Journal of Food Law & Policy

Volume 9 | Number 2 Article 7

2013

The Market for Drug-Free Poultry: Why Robust Regulation of Animal Raising Claims is the Right Prescription to Combat Antibiotic Resistance

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THE MARKET FOR DRUG-FREE POULTRY: WHY ROBUST REGULATION OF ANIMAL RAISING CLAIMS IS THE RIGHT PRESCRIPTION TO COMBAT ANTIBIOTIC RESISTANCE

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I. INTRODUCTION

Since their introduction in the mid-twentieth century, antibiotics have become a mainstay of poultry production for purposes ranging from growth promotion to disease treatment and control. Nevertheless, for almost as long, there have been concerns about the role that these agricultural uses play in the development of antibiotic resistant bacteria. The issue of antibiotic resistance in general is fast becoming a public health crisis and scrutiny of agriculture as a contributing cause continues. Nevertheless, to date, neither regulatory efforts to curb agricultural usage nor private sector actions in response to consumer demand and public-interest campaigns have led to significant changes in addressing the problem.

This article will argue that the most effective course for dealing with the role of agriculture in this public health issue is to enact regulations that

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allow the Food Safety Inspection Service (FSIS)[1] to promulgate more robust labeling requirements for companies making claims about antibiotics use on their poultry products. These requirements should empower consumers with the information they need to encourage change in the industry and align consumer choices with principles for the judicious use of antibiotics backed by the U.S. Food and Drug Administration (FDA),[2] without prematurely forcing producers to abandon tools valuable in protecting food safety and animal welfare.

Part I will set forth the issue presented by antibiotic resistant bacteria and the role the poultry industry plays in its development. In Parts II and III, respectively, this article will describe the regulatory and marketplace responses to antibiotic resistance, including the labeling of poultry products produced without antibiotics. Part IV will take a closer look at the use of antibiotics in the poultry industry, and Part V will consider the problem presented by confusing, inaccurate, or misleading labeling by looking specifically at an advertising and labeling campaign launched by poultry giant Tyson Foods, Inc. (Tyson) in 2007. Finally, in Part VI, this article will suggest that the adoption of improved labeling policies would not only prevent future problems such as those presented by Tyson's campaign, but would strengthen the market for poultry raised either without antibiotics or through the judicious use of antibiotics by empowering consumers with clear and consistent information.

II. THE PROBLEM OF ANTIBIOTIC RESISTANCE

Antibiotics are powerful medical tools for treating bacterial infections in both humans and animals.[3] Their availability has made previously

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1. FSIS is an agency within the U.S. Department of Agriculture with responsibility for, among other things, making sure that poultry products are safe, safely packaged, and labeled in compliance with the Poultry Products Inspection Act. U.S. DEP'T OF AGRIC., ABOUT FSIS, http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Jan. 6, 2014).

2. The FDA is an agency within the U.S. Department of Health and Human Services. As part of its broad jurisdiction over the safety of food and drugs pursuant to the Food, Drug and Cosmetic Act, it has responsibility over approval of new animal drugs, including those used in food-producing animals. *See generally* U.S. FOOD & DRUG ADMIN., FDA ORGANIZATION, http://www.fda.gov/AboutFDA/CentersOffices/default.htm (last visited Jan. 6, 2014).

3. *See generally* Ctr. for Veterinary Med.., U.S. Dep't of Health & Human Servs., *Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,* 209 GUIDANCE FOR INDUSTRY 1 (2012), *available at* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf [hereinafter Guidance for Industry # 209]; Ian Phillips et al., *Does the Use of Antibiotics in Food Animals Pose a Risk to Human*

deadly conditions highly treatable, but the use of an antibiotic naturally results in bacteria gradually becoming resistant to it.[4] When this occurs, a drug that once was capable of curing an infection will no longer be effective against it.[5] There is wide agreement that the misuse or overuse of antibiotics leading to more rapid development of resistant bacteria is a major public health concern.[6] However, the issue is complex and there is little agreement over how best to address it, as antibiotics are used extensively in both human and animal medicine.[7] Nevertheless, because agriculture is a major consumer of antibiotic drugs, food producers have come under scrutiny.[8]

Specifically, there is evidence that animals treated with antibiotics become carriers of strains of bacteria that are resistant to antibiotics of that type or class.[9] When humans consume products from those animals, they are exposed to those drug-resistant bacteria.[10] If a person exposed to drug-

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Health? A Critical Review of Published Data, 53 J. ANTIMICROBIAL CHEMOTHERAPY 28 (2003), *available at* http://www.vet.k-state.edu/depts/dmp /pdf/ANTIBIOTICS.pdf; *see also* Natural Res. Def. Council v. U.S. Food & Drug Admin., 884 F. Supp.2d 127, 127 (S.D.N.Y. 2012); Natural Res. Def. Council v. U.S. Food & Drug Admin., 872 F. Supp.2d 318, 318 (S.D.N.Y. 2012). Antibiotics are a kind of antimicrobial agent and this article, as well as much of the literature on this subject, sometimes uses the terms interchangeably. The Centers for Disease Control and Prevention define antimicrobial agents this way: "[a] general term for the drugs, chemicals, or other substances that either kill or slow the growth of microbes. Among the antimicrobial agents in use today are antibacterial drugs (which kill bacteria), antiviral agents (which kill viruses), antifungal agents (which kill fungi), and antiparisitic drugs (which kill parasites)." CTRS. FOR DISEASE CONTROL, GLOSSARY, http://www.cdc.gov/drugresistance /glossary.html#antimicrobialagents (last visited Jan. 6, 2014).

