates.”) (last visited Nov. 7, 2017).

115 day pregnancies.<sup>17</sup> Gestation crates, composed of metal bars, are so small that pregnant sows are unable to turn around while captive.<sup>18</sup> The cognitive sophistication of pigs is well documented,<sup>19</sup> and therefore the use of such extreme confinement poses grave welfare concerns.<sup>20</sup> Pigs subjected to such confinement have been observed exhibiting abnormal behavior indicative of psychological distress, including “incessantly chewing the air, biting cage bars, and pressing on water bottles.”<sup>21</sup> Dairy cows have also been observed as becoming more aggressive due to their housing on factory farms. In types of housing where cows are not tethered but are tightly packed, the cows are forced to crowd around food sources, which can lead to increased aggression.<sup>22</sup> In housing where they are tethered and not given access to social interaction, cows’ plasma cortisol levels increase, which may lead to a condition that serves as a defense-mechanism by allowing cows to adapt to and withstand greater pain.<sup>23</sup> Many farm animals express aggression by violently biting or pecking the other animals.<sup>24</sup> Industry response to animal aggression has been to alter animals’ body parts to reduce the physical effects.<sup>25</sup>

### B. Physical Modifications and Their Effects

Farm animals are subjected to traumatizing and painful physical modifications, often without pain medication or anesthesia.<sup>26</sup> One common instance of a physical modification in animal agriculture is the docking of dairy cows’ tails. Studies have indicated that cows whose tails have been docked may experience sensations similar to the human phenomenon of “phantom limb.”<sup>27</sup> In some instances, the procedure may cause infection, gangrene, and tetanus.<sup>28</sup> Another common instance of physical modification on the modern factory farm is the beak-trimming of chickens raised for slaughter (known as “broilers”).<sup>29</sup> The process of beak-trimming uses a hot blade to

<sup>17</sup> *Welfare Issues with Gestation Crates*, *supra* note 15, at 1.

<sup>18</sup> *Id.*

<sup>19</sup> See generally Lori Marino & Christina M. Colvin, *Thinking Pigs: A Comparative Review of Cognition, Emotion, and Personality in Sus domesticus*, INT’L J. COMP. PSYCHOL. 28, 2015, [http://animalstudiesrepository.org/cgi/viewcontent.cgi?article=1042&context=acwp\\_asie](http://animalstudiesrepository.org/cgi/viewcontent.cgi?article=1042&context=acwp_asie) [<https://perma.cc/UDW3-AMD6>].

<sup>20</sup> *Welfare Issues with Gestation Crates*, *supra* note 15, at 1.

<sup>21</sup> PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, *The Pork Industry*, <http://www.peta.org/issues/animals-used-for-food/factory-farming/pigs/pork-industry/> [<https://perma.cc/G2L5-JZXS>] (last visited Nov. 7, 2017).

<sup>22</sup> *The Welfare of Cows in the Dairy Industry*, *supra* note 14.

<sup>23</sup> *Id.* (internal citation omitted).

<sup>24</sup> Anastasia S. Stathopoulos, *You Are What Your Food Eats: How Regulation of Factory Farm Conditions Could Improve Human Health and Animal Welfare Alike*, 13 N.Y.U. J. LEGIS. & PUB. POL’Y 407, 413 (2010).

<sup>25</sup> *Id.*

<sup>26</sup> PEW COMM’N ON INDUS. FARM ANIMAL PROD., *supra* note 11.

<sup>27</sup> THE HUMANE SOC’Y OF THE U.S., AN HSUS REPORT: WELFARE ISSUES WITH THE TAIL DOCKING OF COWS IN THE DAIRY INDUSTRY 3 (Oct. 2012), <http://www.humanesociety.org/assets/pdfs/farm/HSUS-Report-on-Tail-Docking-of-Dairy-Cows.pdf> [<https://perma.cc/B8CR-4XNC>] (internal citations omitted).

<sup>28</sup> *Id.*

<sup>29</sup> *The Welfare of Animals in the Chicken Industry*, *supra* note 8, at 1, 7 (internal citations omitted).



remove between one-third and one-half of the beak tip, which can result in “tissue damage and nerve injury, including open wounds and bleeding, resulting in inflammation, as well as acute and possibly chronic pain when a neuroma (a tangled nerve mass) forms in the healed stump of the beak.”<sup>30</sup>

### C. Confinement and Disease

Farm animals suffer significant injuries due to their confinement. The vast majority of egg-laying hens in the United States are confined to battery cages that hold multiple birds. These cages are stacked atop of one another, and allot each hen approximately 67 square inches of space.<sup>31</sup> Hens held in battery cages are more susceptible to diseases, such as osteoporosis and “cage layer fatigue.”<sup>32</sup> These ailments, combined with rough handling and poor design of battery cages, can contribute to injury and even cause death.<sup>33</sup> Hens in battery cages are also predisposed to Fatty Liver Hemorrhagic Syndrome, which causes massive internal bleeding and death.<sup>34</sup> For pigs in gestation crates, conditions are no better. Pregnant sows in gestation crates suffer injuries due to their constant physical contact with the bars of their enclosures and slatted floors.<sup>35</sup> Further, this confinement “has also been found to excessively cause damage to joints and lameness.”<sup>36</sup> Pigs in gestation crates also suffer from reduced muscle and bone strength, as well as urinary tract infections.<sup>37</sup>

### D. Spread of Disease

The conditions of farm animal confinement make outbreaks of disease on factory farms inevitable. Animals on factory farms suffer psychologically and physically, as discussed above, which weakens their immune systems and makes them more susceptible to illness.<sup>38</sup> Farm animals are often denied veterinary care, leading to

<sup>30</sup> *Id.* at 7.

<sup>31</sup> THE HUMANE SOCIETY OF THE U.S., AN HSUS REPORT: THE WELFARE OF ANIMALS IN THE EGG INDUSTRY 1, [http://www.humanesociety.org/assets/pdfs/farm/welfare\\_egg.pdf](http://www.humanesociety.org/assets/pdfs/farm/welfare_egg.pdf) [<https://perma.cc/6YRH-M26M>] (last visited Nov. 7, 2017) [hereinafter *The Welfare of Animals in the Egg Industry*] (internal citations omitted); Jonathan Ward, *From Battery Cages to Barns: A Cost-Benefit Analysis of a National Standard for Cage-Free Egg Production*, 34 U. Mass. Amherst Sch. Pub. Pol’y Capstones 1, 7, (2014) [http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1031&context=cppa\\_capstones](http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1031&context=cppa_capstones) [<https://perma.cc/9RXC-UMLS>]; see also United Egg Prod., *Animal Husbandry Guidelines for U.S. Egg Laying Flocks 2016 Edition*, 1, 21, <http://uepcertified.com/wp-content/uploads/2015/08/2016-UEP-Animal-Welfare-Guidelines-2016-Cage-Free-Edit-002.pdf> [<https://perma.cc/9PZP-56Q>] (last visited Nov. 7, 2017) (stating that “[s]pace allowance should be in the range of 67 to 86 square inches of usable space per bird”).

<sup>32</sup> *The Welfare of Animals in the Egg Industry*, *supra* note 31, at 5–7 (internal citations omitted).

<sup>33</sup> *Id.* (internal citations omitted).

<sup>34</sup> *Id.* at 5 (internal citations omitted).

<sup>35</sup> *Welfare Issues with Gestation Crates*, *supra* note 15, at 3.

<sup>36</sup> *Id.* at 4.

<sup>37</sup> *Id.*

<sup>38</sup> Belanger, *supra* note 11, at 154 (internal citation omitted); Lewis W. Smith, *Helping Industry Ensure Animal Well-Being*, USDA, AGRIC. RES. MAGAZINE, Mar. 2005, at 2, <https://agresearchmag.ars.usda.gov/ar/archive/2005/mar/form0305.pdf> (stating that “when livestock are unduly stressed, they undergo physiological changes that can increase their chances of catching and spreading diseases.”).

unresolved and untreated infections.<sup>39</sup> When animals become sick, confinement exacerbates their condition,<sup>40</sup> making widespread infection more likely.<sup>41</sup> Further, the spread of disease is increased by the unsanitary conditions the animals endure.<sup>42</sup>

Disease can also be spread through populations of farm animals via their feed. To reduce costs,<sup>43</sup> agribusiness recycles rendered animal byproducts and certain manure back into animal feed.<sup>44</sup> For example, farmers include chicken manure (called “chicken litter” by the industry) in feed for cows.<sup>45</sup> Recycling animal byproduct for farm animal feed has been associated with outbreaks of bovine spongiform encephalopathy (also known as “mad cow disease”).<sup>46</sup> With respect to an outbreak of bovine spongiform encephalopathy in Great Britain, FDA has even noted that “[t]here is strong evidence and general agreement that the outbreak was amplified by feeding meat-and-bone meal prepared from cattle to young calves.”<sup>47</sup> Responding to rising concerns about bovine spongiform encephalopathy, FDA issued regulations that prohibit feeding most animal tissue to ruminants.<sup>48</sup> However, the outbreaks of bovine spongiform encephalopathy have demonstrated the public health nightmares that can start on the modern factory farm. Indeed, the U.S. Department of Agriculture has stated that bovine spongiform encephalopathy “presents a public health concern because occurrences of [a variant Creutzfeldt-Jakob Disease] in

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<sup>39</sup> See PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, *Cows Forced to Live in Their Own Waste at Dairy Farm*, <http://investigations.peta.org/north-carolina-dairy-farm/> (last visited Apr. 3, 2017) (describing injury and illness documented in video investigation on a dairy farm); *Eating with Care*, CHOOSEVEG.COM, <http://www.chooseveg.in/animals-in> [<https://perma.cc/VR2A-57HK>] (last visited Apr. 19, 2018).

<sup>40</sup> Stathopoulos, *supra* note 24, at 416.

<sup>41</sup> HRIBAR, *supra* note 5, at 9.

<sup>42</sup> Michael Greger, *The Human/Animal Interface: Emergence and Resurgence of Zoonotic Infectious Diseases*, 33 CRITICAL REVIEWS MICROBIOLOGY 243, 258 (2007) (“The amount of manure produced by high-throughput animal husbandry creates a challenge to the maintenance of hygienic standards . . . . The disease potential of high-density production has been compared to that of cities in the Middle Ages where squalid overcrowding facilitated the sewage-born transmission of cholera and typhoid . . . .”) (internal citation omitted).

<sup>43</sup> Warren Kester, *Big on By-products*, BEEF MAG., Dec. 1, 1997, [http://www.beefmagazine.com/mag/beef\\_big\\_byproducts](http://www.beefmagazine.com/mag/beef_big_byproducts).

<sup>44</sup> *Animal By-Products Statement*, ANIMAL WELFARE APPROVED, <https://animalwelfareapproved.us/standards/animal-byproducts/> (last visited Apr. 24, 2017).

<sup>45</sup> Brad Jacobsen, *We Feed Cows Chicken Poop*, MOTHER JONES (Dec. 19, 2013), <http://www.motherjones.com/environment/2013/12/we-feed-cows-chicken-poop> (discussing industry practice of feeding “chicken litter” to cattle).

<sup>46</sup> FDA, BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) QUESTIONS AND ANSWERS, <https://www.fda.gov/biologicsbloodvaccines/safetyavailability/ucm111482.htm> (last visited Apr. 3, 2017) [hereinafter BSE QUESTIONS AND ANSWERS].

<sup>47</sup> *Id.*

<sup>48</sup> See 21 C.F.R. §§ 589.2000–2001 (2018); FDA, FEED BAN ENHANCEMENT: IMPLEMENTATION QUESTIONS AND ANSWERS, [https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/ucm114453.htm#The\\_2008\\_Regulation](https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/ucm114453.htm#The_2008_Regulation) (last visited Nov. 7, 2017); *Leftovers for Livestock: A Legal Guide for Using Food Scraps as Animal Feed*, CTR. FOR HEALTH LAW & POLICY INNOVATION, at 4 (Aug. 2016), [http://www.chlpi.org/wp-content/uploads/2013/12/Leftovers-for-Livestock\\_A-Legal-Guide\\_August-2016.pdf](http://www.chlpi.org/wp-content/uploads/2013/12/Leftovers-for-Livestock_A-Legal-Guide_August-2016.pdf).

humans have been linked to the consumption of food containing ingredients derived from [bovine spongiform encephalopathy]-infected cattle.”<sup>49</sup>

### *E. Antibiotics in Animal Feed and Effects on Human Health*

FDA reported that in 2015, 15.58 million kilograms (34.34 million pounds) of antibiotics approved for use in food-producing animals were sold in the United States.<sup>50</sup> The report also indicated that 62 percent of the domestic sales of all antibiotics approved for use in food-producing animals were considered “medically important,” as determined by FDA’s Guidance For Industry #152 (GFI No. 152).<sup>51</sup> Further, the report noted a 2 percent increase in domestic sales and distribution of medically important antibiotics from 2014 through 2015, and a 26 percent increase from 2009 through 2015.<sup>52</sup> It is estimated that nearly 80 percent of all the antibiotics distributed and sold in the United States are fed to food animals.<sup>53</sup>

In the absence of acute illness, antibiotics are administered to food animals for purposes of growth promotion and disease prevention.<sup>54</sup> Scientific literature has noted that animal agriculture’s use of antibiotics in animal feed is strongly correlated with the development of antibiotic-resistant bacteria.<sup>55</sup> This bacteria can spread to humans via consumption of animals whose flesh or skin contains antibiotic-resistant bacteria, as indicated by recent *E. coli* and *Salmonella* outbreaks.<sup>56</sup> Humans may also become exposed to antibiotic-resistant bacteria simply by living in an area where a lot of industrial animal operations are located.<sup>57</sup> Additionally, it can spread to humans by way of consumption of or contact with water contaminated by animal waste from factory farms.<sup>58</sup> Antibiotic-resistant bacteria can also spread to humans

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<sup>49</sup> USDA, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, ABOUT BSE, (last modified Feb. 13, 2018), [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/sa\\_bse/ct\\_about\\_bse](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/sa_bse/ct_about_bse).

<sup>50</sup> FDA, 2015 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 17 (Dec. 2016), <https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM534243.pdf> [hereinafter 2015 SUMMARY REPORT ON ANTIMICROBIALS].

<sup>51</sup> *Id.* at 6.

<sup>52</sup> *Id.*

<sup>53</sup> Belanger, *supra* note 11, at 145 (stating that 80 percent of antimicrobials sold in the United States are fed to farmed animals) (internal citation omitted); Wayne Pacelle, *Factory Farms Spawn Immense Suffering, and Also Immensely Dangerous Superbugs?*, A HUMANE NATION (May 27, 2016), <http://blog.humanesociety.org/wayne/2016/05/factory-farms-spawn-dangerous-superbugs.html> (concluding that “[m]ore than 70 percent of medically important antibiotics are sold each year for use in animal agriculture.”).

<sup>54</sup> PEW COMM’N ON INDUS. FARM ANIMAL PROD., *supra* note 11, at 15.

<sup>55</sup> Susan A. Schneider, *Beyond the Food We Eat: Animal Drugs in Livestock Production*, 25 DUKE ENVTL. L. & POL’Y F. 227, 243 (2015) (citations omitted); Lauren Orrico, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combating Antibiotic-Resistant Bacteria*, 27 J.L. & HEALTH 259, 265–66 (2014).

<sup>56</sup> Orrico, *supra* note 55, at 266 (citation omitted); Bruce Friedrich & Stefanie Wilson, *Coming Home to Roost: How the Chicken Industry Hurts Chickens, Humans, and the Environment*, 22 ANIMAL L. 103, 153–54 (noting that fecal contamination contributes to human consumption of antibiotic-resistant bacteria on food animals).

<sup>57</sup> *Exposure to Pig Farms and Manure Fertilizers Associated with MRSA Infections*, JOHNS HOPKINS BLOOMBERG SCHOOL PUB. HEALTH, (Sept. 16, 2013), <http://www.jhsph.edu/news/news-releases/2013/casey-schwartz-mrsa.html>.

<sup>58</sup> Orrico, *supra* note 55, at 266.

by way of farmworkers who come into contact with the “air, dust, animal waste, or insects and rodents that pass through [farming] facilities.”<sup>59</sup> Further, the Centers for Disease Control and Prevention (CDC) estimated in 2013 that more than two million people in the United States become sick with antibiotic-resistance infections annually, and that 23,000 of those infected die as a result of those infections each year.<sup>60</sup>

Public health researchers began paying attention to the nexus of antibiotic resistance and the use of antibiotics on farms in 1969, when the Report of the Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine was published in Great Britain.<sup>61</sup> The report concluded that “the administration of antibiotics to farm livestock, particularly at sub-therapeutic levels, poses certain hazards to human and animal health[.]”<sup>62</sup> Further, its authors recommended that only antibiotics not used to treat human disease or antibiotics that do not lead to resistance of human antibiotics be used for growth promotion purposes in farm animals.<sup>63</sup> The European Union has since banned the use of antibiotics for growth promotion purposes on farms.<sup>64</sup> However, the United States has been slower to adopt regulations that address the issue at all.

## II. FDA INACTION ON ANTIBIOTIC RESISTANCE

The Federal Food, Drug, and Cosmetic Act (FDCA)<sup>65</sup> grants FDA the authority regulate animal drugs and feed via drug sponsors.<sup>66</sup> This provision permits “FDA to withdraw or suspend approval of a generic product if [FDA] finds that the reference drug was withdrawn for reasons of safety or effectiveness.”<sup>67</sup> However, FDA’s response to the growing problem of antibiotic resistance has failed to curb animal agriculture’s reliance on antibiotics for growth promotion and disease prevention purposes.