4. Phillips et al., *supra* note 3, at 28; Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 4; *see also Natural Res. Def. Council*, F. Supp. 2d at 131; *Natural Res. Def. Council*, F. Supp. 2d at 323.

5. Phillips et al., *supra* note 3, at 28; Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 4; *see also Natural Res. Def. Council*, F. Supp. 2d at 131; *Natural Res. Def. Council*, F. Supp. 2d at 322.

6. *See generally* Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 5-17; *see also Natural Res. Def. Council*, F. Supp. 2d at 131; *Natural Res. Def. Council*, F. Supp. 2d at 323.

7. Phillips et al., *supra* note 3, at 29; *see also Natural Res. Def. Council*, F. Supp. 2d at 131-34; *Natural Res. Def. Council*, F. Supp. 2d at 322.

8. Phillips et al., *supra* note 3, at 28-29; Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 4, at 3; *Natural Res. Def. Council*, F. Supp. 2d at 131-132; *Natural Res. Def. Council*, F. Supp. 2d at 322-23.

9. Phillips et al., *supra* note 3, at 32-33.

10. Phillips et al., *supra* note 3, at 33 (stating that "[i]t is well known that antibiotic-resistant bacteria that have been selected in animals may contaminate meat derived from those animals and that such contamination also declines when the selecting antibiotics are not used").

resistant bacteria in this way becomes ill, the infection may not be treatable by the antibiotic to which those bacteria are resistant or by others in its class.[11] Evidence also suggests that farm workers exposed to these animals may become infected with these bacteria, whether or not they become ill.[12] The drug-resistant bacteria may spread to the environment as well.[13] While there is not agreement on how to fix the problem, concern continues to grow.[14]

III. MARKETPLACE RESPONSE TO ANTIBIOTIC RESISTANCE

In response to growing consumer awareness of the dangers of antibiotic resistance, however poorly understood by consumers, food companies have begun to take steps to curb their use.[15]

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11. Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 4.

12. Phillips et al., *supra* note 3, at 33 (stating that "[a]nimals that carry, or in certain cases are infected by, resistant organisms are a hazard to those who work with them since the organisms can be transferred by direct contact").

13. THE PEW COMMISSION ON INDUSTRIAL FARM PRODUCTION, PUTTING MEAT ON THE TABLE: INDUSTRIAL FARM ANIMAL PRODUCTION IN AMERICA, 23, 25 (2008), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Industrial_Agriculture/PCIFAP_FINAL.pdf (noting that antibiotics are present in animal waste and have been found in surface waters near agricultural facilities) [hereinafter PEW COMMISSION].

14. There does not appear to be agreement even among scientists as to the extent of the problem or the best way to address it. For example, some have advocated banning the use of antibiotics for growth promotion in agriculture, as has been done in a number of European Union countries, including Denmark and Sweden. Phillips et al., *supra* note 3, at 44. However, a coalition of scientists reviewing the evidence regarding use of antibiotics in agriculture point out a countervailing argument to that approach:
An important finding, for policy purposes, is that risk management strategies that focus on eliminating resistance are expected to create less than one percent of the public health benefit of strategies that focus on reducing microbial loads (resistant or not). An even more disturbing conclusion was that, if the banning of fluoroquinolones gave even a modest increase in the variance of microbial loads on chickens leaving the processing plant, it would create far more cases of human infection than cases of resistant infection that it might prevent. *Id.* at 42.

15. *See* Elizabeth Weise, *'Natural' Chickens Take Flight,* USA TODAY, Jan. 23, 2006, http://usatoday30.usatoday.com /news/health/2006-01-23-natural-chickens_x.htm. Ms. Weise notes that:

> [f]our of the nation's top 10 chicken producers have virtually ended a practice that health and activist groups for years charged was causing a public health crisis: feeding broiler chickens low doses of antibiotics to make them grow faster and stay healthy. Tyson Foods, Gold Kist, Perdue Farms and Foster Farms say they stopped using

A recent survey by *Consumer Reports* indicated that eighty-six percent of those surveyed thought that meat raised without antibiotics should be available for purchase in their local market.[16] Customer surveys by Tyson, conducted in preparation for a failed "raised without antibiotics" marketing campaign it launched in 2007, indicated that ninety-one percent of consumers thought it was "important to have chicken produced and labeled 'raised without antibiotics'" and that they were willing to pay more for such a product.[17]

Representative Louise Slaughter, a member of the House of Representatives for the Twenty-Eighth District of New York and a microbiologist, has made antibiotic resistance one of her signature issues.[18] In February 2012, she surveyed over sixty food companies and producers to determine their stance on the issue.[19] Thirty-one companies and producers responded to the request for information and Representative Slaughter gathered information from publicly available sources on the policies of an additional twenty-two companies and producers.[20] Responses indicated that many national brands have moved away from the routine use of antibiotics for growth promotion, though they are still used regularly by most companies for prevention and control of disease.[21] The

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> antibiotics for growth promotion. In addition to ending a practice that Europe banned and McDonald's ended a month ago, the four companies also have severely limited antibiotic use for routine disease prevention, though antibiotics are still used to treat disease outbreaks.