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<sup>59</sup> *Citizen Petition from Natural Resources Defense Council*, Docket No. FDA-2016-P-2737 (Sept. 13, 2016), at 17, <https://www.regulations.gov/document?D=FDA-2016-P-2737-0001> [hereinafter *Citizen Petition from Natural Resources Defense Council*] (citations omitted); see also PEW COMM’N ON INDUS. FARM ANIMAL PROD., *supra* note 11, at 16 (citations omitted).

<sup>60</sup> CDC, ANTIBIOTIC THREATS IN THE UNITED STATES 6, 13 (2013), <https://www.cdc.gov/drug-resistance/threat-report-2013/pdf/ar-threats-2013-508.pdf#page=36>.

<sup>61</sup> Schneider, *supra* note 55, at 242.

<sup>62</sup> *Id.* (quoting M.M. Swann, et al., *Report of the Joint Committee on the use of Antibiotics in Animal Husbandry and Veterinary Medicine*, HMSO, London (1969)).

<sup>63</sup> Carlton Gyles, *The Growing Problem of Antimicrobial Resistance*, 52 CANADA VETERINARY J. 817, 817 (Aug. 2011), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135024/pdf/cvj\\_08\\_817.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135024/pdf/cvj_08_817.pdf).

<sup>64</sup> Meghan F. Davis & Lainie Rutkow, *Regulatory Strategies to Combat Antimicrobial Resistance of Animal Origin: Recommendations for a Science-Based U.S. Approach*, 25 TUL. ENVTL. L.J. 327, 367–68 (Summer 2012); EUROPEAN COMMISSION, BAN ON ANTIBIOTICS AS GROWTH PROMOTERS IN ANIMAL FEED ENTERS INTO EFFECT (Dec. 22, 2005), [http://europa.eu/rapid/press-release\\_IP-05-1687\\_en.htm](http://europa.eu/rapid/press-release_IP-05-1687_en.htm).

<sup>65</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301–399 (2018).

<sup>66</sup> 21 U.S.C.A. §§ 342, 360.

<sup>67</sup> Lisa Heinzerling, *The FDA’s Continuing Incapacity on Livestock Antibiotics*, 33 STAN. ENVTL. L.J. 325, 335 (citing 21 U.S.C. § 360(b)(2)(G) (2012)).

*A. Natural Resources Defense Council, Inc. v. FDA*

In 1977, FDA issued notices announcing its intent to withdraw approval for the use of penicillin and tetracyclines for growth promotion purposes in livestock production.<sup>68</sup> FDA noted that subtherapeutic use of antibiotics in livestock production had not been proven safe.<sup>69</sup> Although many entities immediately requested hearings, the FDA Commissioner never scheduled them.<sup>70</sup> Instead, the agency engaged in further research on the risk of feeding subtherapeutic levels of antibiotics to food animals.<sup>71</sup> In 2011, FDA withdrew its notices on penicillin and tetracyclines.<sup>72</sup> The Natural Resources Defense Council (NRDC) and numerous other groups sued the agency, arguing that under the FDCA, FDA had an obligation to withdraw approval of subtherapeutic uses of penicillin and tetracyclines in livestock production after finding that it was not proven safe.<sup>73</sup> Plaintiffs also argued that FDA's decision not to hold withdrawal proceedings was arbitrary and capricious and therefore violated the agency's obligations under the Administrative Procedure Act (APA).<sup>74</sup>

Although the district court granted summary judgment for the plaintiffs, the Second Circuit Court of Appeals reversed.<sup>75</sup> With respect to the plaintiffs' claim under the FDCA, the court took issue with the plaintiffs' interpretation of the statute.<sup>76</sup> The Second Circuit observed that the plaintiffs' interpretation of the statute would require FDA to make two findings that a drug is not proven to be safe before withdrawing approval for that drug.<sup>77</sup> The court accepted the government's interpretation of the statute, which places the holding of a hearing at the discretion of the agency and mandates withdrawing approval for a drug only if the agency finds, after the drug manufacturer's hearing, that the drug is not proven to be safe.<sup>78</sup>

With respect to the plaintiffs' claim under the APA, the court found that FDA's decision not to hold withdrawal proceedings was not arbitrary and capricious. The court reasoned that because it had accepted the government's interpretation of the FDCA, namely that FDA had the discretion to hold a hearing from which it could make a finding mandating the withdrawal of approval for certain drugs, it could not find arbitrary and capricious the agency's decision to approach the issue of

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<sup>68</sup> Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 154 (2d Cir. 2014).

<sup>69</sup> Nat. Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012).

<sup>70</sup> *Id.* at 134.

<sup>71</sup> *Id.* at 135.

<sup>72</sup> *Id.* at 136–37.

<sup>73</sup> *Id.* at 137.

<sup>74</sup> Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 153 (2d Cir. 2014) (citing the Administrative Procedure Act, 5 U.S.C. § 706(2) (2012)).

<sup>75</sup> Nat. Res. Def. Council, Inc., 760 F.3d at 163, 176.

<sup>76</sup> *Id.* at 163, 176. The pertinent language in the statute is, "The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . ." and the parties disagreed about what action of the Secretary is mandatory. *Id.*, at 158.

<sup>77</sup> *Id.* at 159.

<sup>78</sup> *Id.* at 158–59.

antibiotics in animal feed through a voluntary program rather than contentious withdrawal proceedings.<sup>79</sup>

Numerous other articles have explored the deficiencies in the *NRDC v. FDA* case.<sup>80</sup> One scholar argued that the appellate court's interpretation of the FDCA led to a poor policy outcome in contravention of the agency's purpose.<sup>81</sup> Another scholar commented that FDA's assertion that the FDCA would require it to hold a formal hearing before withdrawing approval of a drug is baseless.<sup>82</sup> In any case, it seems clear that unless Congress amends this provision of the FDCA, citizens will be unable to challenge FDA's inaction as effectively as they have challenged the inaction of the Environmental Protection Agency.<sup>83</sup>

### B. *Voluntary Guidance for Industry*

Instead of imposing a binding rule on animal agriculture, FDA decided to address the problem of antibiotic resistance by rolling out voluntary guidance for industry,<sup>84</sup> a type of interpretive rule.<sup>85</sup> GFI No. 209 outlines two recommended principles for judicious use of medically important antimicrobial drugs.<sup>86</sup> The first principle is that “[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health[,]” and the second is that “[t]he use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.”<sup>87</sup> GFI No. 213 clarifies the principles outlined in GFI No. 209, providing that affected industries should inform FDA within three months of the guidance being issued of their intentions to make the suggested changes, and that FDA expects the changes can be implemented within three years.<sup>88</sup>

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<sup>79</sup> *Id.* at 174–75.

<sup>80</sup> See generally *Administrative Law—Reviewability—Second Circuit Upholds FDA’s Decision Not to Withdraw Approval from Potentially Dangerous Animal Drugs*.—Natural Resources Defense Council, Inc. v. FDA, 760 F.3d 151 (2d Cir. 2014), 128 HARV. L. REV. 1011, 1011–18 (2015); Diana R. H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA*, 90 IND. L. J. 1047, 1047–89 (Summer 2015); Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007 (2013).

<sup>81</sup> Kristina Youmaran, *Murky Intentions: The Decision to Allow Subtherapeutic Use of Antibiotics in Animal Feed*, 22 J. ENVTL. & SUSTAINABILITY L. 157, 171–72 (2015) (internal citations omitted).

<sup>82</sup> Heinzerling, *supra* note 80, at 1019 (internal citations omitted).

<sup>83</sup> Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 173 (2d Cir. 2014) (distinguishing the instant case from *Massachusetts v. EPA*, 549 U.S. 497 (2007)).

<sup>84</sup> FDA, GUIDANCE FOR INDUSTRY NO. 209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS (April 13, 2012), <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf> [hereinafter GFI No. 209]; FDA, GUIDANCE FOR INDUSTRY NO. 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 NO. 209 (Dec. 2013), <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> [hereinafter GFI No. 213].

<sup>85</sup> Orrico, *supra* note 55, at 277–78 (internal citation omitted).

<sup>86</sup> GFI No. 209, *supra* note 84, at 20.

<sup>87</sup> *Id.* at 21–22.

<sup>88</sup> GFI No. 213, *supra* note 84, at 5, 9.

Importantly, GFI No. 213 created a carve-out for antibiotics used to prevent disease.<sup>89</sup> GFI No. 213 gives veterinarians great discretion in determining whether using antimicrobials for disease prevention may constitute judicious use,<sup>90</sup> providing a long list of factors that veterinarians may consider in making this determination.<sup>91</sup> FDA has identified a number of issues that may increase animals' susceptibility to bacterial disease, including "environmental factors (such as temperature extremes and inadequate ventilation), host factors (such as age, nutrition, genetics, immune status), and other factors (such as stress of animal transport)."<sup>92</sup> All of these risk factors listed are standard practice on the modern factory farm, from poor ventilation to stressful conditions. This expansive list of risk factors is troubling, since its inclusion in GFI No. 213 indicates that industry can and will continue its antibiotic practices on factory farms by merely modifying its justification for using those medicines.<sup>93</sup> Further, GFI No. 213 provides no incentive for industry to improve living conditions for animals, which would have a positive effect on their health and render constant medication unnecessary.<sup>94</sup>

Even looking past the exemption for disease prevention, it is unclear whether addressing antibiotics used for the purpose of growth promotion is significant. FDA's unwillingness to define "subtherapeutic" and "nontherapeutic" have led to confusion about where one should draw a distinction between growth promotion and disease prevention purposes.<sup>95</sup> In addition, since FDA's data does not draw this distinction,<sup>96</sup> the exact amount of antibiotics used for growth promotion on farms is unknown,<sup>97</sup> although the NRDC and other sources have suggested that this number may account for 10–15 percent of antibiotics used by agribusiness.<sup>98</sup>

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<sup>89</sup> Sarah R. Haag, *FDA Industry Guidance Targeting Antibiotics Used in Livestock Will Not Result in Judicious Use or Reduction in Antibiotic-Resistant Bacteria*, 26 *FORDHAM ENVTL. L. REV.* 313, 340 (Winter 2015).

<sup>90</sup> Lisa Heinzerling, *The FDA's Continuing Incapacity on Livestock Antibiotics*, 33 *STAN. ENVTL. L.J.* 325, 331 (2014) (internal citations omitted).

<sup>91</sup> GFI No. 213, *supra* note 84, at 7.

<sup>92</sup> GFI No. 213, *supra* note 84, at 7.

<sup>93</sup> Heinzerling, *supra* note 90, at 340 (internal citations omitted); Humane Society of the United States, Comment Letter on FDA Notice to Establish the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (Mar. 13, 2017), at 2, <https://www.regulations.gov/document?D=FDA-2016-D-2635-0251> [<https://perma.cc/T8XW-UX32>] [hereinafter Humane Society Comment Letter] (internal citations omitted).

<sup>94</sup> See generally Humane Society Comment Letter, *supra* note 93 (suggesting that FDA should require industry to develop animal husbandry practices to address conditions, confinement, feed and nutrition, waste handling, ventilation, lighting, transportation, in order to help decrease the need to antimicrobial use).

<sup>95</sup> Heinzerling, *supra* note 90, at 339 (citing GFI No. 209, at 4 n.3); Nathalie Prescott, *Antibiotics: It's What's for Dinner*, 28 *GEO. ENVTL. L. REV.* 307, 321 (Winter 2016); Belanger, *supra* note 11, at 174.

<sup>96</sup> 2015 SUMMARY REPORT ON ANTIMICROBIALS, *supra* note 50, at 8 ("[T]he sales and distribution data submitted by animal drug sponsors and summarized in this report are not indicative of how these antimicrobial drugs were actually used in animals (e.g., in what species and for what indications).").

<sup>97</sup> Beth Hoffman, *New FDA 'Rules' Not Likely to Reduce Antibiotic Use on Farm*, *FORBES* (Dec. 13, 2013), <https://www.forbes.com/sites/bethhoffman/2013/12/13/new-fda-rules-will-not-reduce-antibiotic-use-on-farm/#4dd0f58878fe> [<https://perma.cc/5HCF-T53Z>] (noting that the Animal Health Institute estimates that 10–15 percent of antibiotic use on farms is for growth promotion).

<sup>98</sup> *Citizen Petition from Natural Resources Defense Council*, *supra* note 59, at 6 (citing Hoffman, *supra* note 97).

Another major issue with FDA guidance is that it imposes no legally-binding obligations. Both documents state plainly on each page that they “Contain[] Nonbinding Recommendations.”<sup>99</sup> Closer examination of the guidance reveals that “FDA’s plan involves not just one, but three, different layers of voluntary activity[,]” by sponsors of non-generic drugs, sponsors of generic drugs, and sponsors of combination drugs.<sup>100</sup> Although FDA has reported a positive response from drug sponsors since the rollout of the voluntary guidance,<sup>101</sup> one scholar has noted that perhaps this is a valid reason to be suspicious of the guidance.<sup>102</sup>

### C. Citizen Petition Revisited

In September 2016, the NRDC and other advocacy groups filed a citizen petition with FDA, urging the agency to withdraw approval for the growth promotion or disease prevention uses of certain medically important antibiotics in animals.<sup>103</sup> The petition argues that FDA has a duty to withdraw approval for drugs that are not shown to be safe for human health,<sup>104</sup> which is the same argument that the NRDC made in *NRDC v. FDA*.<sup>105</sup> However, the petition squarely addresses the prior case, arguing that the facts on the ground have changed and would not presently support a finding that the agency’s preference for a voluntary approach is not arbitrary and capricious.<sup>106</sup> Further, the petition argues that FDA’s voluntary approach has not resulted in the “immediate and significant reductions in animal antibiotic use” that the Second Circuit believed was achievable.<sup>107</sup> In addition, the petition also encourages FDA to use informal procedures to address withdrawal proceedings, arguing that the FDCA does not require formal hearings to institute withdrawal proceedings.<sup>108</sup>

Although the NRDC has obviously taken steps to cure some of the issues that it had in the Second Circuit case, it is unlikely that the petition will spur agency action. In March 2017, the agency issued a letter in response to the petition, notifying the petitioners that the agency requires additional time to issue a final response, which it will do “after completing the analyses of all the legal and policy issues related to this petition.”<sup>109</sup> As of October 31, 2017, the agency has yet to issue a final response.<sup>110</sup>

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<sup>99</sup> Prescott, *supra* note 95, at 321 (internal citations omitted); *see also* GFI No. 209; GFI No. 213.

<sup>100</sup> 2015 SUMMARY REPORT ON ANTIMICROBIALS, *supra* note 50, at 333 (citing GFI No. 213, at 15).

<sup>101</sup> *Id.* at 334 (internal citation omitted); Hoffman, *supra* note 97 (discussing the positive response from Zoetis, “one of the world’s largest animal health providers.”).

<sup>102</sup> Haag, *supra* note 89, at 338.

<sup>103</sup> *Citizen Petition from Natural Resources Defense Council*, *supra* note 59, at 4 (specifically addressing macrolides, lincosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides).

<sup>104</sup> *Id.* at 8.

<sup>105</sup> Nat. Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 141 (S.D.N.Y. 2012).

<sup>106</sup> *Citizen Petition from Natural Resources Defense Council*, *supra* note 59, at 24.

<sup>107</sup> *Id.* (citing Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 174 (2d Cir. 2014)).

<sup>108</sup> *Citizen Petition from Natural Resources Defense Council*, *supra* note 59, at 38–39 (internal citations omitted).

<sup>109</sup> *Interim Response Letter from CVM to Natural Resources Defense Council*, Docket No. FDA-2016-P-2737 (March 10, 2017), <https://www.regulations.gov/document?D=FDA-2016-P-2737-0125>.

<sup>110</sup> Docket No. FDA-2016-P-2737, <https://www.regulations.gov/docket?D=FDA-2016-P-2737> (last visited Nov. 7, 2017).



### III. ARGUMENT FOR A MARKET-BASED APPROACH

It seems unlikely that FDA will take further action in the near future to reduce antibiotic resistance. As the agency argued in *NRDC v. FDA*, withdrawal of approval for certain antibiotics in animal feed involves time-consuming and expensive administrative procedures.<sup>111</sup> Further, because of the *NRDC v. FDA* decision, courts will be unable to compel FDA to engage in rulemaking without Congress amending the citizen petition provisions of the FDCA.<sup>112</sup> There are also political realities that will likely prevent additional regulation from FDA. One such reality is the phenomenon of “agency capture.” In addition, Executive Order 13771 (the so-called “Two-for-One” Regulation Executive Order) indicates that the United States is transitioning from a centralized regulatory regime to a more free-market approach. In light of this, it would be wise to consider a market-based approach for combating antibiotic resistance. A market-based approach that relies on and responds to consumer choice rather than a public regulatory regime would effectively be insulated from a political climate that is quickly becoming hostile to regulation.