16. CONSUMER REPORTS, MEAT ON DRUGS: THE OVERUSE OF ANTIBIOTICS IN FOOD ANIMALS & WHAT SUPERMARKETS AND CONSUMERS CAN DO TO STOP IT 3 (2012), http://www.consumerreports.org/content/dam/cro/news_articles/health/CR%20Meat%20On%20Drugs%20Report%2007-12b.pdf.

17. *Tyson Chickens 'Raised Without Antibiotics,'* WORLD POULTRY, June 20, 2007, http://www.worldpoultry.net /Home/General/2007/6/Tyson-chickens-Raised-Without-Antibiotics-WP001465W/ [hereinafter WORLD POULTRY].

18. BIOGRAPHY, http://www.louise.house.gov/biography/ (last visited Jan. 6, 2014).

19. Press Release, Slaughter Asks Fast Food Companies, "What's in the Beef?" (Feb. 16, 2012), *available at* http://www.louise.house.gov/index.php?option=com_content&task=view&id=2662&Itemid=100069; *see also* Letter from Louise M. Slaughter, Congresswoman, to Fast Food Restaurant Companies (Feb. 16, 2012), *available at* http://louise.house.gov/images/user_images/gt/stories/Fast_Food_Letter.pdf.

20. "WHAT'S IN THE BEEF?" SURVEY RESULTS, http://www.louise.house.gov/survey-results (last visited Jan. 6, 2014) [hereinafter *Survey Results*]; DIRECT SURVEY RESPONSES, http://www.louise .house.gov/uploads/master_list_responses_FINAL_final.pdf (last visited Jan. 6, 2014).

21. *Survey Results*, *supra* note 20; *see also* DIRECT SURVEY RESPONSES, *supra* note 20.

response rate as well as the ready availability of corporate policies on antibiotic use speaks to the level of prominence the issue has gained in corporate consciousness.

IV. REGULATORY RESPONSE TO ANTIBIOTIC RESISTANCE

At the same time that companies and producers have been voluntarily moving away from reliance on antibiotics in production, efforts to address this public health issue head on by banning or restricting the use of antibiotics in agricultural production have moved forward in fits and starts in the courts and the legislative and administrative branches.

As far back as 1970, the FDA was sufficiently concerned about the potential risks raised by the use of medically important antibiotics in livestock production to convene a task force to study the issue.[22] As the regulatory body with jurisdiction over approval of all new animal drugs, the FDA was responsible for having approved the use of antibiotics in food producing animals, as well as the conditions and restrictions on such use. In order for it to approve a new drug, the FDA must find that it is safe and effective; in the case of food-producing animals, this means safe for the humans that will consume that food, as well as safe for the animals.[23] Once a drug is approved, the FDA may suspend the drug's application if new evidence (or other information) shows that the drug is not, in fact, safe.[24] The FDA's task force concluded that the use of antibiotics, "especially in growth promotant and subtherapeutic amounts" encourages the development of bacteria strains resistant to antibiotics.[25] The task force set forth recommendations that included restricting the use of specific antibiotics in animal feeds for certain uses.[26] In response to the task force's recommendations, the FDA initiated a process with respect to the specified

22. Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 6.

23. 21 C.F.R. § 514.1(b)(8) (2013).

24. 21 U.S.C. § 360b(e)(1)(B) (2013). The FDA also establishes safe residue levels for all animal drugs and withdrawal periods necessary to remain below those maximum residue levels. *See infra* note 101. The approved uses of the drug are set forth in its label, but "extralabel" uses—uses different from what is set forth in the label, such as variations in doses, frequencies, routes of administration, species, etc.—are also permitted pursuant to the Animal Medicinal Drug Clarification Act of 1994. 21 U.S.C. § 360b(a)(4)(A). However, the FDA may prohibit extralabel use by order if it finds that the extralabel use could lead to an adverse event affecting the public health. 21 U.S.C. § 360b(a)(4)(D).

25. Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444 (Feb. 1, 1972).