#### A. Agency Capture and FDA

Agency capture has the potential to impede future regulations addressing the issue of antibiotics administered to farm animals. The phrase “agency capture” refers to “the phenomenon where regulated interests exert such an influence over their regulators that they essentially control the agencies, at the expense of the intended beneficiaries of the regulatory system.”<sup>113</sup> One explanation for this phenomenon is the “revolving door”<sup>114</sup> or “actual flow of individuals”<sup>115</sup> between administrative agencies and industry, which relies on the assumption that employees of administrative agencies intend to work in the private sector within the industry they are currently regulating, and, in order to preserve those professional relationships, they will be more likely to advocate for positions that favor the regulated industry.<sup>116</sup> Another explanation for the phenomenon is that industry may find it easier to exert influence over the few high-level officials at regulatory agencies rather than a majority of representatives and senators.<sup>117</sup> Yet another explanation is that an agency is at the mercy of the industry it regulates with respect to whether its regulatory decisions become major political issues.<sup>118</sup> An industry group has both the resources

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<sup>111</sup>*Nat. Res. Def. Council, Inc.*, 760 F.3d at 156.

<sup>112</sup>Haag, *supra* note 89, at 326 (internal citation omitted).

<sup>113</sup>Winters, *supra* note 80, at 1081.

<sup>114</sup>William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1590–91 (Dec. 2007).

<sup>115</sup>Winters, *supra* note 80, at 1081.

<sup>116</sup>Wentong Zheng, *The Revolving Door*, 90 NOTRE DAME L. REV. 1265, 1267 (2015), <http://scholarship.law.ufl.edu/cgi/viewcontent.cgi?article=1686&context=facultypub>.

<sup>117</sup>However, a logical counter-argument posits that an agency employee who intends to seek employment in the regulated industry may make herself a formidable opponent of the industry to demonstrate her expertise, and to convince an employer that it would be advantageous to hire her away from the agency.

<sup>118</sup>Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1566 (1992).

<sup>119</sup>Roger Noll, *The Economics and Politics of Regulation*, 57 VA. L. REV. 1016, 1030 (1971).

and the motivation to raise a ruckus when an agency acts contrary to its interests, while the public lacks both.<sup>120</sup>

FDA is no stranger to agency capture.<sup>121</sup> Indeed, there have been “mounting charges of regulatory capture” launched at the agency.<sup>122</sup> One scholar observed that politically-motivated budget cuts can lead to agency capture, specifically noting that “FDA has received moderate funding increases, but only to accelerate its process for approving new drugs, leaving its other functions, such as protecting the food supply, short of money.”<sup>123</sup> Others have criticized perceived “political meddling in the drug-approval process” at FDA.<sup>124</sup> Another legal academic has called into question FDA’s legitimacy, arguing that regulatory capture has led to over-politicization of the agency,<sup>125</sup> which has undermined its scientific credibility.<sup>126</sup>

Further, industry’s capture of FDA may explain why the agency has failed to adequately address agribusiness’s problematic use of antibiotics. FDA’s long period of inaction following its issuance of the 1977 notices to withdraw approval for the use of tetracyclines and penicillin for growth promotion purposes in livestock can be attributed to the industry’s control of the agency.<sup>127</sup> In addition, the agency’s implementation of voluntary recommendations, as opposed to binding regulations, indicate that FDA’s primary concern was with how regulations might affect private interests, including “veterinarians, the animal feed industry, and animal producers,” rather than the public good.<sup>128</sup> Therefore, it is more than reasonable to conclude that this pattern of inaction or inadequate action with respect to administration of antibiotics to farm animals will continue as a result of agency capture.

### B. *Two-for-One Executive Order*

On his tenth day in office, President Trump signed Executive Order 13771 (EO), which places additional requirements on administrative agencies in their rulemaking function. The regulation requires agencies to: (1) identify at least two existing regulations to be repealed for each regulation it proposes or promulgates, and (2) ensure that the total incremental cost of new and repealed regulations is \$0 or less for fiscal year 2017.<sup>129</sup> Public Citizen, along with other advocacy groups, has challenged the EO in court, alleging that it exceeds the president’s constitutional authority, that

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<sup>120</sup>*Id.*

<sup>121</sup>Brian Daluiso, “*Is the Meat Here Safe?*” *How Strict Liability for Retailers Can Lead to Safer Meat*, 92 B.U. L. REV. 1081, 1098–99 (May 2012) (discussing how agency capture at FDA led to regulations that favor the interests of agribusiness).

<sup>122</sup>Christine H. Kim, *The Case for Preemption of Prescription Drug Failure-to-Warn Claims*, 62 FOOD & DRUG L.J. 399, 401 (2007) (internal citations omitted).

<sup>123</sup>Sidney A. Shapiro, *The Complexity of Regulatory Capture: Diagnosis, Causality, and Remediation*, 17 R.W.U. L.R. 101, 111 (2012) (internal citation omitted).

<sup>124</sup>Alastair J.J. Wood, Jeffrey M. Drazen & Michael F. Greene, *A Sad Day for Science at the FDA*, 353 N. ENGL. J. MED. 1197, 1197 (2005).

<sup>125</sup>James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 98 CORNELL L. R. 939, 940, 978 (2008).

<sup>126</sup>*Id.* at 977.

<sup>127</sup>Winters, *supra* note 80, at 1081–82 (internal citations omitted).

<sup>128</sup>Haag, *supra* note 89, at 340 (internal citations omitted).

<sup>129</sup>Exec. Order No. 13771, 82 Fed. Reg. 9339 (Feb. 3, 2017).

it violates the president's duty under the Take Care Clause of the Constitution, and that it would require agencies to issue regulations that are arbitrary and capricious, in violation of the APA.<sup>130</sup> Public Citizen's complaint argues, in part, that the EO would require arbitrary and capricious agency action because it "directs agencies to disregard the benefits of new and existing rules—including benefits to consumers, to workers, to people exposed to pollution, and to the economy—even when the benefits far exceed costs."<sup>131</sup>

Given FDA's prior unwillingness to promulgate legally-binding regulations to curb the use of antibiotics on farms, it is reasonable to assume that FDA will not take further action now. In addition, the fate of FDA's current guidance for industry (GFI Nos. 152, 209, 213) may be unclear as well. Section 4 of the EO provides that the term "regulation" or "rule" refers to "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy . . ."<sup>132</sup> Under this definition, it seems that interpretive rules and policy statements would be considered "regulations" and be subject to the requirements of the EO. Therefore, it is possible that FDA could even "repeal" its guidance for industry on antibiotic use in animals in favor of promulgating regulations on an issue of higher priority for the agency.

### C. *Moving to the Marketplace*

Given the significant downsides to FDA's current approach and the unlikelihood of FDA imposing binding regulations on industry, it would be wise for public health and animal welfare advocates to employ the use of market-based approaches in advancing their agendas. To some extent, this is already happening with respect to antibiotics in animal feed.<sup>133</sup> However, the success of these campaigns has been limited.

#### I. *Consumers Union Campaign*

A promising example of a market-based approach in this context is an antibiotic-free campaign spearheaded by the Consumers Union and the NRDC, which has focused on pushing retailers to demand meat raised without antibiotics from their suppliers.<sup>134</sup> Two scholars who recently wrote about a similar Consumers Union campaign noted that targeting retailers specifically was a strategic approach because retailers are particularly susceptible to pressure by advocacy organizations, because these organizations have the potential to inflict great reputational harm in an era when consumers care about the ways products they buy impact the world.<sup>135</sup>

Another key aspect of the Consumers Union campaign strategy is that it provides education to consumers. This educational element is important to keep consumers

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<sup>130</sup>Complaint at 3–4, *Public Citizen, Inc., et al. v. Trump, et al.*, No. 1:17-cv-00253 (D.D.C. filed Feb. 2, 2017), ECF No. 1.

<sup>131</sup>*Id.* at 4.

<sup>132</sup>82 Fed. Reg. at 9339, 9340.

<sup>133</sup>See generally Zdravka Tzankova & Lauren Gwin, *Surf-N-Turf, But The Sustainable Kind? The Limits and Potential of Market-Driven Regulation in Food Production*, 5 SEATTLE J. ENVTL. L. 303 (2015).

<sup>134</sup>*Id.* at 317–18.