26. *Id.* at 2445.

antibiotics to withdraw approval unless such drugs were shown to be safe based on criteria established by the FDA.[27] However, the process stalled for myriad reasons, including the complexities of the scientific and political issues that surrounded it and was ultimately given up more than twenty-five years later.[28]

A similar initiative to ban the extralabel use of cephalosporin, a critically important and widely used antibiotic for the treatment of disease in humans, in food producing animals was published in the Federal Register in 2008, pursuant to the FDA's authority under § 512(e)(1)(B) of the Food Drug & Cosmetic Act.[29] Cephalosporins are commonly used in food-producing animals, including for controlling *E. coli* infections that often lead to early mortality in newly-hatched chicks and turkey poults.[30] However, they are also the most frequently prescribed antibiotic for human diseases, and certain cephalosporins are the preferred drug for treating a number of serious infections in people, including systemic infections arising from *Salmonella.* [31] Nevertheless, the action was withdrawn some months later in order to allow the FDA the opportunity to consider the numerous comments it received from various concerned parties on the matter.[32] In 2012, FDA issued a more narrowly tailored notice regarding cephalosporin in response to the comments received in 2008.[33] The modified response would limit certain uses, but continue to allow others.[34]

The FDA's current policy relies on other strategies it deems more expedient and, perhaps, less controversial than those reflected in these earlier initiatives.[35] Currently, the FDA's stated approach is to seek

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27. Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 6; *see also* Natural Res. Def. Council v. U.S. Food & Drug Admin., 884 F. Supp.2d 127, 136 (S.D.N.Y. 2012); Natural Res. Def. Council v. U.S. Food & Drug Admin., 872 F. Supp.2d 318, 322-325 (S.D.N.Y. 2012).

28. Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 6-7; *see also Natural Res. Def. Council*, 884 F. Supp. 2d at 136.

29. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition, 73 Fed. Reg. 38,110 (July 3, 2008) (to be codified at 21 C.F.R. pt. 30).

30. *Id.*

31. *Id.*

32. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Revocation of Order of Prohibition; Withdrawal, 73 Fed. Reg. 71,923 (Nov. 21, 2008) (to be codified at 21 C.F.R. pt. 530).

33. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition, 77 Fed. Reg. 735 (Jan. 6, 2012) (to be codified at 21 C.F.R. pt. 530).

34. *Id.*

35. *See generally* Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444, 2445 (Feb. 1, 1972); *see also* Natural Res. Def. Council v. U.S. Food & Drug Admin., 884 F. Supp.2d 127, 134 (S.D.N.Y. 2012); Natural Res. Def. Council v. U.S. Food & Drug Admin., 872 F. Supp.2d 318, 322-23 (S.D.N.Y. 2012). *See generally*

voluntary compliance by all stakeholders in the judicious use of antibiotics as outlined in its Guidance for Industry #209 and supplemented with specific recommendations in its Guidance for Industry #213.[36] This would include adoption of two basic principles:

Principle 1: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.[37]

Principle 2: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.[38]

With respect to medically important antibiotics currently available on an over-the-counter basis, FDA's Guidance for Industry #213 calls on pharmaceutical companies to take action voluntarily in furtherance of the above principles by revising their labeling to require a prescription from or oversight by a veterinarian for use in food-producing animals.[39]

Frustrated with the time it would take the FDA to review use of existing antibiotic drugs on a case-by-case basis under the current regulatory framework, Representative Louise Slaughter sponsored a bill called the Preservation of Antibiotics for Medical Treatment Act of 2011 (PAMTA).[40] If enacted, PAMTA would require approval for the non-therapeutic use in food-producing animals of any drug used or intended for

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FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA'S STRATEGY ON ANTIMICROBIAL RESISTANCE - QUESTIONS AND ANSWERS, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm (last visited Jan. 6, 2014).

36. Guidance for Industry #209, *supra* note 3, at 20; *See generally* Ctr. for Veterinary Med, U.S. Dep't of Health & Human Servs., *Guidance for Industry: 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* , 213 GUIDANCE FOR INDUSTRY 1 (2013), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf [hereinafter Guidance for Industry #213].

37. Guidance for Industry #209, *supra* note 3, at 21.

38. *Id.* at 22. For an analysis of the unique ways these principles would affect the poultry industry, *see* David A. Pyle, *Judicious Use of Antimicrobials in Poultry Production,* ZOOTECNICA INT'L (July 1, 2006), http://www. zootecnicainternational. com/article-archive/veterinary/755-judicious-use-of-antimicrobials-in-poultry-production-.html.

39. Guidance for Industry #213, *supra* note 36, at 4-5.

40. H.R. 965, 112th Cong. (1st Sess. 2011).

use in humans to prevent or treat disease or infection caused by microorganisms within two years of enactment, unless there has been shown a "reasonable certainty of no harm to human health due to the development of antimicrobial resistance that is attributable in whole or in part" to such use.[41] The bill was referred to the House Subcommittee on Health on March 14, 2011.[42] No further action has been taken.[43]

In June 2012, Judge Theodore H. Katz issued the second of two orders likely to lead to further restrictions on the use of certain medically important antibiotics in livestock production.[44] The first order required the FDA to follow through on the actions it initiated back in the 1970's with respect to penicillin and tetracycline-related drugs.[45] The second requires it to reconsider its response to two citizen petitions asking the FDA to ban certain uses of all antibiotics in the production of food animals.[46] The FDA had argued in both cases that withdrawal hearings would be too time consuming and resource-intensive and that, instead, it was addressing the public health concern through the voluntary process set out in its guidance documents.[47]

Thus, in many ways the voluntary response of food companies to consumer demands has effected greater and speedier change than the legal maneuvering has or is likely to do in the near future. However, as will be discussed below, the current labeling process at FSIS is an impediment to the effective working of the market.

V. USE OF ANTIBIOTICS IN COMMERCIAL POULTRY PRODUCTION

In May 2007, FSIS approved Tyson's proposed use of the label "raised without antibiotics" on chicken products,[48] and Tyson launched a $70 million advertising and marketing campaign related to its new product

41. *Id.*

42. LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 112TH CONGRESS (2011 - 2012), H.R. 965, ALL INFORMATION, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR00965:@@@L&summ2=m& (last visited Jan. 7, 2014).

43. LIBRARY OF CONGRESS, BILL SUMMARY & STATUS, 112TH CONGRESS (2011 – 2012), H.R. 965, ALL CONGRESSIONAL ACTION, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR00965:@@@X (last visited Jan. 7, 2014).

44. *See generally* Natural Res. Def. Council v. U.S. Food & Drug Admin., 884 F. Supp.2d 127 (S.D.N.Y. 2012); *see also* Natural Res. Def. Council v. U.S. Food & Drug Admin., 872 F. Supp.2d 318, 318 (S.D.N.Y. 2012).

45. *Natural Res. Def. Council*, 884 F. Supp.2d at 151.

46. *Natural Res. Def. Council*, 872 F. Supp.2d at 341-42.

47. *Natural Res. Def. Council*, 884 F. Supp.2d at 140; *Natural Res. Def. Council*, 872 F. Supp.2d at 325.

48. WORLD POULTRY, *supra* note 17.

line.[49] Tyson had determined that a large proportion of its customer base—over ninety percent—may be willing to purchase chicken raised without antibiotics and were willing to pay a premium to do so.[50] Tyson's then-Senior Vice President of Fresh Meal Solutions, Dave Hogberg, was quoted as saying, "[w]e are the first major poultry company to offer fresh chicken raised without antibiotics on a large scale basis and at an affordable price for mainstream consumers."[51]

Intensive animal agriculture began in the early twentieth century, when the production of crops such as corn and soybeans outstripped the food demands of population growth and could be redirected to feed for animal production.[52] "Vertically integrated" poultry production is now the norm, meaning that one company controls all aspects of production from when the eggs are laid to when the packaged meat product is stocked at the grocery.[53] While large-scale production has enabled greater quantities of a more cost-effective, consistent-quality product to be produced, it also increases the risks associated with disease in flocks. More animals raised

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49. *Tyson and USDA Reach an Agreement on Antibiotics Label,* WORLD POULTRY, Dec. 21, 2007, http:// www.worldpoultry.net/Home/General/2007/12/Tyson-and-USDA-reach-an-agreement-on-antibiotics-label-WP002026W/.

50. WORLD POULTRY, *supra* note 17.

51. *Id.*

52. PEW COMMISSION, *supra* note 13, at 5. Traditionally, in the United States, individuals and families raised small crops of grains, fruits, and vegetables and small numbers of farm animals in order to produce the food needed to support themselves. *Id.* at 1. This "subsistence farming" continued on a widespread basis until well into the 1800's when the development of mechanical agricultural tools made more intensive production possible. *Id.* The production of crops on an industrial scale, supported by advances in transportation, food preservation, genetic selection, chemical fertilizers and pesticides, etc., fueled the growing urbanization of the country. *Id.* at 1, 3. Food could now be produced in the countryside and transported to cities. *Id.*

53. *Id.* at 5. The poultry company typically contracts with independent growers to raise the chicks or turkey poults until they are ready to be slaughtered and processed, but supplies and controls what they are fed, whether and how they are medicated, and other aspects of their care. *Id. See also* AM. ACAD. OF MICROBIOLOGY, THE ROLE OF ANTIBIOTICS IN AGRICULTURE (2002), *available at* http://www.fws.gov/fisheries /aadap/PDF/the%20role%20of%20antibiotics%20in%20agriculture%202002%20Amer %20Acad%20Microbiologistspdf.pdf. This vertical integration grew out of the process employed in meeting contracts with the War Department during World War II for poultry products for the troops and has continued as the preferred model for large scale animal production. PEW COMMISSION, *supra* note 13, at 5; *see also* H. STEINFELD ET AL., LIVESTOCK'S LONG SHADOW: ENVIRONMENTAL ISSUES AND OPTIONS (2006), *available at* ftp://ftp.fao.org/docrep /fao/010/a0701e/a0701e.pdf. Vertical integration allows the producer to take advantage of economies of scale and exercise greater control over all the factors affecting the quality and safety of the product. PEW COMMISSION, *supra* note 13, at 5; *see also* STEINFELD ET AL., *supra.*

in close quarters means greater possibility of disease outbreaks, the ability for disease to spread more quickly and for the producer to experience greater losses if it does. [54] As a result, availability of antibiotics has been essential to the success of large-scale animal production.

Antibiotics are used to treat disease outbreaks in livestock as they are in humans.[55] In poultry production, though, rather than treating individual sick birds, medicine is administered in food or water to the entire flock.[56] The reasons for this are two-fold: a) due to the large numbers of birds comprising a flock, it is impractical to identify, separate, and treat each individual chicken or turkey experiencing symptoms;[57] and b) because of the close quarters and densely populated houses, the remainder of the flock is at great risk of contracting or having already contracted the illness by the time an outbreak is identified.[58] Accordingly, treatment of the whole flock serves both a therapeutic and prophylactic role.