<sup>135</sup>*Id.* at 318–20.

informed and engaged in the issue, and to maintain the campaign's leverage of potential reputational harm. Accordingly, the NRDC recently made a report available on its website that identified retailers and producers whom the NRDC identified were "at the forefront of this market change."<sup>136</sup> Similarly, Consumers Union published an industry scorecard, which grades popular fast food restaurants based on their public statements and responses to surveys.<sup>137</sup> According to Consumers Union's scorecard, "nine out of 25 companies surveyed (up from five in 2015) had adopted publicly-available policies that phase out routine antibiotics use in some or all of their meat and poultry supply . . ."<sup>138</sup> However, the scorecard also stated that the chain restaurant industry had "made little progress" with respect to setting policies related to other animal proteins, including turkey, pork, and beef.<sup>139</sup>

## 2. *Chicken Producer Reactions*

Perdue began eliminating antibiotics from its broiler chicken feed in 2007,<sup>140</sup> and announced that as of February 2016, 67 percent of its chickens were raised without the use of any antibiotics.<sup>141</sup> In October 2016, Perdue Farms announced that it had eliminated the use of all antibiotics in 95 percent of its chickens.<sup>142</sup> According to Perdue, the remaining 5 percent accounts for chickens who get sick,<sup>143</sup> and "[t]hese chickens are removed from the no-antibiotics-ever program and sold through other channels."<sup>144</sup> Notably, Perdue also claims that its "No Antibiotics Ever" policy refers not only to human antibiotics, but also to ionophores, or animal antibiotics.<sup>145</sup> Tyson Foods has taken a less ambitious approach, announcing in 2015 that it would attempt to eliminate human antibiotics from its broiler chicken feed by September 2017.<sup>146</sup>

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<sup>136</sup>*Meat Raised Without the Routine Use of Antibiotics is Going Mainstream*, NRDC (June 2016), at 2, [https://www.nrdc.org/sites/default/files/antibiotic-free-meats-cs\\_0.pdf](https://www.nrdc.org/sites/default/files/antibiotic-free-meats-cs_0.pdf) [hereinafter *Meat Raised Without the Routine Use of Antibiotics is Going Mainstream*].

<sup>137</sup>*Chain Reaction II: How Top Restaurants Rate on Reducing Use of Antibiotics in Their Meat Supply*, CONSUMERS UNION (Sept. 2016), <http://consumersunion.org/wp-content/uploads/2016/09/ChainReaction2-Report-2016-FINAL-2.pdf> [hereinafter *Chain Reaction II*].

<sup>138</sup>*Id.* at 7.

<sup>139</sup>*Id.* at 8.

<sup>140</sup>Dan Charles, *Perdue Goes (Almost) Antibiotic-Free*, THE SALT (Oct. 7, 2016, 2:12 PM), <http://www.npr.org/sections/thesalt/2016/10/07/497033243/perdue-goes-almost-antibiotic-free> [<https://perma.cc/PTN6-X79K>].

<sup>141</sup>Perdue No Antibiotics EVER Fact Sheet, <https://www.perduefarms.com/news/press-releases/perdue-no-antibiotics-ever-fact-sheet/> [<https://perma.cc/24ND-W5B9>] (last visited April 19, 2018).

<sup>142</sup>Charles, *supra* note 140.

<sup>143</sup>*Id.*

<sup>144</sup>*Perdue Farms Becomes First Major Poultry Company to Eliminate Use of All Antibiotics* (Oct. 7, 2016), <https://www.perduefarms.com/news/press-releases/first-major-poultry-company-to-eliminate-routine-use-of-all-antibiotics/> [<https://perma.cc/TW8Y-RCTL>].

<sup>145</sup>Charles, *supra* note 140.

<sup>146</sup>*Tyson Foods Strives to Eliminate Human Antibiotics From Broiler Chicken Flocks by 2017* (Apr. 28, 2015), <http://www.tysonfoods.com/media/news-releases/2015/04/antibiotics-announcement.aspx> [hereinafter *Tyson Foods Strives to Eliminate Human Antibiotics From Broiler Chicken Flocks by 2017*].

Sanderson Farms, another major producer of chicken, has refused to modify its position on antibiotics in the face of pressure from consumers and industry actors.<sup>147</sup> Instead, Sanderson rolled out a marketing campaign mocking the “raised without antibiotics” claims, labeling them a “marketing gimmick.”<sup>148</sup> Sanderson’s chief financial officer cited the company’s commitment to animal welfare when asked about its use of antibiotics.<sup>149</sup>

### 3. Other Meat Supply Chains

Unsurprisingly, the NRDC report and the Consumers Union scorecard reported incremental reduction of antibiotic use with respect to turkey, beef, and pork.<sup>150</sup> Part of this disparity is caused by the varying degrees of control that industry has over each type of animal.<sup>151</sup> One way in which this control varies in the meat industry is based on how the businesses are structured.<sup>152</sup> The vertical integration of the chicken industry grants producers the power to mandate the ways in which chickens are raised; in contrast, the beef industry is more fragmented.<sup>153</sup> Another way in which the control varies is due to the length of time that animals typically live before slaughter. For example, since chickens only live for four weeks, farmers are able to determine promptly whether certain practices are effective.<sup>154</sup> Meanwhile, pigs live for six months and cows for eighteen months,<sup>155</sup> making it more difficult for companies to implement change quickly.<sup>156</sup> Similarly, the comparatively longer lives of pigs and cows may make it more difficult to avoid administering antibiotics.

Another reason that the rest of the meat industry has not caught up to chicken producers is the lack of financial incentive.<sup>157</sup> Prices for conventionally-raised beef have surged in recent years in the United States,<sup>158</sup> due to inclement weather that reduced the amount of cattle in 2014.<sup>159</sup> Additionally, although producers can charge more for beef raised without the routine use of antibiotics, ranchers would also see

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<sup>147</sup>Stephanie Strom, *Poultry Producer Sanderson Farm Stands Its Ground: It’s Proud to Use Antibiotics*, N.Y. TIMES (Aug. 1, 2016), [https://www.nytimes.com/2016/08/02/business/poultry-producer-sanderson-farms-stands-its-ground-its-proud-to-use-antibiotics.html?\\_r=0](https://www.nytimes.com/2016/08/02/business/poultry-producer-sanderson-farms-stands-its-ground-its-proud-to-use-antibiotics.html?_r=0).

<sup>148</sup>*Id.*

<sup>149</sup>*Id.*

<sup>150</sup>*Chain Reaction II*, *supra* note 137, at 14; *Meat Raised Without the Routine Use of Antibiotics is Going Mainstream*, *supra* note 136, at 3.

<sup>151</sup>Tom Philpott, *How Factory Farms Play Chicken With Antibiotics*, MOTHER JONES (May/June 2016), <http://www.motherjones.com/environment/2016/05/perdue-antibiotic-free-chicken-meat-resistance> [<https://perma.cc/9TB4-UP6V>].

<sup>152</sup>Kelsey Gee, *Antibiotic-Free Beef Is a Taller Order*, WALL ST. J. (Mar. 4, 2015), <https://www.wsj.com/articles/antibiotic-free-beef-is-a-taller-order-1425509343> [<https://perma.cc/WZE6-DYJ5>].

<sup>153</sup>*Id.*

<sup>154</sup>Philpott, *supra* note 151.

<sup>155</sup>*Id.*

<sup>156</sup>Kelsey Gee, *supra* note 152.

<sup>157</sup>David Kesmodel, *Beef’s Meaty Profits Slow Effort to Boost Antibiotic-Free Production*, WALL ST. J. (Sept. 15, 2015), <https://www.wsj.com/articles/beefs-meaty-profits-slow-effort-to-boost-antibiotic-free-production-1442309400?mod=e2tw> [<https://perma.cc/DEU6-TFA4>].

<sup>158</sup>Gee, *supra* note 156.

<sup>159</sup>Kesmodel, *supra* note 157.

an increase in costs, including the labor required to submit paperwork and undergo audits.<sup>160</sup>

#### 4. *Problems with the Current Approach*

One significant issue with the current approach is its inability, thus far, to effect adequate change with respect to animals other than chickens. Given that 8.5 billion of the 10 billion animals slaughtered each year in the United States are chickens,<sup>161</sup> it certainly makes sense to begin the conversation with chickens. However, animal welfare and human health concerns necessitate developments with respect to turkeys, cows, and pigs as well.

Another problem with the current approach stems from some confusion about how industry defines an “antibiotic.” For one, it seems that industry has not yet determined whether ionophores (animal antibiotics) should be considered “antibiotics” for the purpose of discussing reduction of use on farms. This has led to some disparities in outcome. For example, Chick-fil-A and Perdue have adopted standards prohibiting the use of ionophores in addition to antibiotics important for human health,<sup>162</sup> while Taco Bell has articulated standards prohibiting only the use of antibiotics important for human health.<sup>163</sup> There is also ambiguity with respect to the term “human antibiotic,” and whether that term denotes all antibiotics used by humans or just the ones deemed medically important by GFI No. 152. This, too, leads to disparities in outcome. Tyson’s policy statement refers simply to “human antibiotics,” while Pizza Hut’s policy statement refers to “antibiotics important to human medicine.”<sup>164</sup>

#### D. *A Proposed Model*

The current model for consumer campaigns for reducing antibiotics fed to farm animals has enjoyed moderate success, particularly with respect to broiler chickens. Although I previously identified some issues with the approach, I believe that the retailer-focused campaign with an educational aspect for the public is an effective model. In this section, I propose a producer-oriented approach that could supplement the retailer-focused campaign discussed in the previous section. The producer-oriented approach that I identify here draws upon models for environmental stewardship<sup>165</sup> and animal welfare,<sup>166</sup> which can provide additional guidance for how

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<sup>160</sup>*Id.*

<sup>161</sup>*The Welfare of Animals in the Chicken Industry*, *supra* note 8, at 1; *Farm Animal Welfare*, *supra* note 2.