In addition, in the 1940's, researchers trying to understand the makeup of animal proteins accidentally discovered that poultry fed antibiotics grew faster than others.[59] As a result, producers began routinely

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54. David Tilman et al., *Agricultural Sustainability and Intensive Production Practices*, 418 NATURE 671, 671 (2002), *available at* http://www.nature.com/nature/journal/v418/n6898/pdf/nature01014.pdf.

55. Phillips et al., *supra* note 3, at 28.

56. *Id.* at 29 (stating that "[w]hen antibiotic treatment is necessary, it often has to be administered to food animals in feed or water. Individual animal treatment is almost never practical for poultry").

57. *Id.*; *see also* AM. ACAD. OF MICROBIOLOGY, *supra* note 53, at 3 (noting that "[p]oultry generally are given antibiotics in feed or water since individual treatment is impractical and not economical; this method of dispensing antibiotics exposes all the animals to antibiotics, but the individual dose is unknown and inconsistent").

58. Phillips et al., *supra* note 3, at 29 (stating that "[i]n livestock production, the objective is to limit progression of disease in the population, since illness decreases animal performance. Herd or flock treatment is often indicated when illness is first recognized in a small proportion of the animals").

59. F.T. Jones & S.C. Ricke, *Observations on the History of the Development of Antimicrobials and Their Use in Poultry Feeds*, 82 POULTRY SCI. 613, 613 (2003), *available at* http://ps.fass.org/content/82/4/613.full.pdf+html; Phillips et al., *supra* note 3, at 29. Phillips et al. note that:

> [t]he growth promoting effects of antibiotics were first discovered in the 1940s when chickens fed by-products of tetracycline fermentation were found to grow faster than those that were not fed those by-products. Since then, many antimicrobials have been found to improve average daily weight gain and feed efficiency in livestock in a variety of applications, and this is known as 'growth promotion'.

adding antibiotics to feed to promote growth.[60] Veterinarians now understand that the antibiotics work to prevent or control coccidiosis and other diseases of the intestinal tract which interfere with effective feed conversion.[61] Thus, even though still referred to as "growth promotants," they are doing so by preventing or controlling disease.[62]

VI. CONFUSING, INACCURATE, AND MISLEADING LABELING

After Tyson's new products had already gone to market, FSIS withdrew its consent for the label after realizing that Tyson used ionophores in its feed to prevent coccidiosis.[63] Ionophores are a class of antibiotics used, not for treating bacterial infections but, rather, to treat parasites in the intestinal tract.[64] Though not used in human medicine and not deemed antibiotics by the FDA, ionophores were considered antibiotics by FSIS.[65] After negotiations, FSIS and Tyson agreed on a new, revised

60. The goal of large-scale, intensive animal production is to produce the greatest number of pounds of safe, high-quality product for the lowest cost. *See generally,* Jay P. Graham et al., *Growth Promoting Antibiotics in Food Animal Production: An Economic Analysis,* 122 PUB. HEALTH REP. 79 (2007), *available at* http://www.jhsph.edu/sebin/s/a/ antibiotics_poultry07.pdf. To measure success in this effort, the poultry industry uses the feed conversion ratio. *Id.; see also* PEW COMMISSION, *supra* note 13, at 5. Factors that affect the cost of feed, the amount of feed consumed, or the amount of weight gained will all affect the feed conversion ratio. In addition, disease also affects the cost of production, as money spent on raising the chicks or turkey poults prior to the death of the animal will not contribute to marketable product, additional expense will be incurred in dealing with the consequences of the outbreak (including treatment of animals and disposition of carcasses). Further, even if diseased birds do not die, they may, nevertheless, be excluded from sale due to safety or quality issues—known in the industry as "condemnations." Something that increases weight gain without requiring additional feed (after taking into account the cost of the growth-promoting additive) will improve the feed conversion ratio. *See* Graham et al., *supra,* at 83.

61. *Video: Poultry Insight: Why and When are Antibiotics Used in Poultry Production?,* WORLD POULTRY, Nov. 13, 2012, http://www.worldpoultry.net/Home/General/2012/11/Poultry-Insight-Why-and-when-are-antibiotics-used-in-poultry-production-1104566W/ [hereinafter *Poultry Insight*].

62. *Id.*

63. *USDA Wants Removal of Tyson's "No Antibiotics Label",* WORLD POULTRY, Nov. 20, 2007, http://www.worldpoultry.net/Broilers/Markets—Trade/2007/11/USDA-wants-removal-of-Tysons-ano-antibiotics-labela-WP001924W/ [hereinafter WORLD POULTRY II].

64. *Poultry Insight, supra* note 61.