<sup>162</sup>*Meat Raised Without the Routine Use of Antibiotics is Going Mainstream*, *supra* note 136, at 11; Charles, *supra* note 140.

<sup>163</sup>*Statement Regarding Antibiotics* (April 18, 2016), <https://www.tacobell.com/news/statement-regarding-antibiotics> [<https://perma.cc/49X5-ACZP>].

<sup>164</sup>*Tyson Foods Strives to Eliminate Human Antibiotics From Broiler Chicken Flocks by 2017*, *supra* note 146; *Pizza Hut Announces New Food Commitments, Launches Microsite Dedicated to Food You Feel Good About Story*, HUTLIFE (May 31, 2016), <http://blog.pizzahut.com/pizza-hut-announces-new-food-commitments-launches-microsite-dedicated-to-food-you-feel-good-about-story/> [<https://perma.cc/3F3X-5NZS>].

<sup>165</sup>See Mark A. Cohen & Michael P. Vandenbergh, *The Potential Role of Carbon Labeling in a Green Economy*, 34 ENERGY ECON. 5, 6 (2012) (citing Energy Star and dolphin-safe tuna labels as examples of consumer labels that have affected the market).

advocates for the reduction of antibiotic use on farms can accomplish their goals outside of the public regulatory system.

There are many reasons, discussed in this paper, to believe that FDA will not act in the near future to combat antibiotic resistance. However, engaging in a corporate governance regime during this period of deregulation may prove helpful in the future when FDA might again act. Indeed, it appears that corporate adoption of voluntary industry standards led to a complete ban on the use of antibiotics in animal feed in Denmark.<sup>167</sup>

Further, the theory of agency capture indicates that industry's adoption of a relatively strict standard for its use of antibiotics in farm animals may lead to eventual government regulation. Scholars have acknowledged a "free-rider problem inherent in individual purchase decisions involving a public good."<sup>168</sup> However, it is not difficult to imagine how a free-rider problem can develop within an industry that is widely adopting similar standards for antibiotic use and animal husbandry, at least in part for the public good. As giants in the chicken industry adopt antibiotic husbandry policies that seem to place animal welfare and human health ahead of profits, and other producers hold out,<sup>169</sup> those holdouts will not be punished or pushed out of the market unless consumers stop buying their products.<sup>170</sup> I hypothesize that once a critical mass of the producers of chicken have adopted standards limiting or eliminating the use of antibiotics in their broiler chickens, the industry would then benefit from mandatory compliance for the producers who have held out.<sup>171</sup> Therefore, if industry interests have indeed held agencies captive, and if industry does throw its considerable resources behind pushing through certain types of regulation,<sup>172</sup> it is possible that agribusiness will eventually urge FDA to develop a rule that legally binds all of industry to the high standards the majority of the market had adopted.

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<sup>166</sup>See Wayne Pacelle, *Putting the Campaign to Help Broiler Chickens on the Front Burner*, A HUMANE NATION (Apr. 3, 2017), [http://blog.humanesociety.org/wayne/2017/04/putting-campaign-help-broiler-chickens-front-burner.html?credit=fb\\_postwp040317](http://blog.humanesociety.org/wayne/2017/04/putting-campaign-help-broiler-chickens-front-burner.html?credit=fb_postwp040317) [<https://perma.cc/9RUY-2K3J>] (discussing the Humane Society's retailer-focused animal welfare campaign).

<sup>167</sup>U.S. GOV'T ACCOUNTABILITY OFF., GAO-11-801, ANTIBIOTIC RESISTANCE: AGENCIES HAVE MADE LIMITED PROGRESS ADDRESSING ANTIBIOTIC USE IN ANIMALS 37 (2011) ("Government and industry officials we spoke with in Denmark emphasized that their bans on growth promotion antibiotics began as voluntary industry efforts that were later implemented as regulations by the government.").

<sup>168</sup>See Cohen & Vandenberg, *supra* note 165, at 5.

<sup>169</sup>Strom, *supra* note 145, at 1–2.

<sup>170</sup>See Cohen & Vandenberg, *supra* note 165, at 5.

<sup>171</sup>In fact, the Egg Products Inspection Act Amendments of 2012 was supported by a large number of industry groups, including the United Egg Producers, the Arkansas Egg Council, Association of California Egg Farmers, Colorado Egg Producers Association, Florida Poultry Association, Georgia Egg Association, Michigan Agri-Business Association, Michigan Allied Poultry Industries, New England Brown Egg Council, North Carolina Egg Association, Ohio Egg Processors Association, and Rocky Mountain Farmers Union. *Senate Bill Introduced to Improve Housing for Egg-Laying Hens and Provide Stable Future for Egg Farmers*, THE HUMANE SOC'Y OF THE U.S. (May 24, 2012), [http://www.humanesociety.org/news/press\\_releases/2012/05/hen\\_bill\\_052412.html?credit=web\\_id338134607](http://www.humanesociety.org/news/press_releases/2012/05/hen_bill_052412.html?credit=web_id338134607).

<sup>172</sup>Noll, *supra* note 119, at 1030.

### 1. *Third-Party Certification for Producers*

Scholars have recognized a swing “from government to governance.”<sup>173</sup> Corporate entities are now developing socially-responsible production policies, changing the landscape of the market while also attempting to keep up with consumer demand.<sup>174</sup> This has led to companies developing policies that actively undertake improving the environment, rather than just avoiding liability under environmental law.<sup>175</sup> This shift towards governance has also led to the rise of third-party certification and certification boards, which are regarded as a legitimate means of enforcing compliance with standards due to their independence from supply chains.<sup>176</sup> In addition, these third-party certification regimes have allowed non-profit organizations and advocacy groups to take an influential role in setting industry standards.<sup>177</sup>

There is currently an overabundance of certifications on the market, which can prove perplexing for consumers.<sup>178</sup> Further exacerbating consumer confusion is an across the board failure to define ambiguous terms used in existing industry standards.<sup>179</sup> The lack of clarification between “animal antibiotics” and “human antibiotics,” between “all human antibiotics” and “medically important antibiotics,” and between “routine use of antibiotics” and “therapeutic antibiotics,” have rendered the current certifications largely incomprehensible. However, given consumers’ inherent trust in the legitimacy of third-party certifiers, I argue that there is room on the market for a third-party certification system that takes on the task of assigning meaning to the word “antibiotic.”<sup>180</sup>

An appropriate standard for third-party certification in this context could require, for example, that producers seeking certification cease administering all human antibiotics and ionophores to their food-producing animals, with an exception for individual animals that have become sick. This is a stricter standard than that articulated by FDA in GFI Nos. 209 and 213; however, it would allow for producers participating in the certification program to advertise that their product is “raised without routine use of antibiotics” based on the certification’s standards without opening themselves to liability under the false advertising provision of the Lanham Act.<sup>181, 182</sup>

<sup>173</sup>Maki Hatanaka & Lawrence Bush, *Third-Party Certification in the Global Agrifood System: An Objective or Socially Mediated Governance Mechanism?*, 48 *SOCIOLOGIA RURALIS* 73, 76 (2008).

<sup>174</sup>*See id.* at 77; *see also* Charles, *supra* note 140.

<sup>175</sup>Michael P. Vandenberg, *The Emergence of Private Environmental Governance*, 44 *ENVTL. L. REP.* 10,125 (2014), [https://www.eli.org/sites/default/files/docs/44\\_10125.pdf](https://www.eli.org/sites/default/files/docs/44_10125.pdf) [<https://perma.cc/CP2F-DWJG>].

<sup>176</sup>Hatanaka & Bush, *supra* note 173, at 77.

<sup>177</sup>Cohen & Vandenberg, *supra* note 165, at 3–5, 24.

<sup>178</sup>Ralph E. Horne, *Limits to labels: The Role of Eco-Labels in the Assessment of Product Sustainability and Routes to Sustainable Consumption*, 33 *INT’L J. CONSUMER STUD.* 175, 179 (2009).

<sup>179</sup>*See supra* Part IV(C)(4).

<sup>180</sup>*See* Results from a Recent Survey of American Consumers, LAKE RESEARCH PARTNERS (June 29, 2016), at 3, [https://www.aspc.org/sites/default/files/publicmemo\\_aspc\\_labeling\\_fi\\_rev1\\_0629716.pdf](https://www.aspc.org/sites/default/files/publicmemo_aspc_labeling_fi_rev1_0629716.pdf) [<https://perma.cc/3Z5Y-U2J2>] (“Seventy-eight percent of consumers think that there should be an objective third party checking on the welfare of animals on farms.”).

<sup>181</sup>*See* Sanderson Farms, Inc. v. Tyson Foods, Inc., 547 F. Supp. 2d 491, 493 (D. Md. 2008) (“It is undisputed in this case the ionophores are antibiotics.”).