65. WORLD POULTRY II, *supra* note 63.

label — "raised without antibiotics that impact antibiotic resistance in humans."[66]

In January, however, Tyson was sued by several of its major competitors, claiming that the labeling was inaccurate and misleading, initially because the label implies that the other producers are using those types of drugs, which is not the case, and later because Tyson, in fact, injected the eggs with the antibiotics gentamicin and ceftiofur, in conjunction with certain vaccinations made prior to hatch.[67] The suit by competitors was followed by a class action lawsuit by consumers[68] and a withdrawal of approval of the label by the FSIS, in light of the new information about *in ovo* injections of antibiotics that are approved for use with humans.[69]

Ultimately, Tyson stopped using the labeling and brought suit against the USDA, saying that the regulatory process was flawed.[70]

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66. *Tyson and USDA Reach an Agreement on Antibiotics Label, supra* note 49; *Tyson to Use New Label for 'Raised Without Antibiotics Chicken'*, WORLD POULTRY, Jan. 2, 2008, http://www.worldpoultry.net/Broilers/Markets—Trade/2008/1/Tyson-to-use-new-label-for-Raised-Without-Antibiotics-Chicken-WP002036W/.

67. Sanderson Farms, Inc. v. Tyson Foods, 547 F. Supp. 2d 491 (D. Md. Apr. 22, 2008); *Tyson Appeal Denied in 'Raised Without Antibiotics' Case,* WORLD POULTRY, May 2, 2009, http://www.worldpoultry.net/Home/General/2008/5/Tyson-appeal-denied-in-raised-without-antibiotics-case-WP002485W/; *U.S. Court Says Tyson Must Stop Advertising Claims*, WORLD POULTRY, Apr. 24, 2008, http://www.worldpoultry.net/Broilers/Markets—Trade/2008/4/US-court-says-Tyson-must-stop-advertising-claims-WP002460W/; *U.S. Poultry Giants Fight Over Antibiotic Use,* WORLD POULTRY, Apr. 11, 2008, http://www.worldpoultry.net/Broilers/Markets—Trade/2008/4/US-poultry-giants-fight-over-antibiotic-use-WP002411W/; *see also* Second Amended Complaint, Sanderson Farms, Inc. v. Tyson Foods, No. 1:08-cv-00210, 2008 WL 4334901 (D. Md. May 5, 2008) (noting that "[g]entimicin is an antibiotic approved for use in human medicine" and "[c]eftiofur is a third generation cephalosporin; cephalosporins are approved for use in human medicine").

68. Rory Harrington, *Tyson Agrees to Pay $5m in "Antibiotic-free" Chicken Settlement,* FOODPRODUCTIONDAILY.COM, Jan. 15, 2010, http://www.foodproductiondaily.com/Processing/Tyson-agrees-to-pay-5m-in-antibiotic-free-chicken-settlement; *Tyson Removes 'Raised Without Antibiotics' Label,* WORLD POULTRY, June 4, 2008, http://www.worldpoultry.net /Broilers/Markets—Trade/2008/6/Tyson-removes-raised-without-antibiotics-label-WP002596W/; *Tyson Settles Suit Over Antibiotic Labeling,* WORLD POULTRY, Jan. 22, 2010, http://www.worldpoultry.net/Home/General/2010/1/Tyson-settles-suit-over-antibiotic-labelling-WP006982W/.

69. Am. Veterinary Med. Ass'n, *USDA Rescinds "Raised Without Antibiotics" Label on Tyson Chicken*, July 15, 2008, https://www.avma.org/News/JAVMANews/Pages/080715s.aspx.

70. *Antibiotic-free Labelling - Tyson Sues USDA,* WORLD POULTRY, June 17, 2008, http://www.worldpoultry.net/Broilers/Markets—Trade/2008/6/Antibiotic-free-labelling—-Tyson-sues-USDA-WP002639W/.

FSIS is responsible for approving the types of claims a company may make on its labeling regarding use of antibiotics.[71] Unlike food labels regulated by the FDA, the content of all meat and poultry food labels must be approved by FSIS in advance.[72] Certain information is mandatory, such as product name, country of origin, list of ingredients, and certain nutrition information, but other information may be included at the discretion of the producer, if it is truthful and not misleading.[73]

A particular category of discretionary information is known as "animal raising claims" or "production claims" and has to do with how the animal that produced the food product was raised.[74] Examples include "vegetarian fed diet," "free-range," or "not fed animal by-products."[75] Within this category are claims about whether or under what circumstances the animal was treated with antibiotics.[76]

Currently, while any such claim must be approved by FSIS, there is not a defined set of acceptable claims or claim language dictated by FSIS or established guidelines for how an animal must be raised to satisfy the requirement that the claim is truthful and not misleading.[77]

The Agricultural Marketing Service (AMS) of the USDA plays a different but related role in the labeling of meat products, by offering voluntary "Process Verified" programs.[78] These programs enable companies to have their facilities audited to verify specific production or animal raising claims.[79] Once verified, they may include a "USDA Process

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71. Poultry Products Inspection Act, 21 U.S.C. §§ 451-72 (2012).

72. *Id.*; OFFICE OF POLICY, PROGRAM, & EMP. DEV., U.S. DEP'T OF AGRIC., A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 4 (2007), *available at* http://www.fsis.usda.gov/PDF/Labeling_Requirements_Guide.pdf [hereinafter GUIDE]; *See generally* 9 C.F.R. §§ 300-592.