Further, a third-party certification system that provides for independent audits to demonstrate corporate compliance may help prevent the phenomenon of “greenwashing,” which results from limited corporate disclosure of only select information that has the effect of misleading consumers as to the sustainability of their products.<sup>183</sup> Eliminating the possibility of greenwashing will help inform consumer choice.

## 2. *Prioritize Animal Welfare*

In its comments to FDA, submitted on March 13, 2017, the Humane Society of the United States (HSUS) urged the agency to make antibiotic use by industry contingent on its development of welfare-oriented animal husbandry practices.<sup>184</sup> In making this recommendation, HSUS drew on the experience of farmers in Denmark, after the country imposed a total ban on antibiotic use in food animals.<sup>185</sup> In Denmark, mortality rates in pigs increased shortly after the implementation of the ban,<sup>186</sup> but farmers were able to develop husbandry practices, including reducing confinement and improving nutrition, that led to mortality rates in pigs similar to those seen before the ban.<sup>187</sup> HSUS concluded that Denmark’s experience proves that focusing on improving animal welfare can reduce the industry’s need for antibiotics.<sup>188</sup>

There is currently a proliferation of third-party certifications whose standards focus on animal welfare.<sup>189</sup> However, of the six third-party certifiers listed by the American Society for the Prevention of Cruelty to Animals (ASPCA), only two programs have currently certified mega-producers of broiler chickens.<sup>190</sup> Therefore, I argue that while a market-based approach to battling antibiotic resistance should prioritize animal welfare, such welfare standards should not reach so far as to prevent producers from applying for certification.

Perdue’s recent steps to improve animal welfare with respect to its chickens may serve as an appropriate model for the broiler chicken industry. These improvements

<sup>182</sup>Competitors have standing to sue other competitors for false advertising under the Lanham Act. See generally Malla Pollack, *Suing for False Advertising under Federal Lanham Act*, 111 AM. JURIS. TRIALS 303 (originally published 2009) (Feb. 2018 update).

<sup>183</sup>See Cohen & Vandenberg, *supra* note 165 (citing Energy Star and dolphin-safe tuna labels as examples of consumer labels that have affected the market).

<sup>184</sup>Humane Society Comment Letter, *supra* note 93, at 4.

<sup>185</sup>*Id.* at 6 (internal citations omitted).

<sup>186</sup>*Id.* (internal citations omitted).

<sup>187</sup>THE HUMANE SOC’Y OF THE U.S., AN HSUS REPORT: WELFARE ISSUES WITH THE USE OF HORMONES AND ANTIBIOTICS IN ANIMAL AGRICULTURE 6 (Jan. 2016), <http://www.humanesociety.org/assets/pdfs/farm/welfare-issues-with-hormones.pdf> [<https://perma.cc/US2V-EKA3>] [hereinafter *Welfare Issues with the Use of Hormones and Antibiotics in Animal Agriculture*].

<sup>188</sup>*Id.*

<sup>189</sup>AM. SOC’Y FOR THE PREVENTION OF CRUELTY TO ANIMALS, *Meat, Eggs, and Dairy Label Guide*, [https://www.aspc.org/sites/default/files/frm\\_wlfr\\_food\\_lbl\\_guide\\_013117.pdf](https://www.aspc.org/sites/default/files/frm_wlfr_food_lbl_guide_013117.pdf) [<https://perma.cc/AE74-QZXC>] (last visited Nov. 7, 2017).

<sup>190</sup>*All Producers*, HUMANEHEARTLAND.ORG, <http://humaneheartland.org/humane-certified-producers/category/all-producers> [<https://perma.cc/94KU-NEUD>] (last visited Nov. 7, 2017); USDA, *Organic INTEGRITY Database*, <https://organic.ams.usda.gov/integrity/> [<https://perma.cc/V3AQ-K5M3>] (last visited Nov. 7, 2017).

include installing windows,<sup>191</sup> giving each bird more space,<sup>192</sup> and providing enrichment and opportunity to engage in natural behaviors.<sup>193</sup> These efforts are admirable and should be followed by the rest of the industry. Importantly, Perdue did not develop these standards alone; rather, animal welfare groups including HSUS, Mercy for Animals, and Compassion in World Farming worked with Perdue to develop workable standards to improve the welfare of broiler chickens.<sup>194</sup>

Since chickens have received the most attention from producers with respect to implementing voluntary standards for antibiotics use and animal welfare, there are fewer promising models for animal husbandry outside of broiler chickens. Moreover, because the objective of this third-party certification would be to govern agribusiness giants, it will be necessary for industry and animal advocacy groups to find a middle ground and compromise. Although we have seen that ad hoc partnerships among animal welfare organizations and industry players can work,<sup>195</sup> the third-party certification model could serve as a more formalized tool to incorporate these varying perspectives in the development of influential industry standards.

Further, as I noted above, a standard for use of antibiotics that prioritizes animal welfare should prohibit the routine use of both human antibiotics and ionophores for growth promotion and disease prevention purposes. Prohibiting the routine use of both human and animal antibiotics would not only address the risk of antibiotic-resistant bacteria spreading to humans, but would also improve animal welfare. If agribusiness is left without drugs to mitigate animals' poor physical health as a result of terrible living conditions, industry will be further incentivized to improve conditions for farm animals.

I also argue that this standard should allow for antibiotics to be administered to animals who have become ill. Although I doubt the sincerity of Sanderson Farm executives who pointed to animal welfare as a reason not to phase out the use of antibiotics on their farms,<sup>196,197</sup> I agree that legitimate animal welfare concerns may arise from an outright ban on the use of antibiotics in all circumstances. If animals who have been administered antibiotics at any time are precluded from entering the supply chains, farmers have less of an economic incentive to care for those animals, leading to prolonged animal suffering.<sup>198</sup>

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<sup>191</sup> *Commitments to Animal Care 2017*, PERDUEFARMS.COM, <https://www.perdufarm.com/news/press-releases/commitments-to-animal-care-2017-announcement/> [<https://perma.cc/29CG-7TNR>] (last visited Nov. 7, 2017).

<sup>192</sup> *Id.*

<sup>193</sup> Stephanie Strom, *Perdue Aims to Make Chickens Happier and More Comfortable*, N.Y. TIMES (June 26, 2016), <https://www.nytimes.com/2016/06/27/business/perdue-aims-to-make-chickens-happier-and-more-comfortable.html> [<https://perma.cc/XV6Q-AFVJ>].

<sup>194</sup> Wayne Pacelle, *Breaking news: Perdue Announces Major Reforms for Chickens; Progress Spotlights Poultry Problems, Solutions*, A HUMANE NATION (June 26, 2016), <http://blog.humanesociety.org/wayne/2016/06/perdue-animal-welfare-reforms.html> [<https://perma.cc/C8B7-LBWR>].

<sup>195</sup> *Id.*

<sup>196</sup> Strom, *supra* note 147.

<sup>197</sup> Sanderson Farms is in the business of raising chickens to grow unnaturally large and inhumanely slaughtering them at less than two months old. See *The Welfare of Animals in the Chicken Industry*, *supra* note 8 at 1, 10.

<sup>198</sup> *Welfare Issues with the Use of Hormones and Antibiotics in Animal Agriculture*, *supra* note 187, at 6 (citing Mhairi A. Sutherland, Jim Webster & Ian Sutherland, *Animal Health and Welfare Issues Facing Organic Production Systems*, 3 ANIMALS 1021, 1031 (2013)).

#### IV. CONCLUSION

The role of government is to regulate in the public interest; that is, to act when issues arise that require intervention. To date, FDA has failed to promulgate regulations that adequately address the growing issue of antibiotics used for growth promotion and disease prevention purposes in farm animals. It is highly unlikely that FDA will take regulatory action in the near future, given the likelihood that the agency has been “captured” by industry interests, as well as the political climate that is moving away from centralized regulation, as indicated by the “two-for-one” EO. Transitioning to the market-based approach offers a solution that will be insulated from a deregulatory regime and may even lead to the promulgation of stricter regulations under a different administration. Although the retailer-based campaigns that have targeted antibiotics used on farms have led to some changes in antibiotic use with respect to broiler chickens, this alone is not enough to combat the serious animal welfare issues caused and exacerbated by the overuse of antibiotics.

My proposal for a third-party certification model prioritizes animal welfare but seeks to reach a comfortable middle ground between the interests of industry and animal advocacy organizations. This approach will allow for a certification system that appeals to industry giants, and in doing so, helps to mitigate the most egregious abuses on factory farms. Further, my proposal prohibits the routine use of both human and animal antibiotics for growth promotion and disease prevention, yet permits the use of antibiotics in the case of illness, thereby encouraging agribusiness to treat farm animals more humanely while also eliminating incentives to deny animals medical care when necessary.