73. *See* Am. Veterinary Med. Ass'n, *supra* note 69.

74. OFFICE OF POLICY, PROGRAM, & EMP. DEV., U.S. DEP'T OF AGRIC., ANIMAL PRODUCTION CLAIMS OUTLINE OF CURRENT PROCESS 1, *available at* http://www.fsis.usda.gov/OPPDE/larc/Claims/RaisingClaims.pdf.

75. FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., ANIMAL RAISING CLAIMS IN THE LABELING OF MEAT AND POULTRY PRODUCTS, POWERPOINT PRESENTATION FROM PUBLIC MEETING REGARDING ANIMAL RAISING CLAIMS SLIDE 4 (2008), *available at* http://www.fsis.usda.gov/PDF/Claims_Poretta_101408.pdf.

76. GUIDE, *supra* note 72, at 18, 21.

77. *Id.* at 18-21; *see also* FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., *supra* note 75, at slides 6-8.

78. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., GRADING, CERTIFICATION, VERIFICATION, http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=GradingCertificationandVerfication&leftNav=GradingCertificationandVerfication&page=ProcessVerified.usda.govHomePage (last visited Jan. 8, 2014).

79. *Id.*

Verified" seal on their labels along with the approved claim.[80] As with animal raising claims in general, most claims that have been verified through this program were put forth by the company and include "All Vegetarian Diet," "No Animal By-Products," "Humanely Raised,"[81] "Raised Cage Free," and "No Antibiotics Ever," among others.[82] However, the AMS also develops programs with which companies and producers may choose to comply, with the expectation that it will bring added value to their products.[83] One such program that touches on antibiotics usage is called "Never Ever 3": no antibiotics, no growth promotants, and no animal by-products—"never ever".[84] This program was launched in April 2009, but does not appear to have gotten much traction; as of the October 4, 2012, update, no poultry products are listed on the Official Listing of

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80. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., QUALITY SYSTEMS VERIFICATION PROGRAMS GENERAL POLICIES AND PROCEDURES 1 (2010), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5073953 [hereinafter *Quality Systems*]; AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC, USDA PROCESS VERIFIED PROGRAM 9 (2011), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5097560 [hereinafter *Verified Program*].

81. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., OFFICIAL LISTING OF APPROVED USDA PROCESS VERIFIED PROGRAMS 9 (2013), http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081908 [hereinafter *Approved Programs*], noting that the Humanely Raised Program claim is in accordance with Perdue's Best Practices, which include:

- Education, training, and planning
- Hatchery Operations
- Proper Nutrition and Feeding
- Appropriate Comfort and Shelter
- Health Care
- Normal Patterns of Behavior
- On-Farm Best Practices
- Catching and Transportation
- Processing

Humanely Raised Program claim is based on the principles outlined in the National Chicken Council's Animal Welfare Guidelines to ensure the proper care, management, and handling of broiler chickens. *See generally* NAT'L CHICKEN COUNCIL, ANIMAL WELFARE GUIDELINES AND AUDIT CHECKLIST FOR BROILERS, *available at* http://www.nationalchickencouncil.org/wp-content/uploads/2012/01/NCC-Animal-Welfare-Guidelines-2010-Revision-BROILERS.pdf.

82. *Approved Programs*, *supra* note 81, at 1.

83. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., ANIMAL RAISING CLAIMS 25-27 (2008), *available at* http://www.fsis.usda.gov/PDF/Animal_Raising_Claims_101408.pdf [hereinafter Transcript].

84. AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., NEVER EVER 3 (NE3) 2 (2009), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066028.

Approved USDA Process Verified Programs as complying with this program.[85]

Tyson's foray into the market for no antibiotic products is illustrative of the dilemmas posed by the current labeling system. But it is not an isolated incident. In conjunction with *Consumer Reports*' survey of consumers noted above, the organization also researched the availability of meat that was labeled in a manner indicating that antibiotics had not been used in its production.[86] Their researchers identified a plethora of labels in the marketplace, not all of which had been approved by the USDA and many of which had the potential to be confusing if not actually misleading.[87]

In response to the Tyson fiasco, USDA began a process of reviewing its policies with respect to animal raising claims in meat and poultry product labels.[88] The agency published a notice to solicit public input and held a public meeting.[89]

VII. TRUTHFUL AND NON-MISLEADING LABELING ABOUT ANTIBIOTICS IS NEEDED

Participants in the meeting represented stakeholders ranging from farmers to the Union of Concerned Scientists, poultry production companies to consumer protection interest groups.[90] Surprisingly, given the diverse backgrounds of the group, the comments were consistent in calling on the USDA to promulgate clear and coherent standards for animal raising claims, rather than approving such claims on a case-by-case basis, and for making the standards and the process more transparent.[91] Comments also highlighted the need for compliance with standards to be verified by either the AMS process verified program or certified third party

85. *See generally Approved Programs*, *supra* note 81.

86. CONSUMER REPORTS, *supra* note 16, at 3.

87. *Id.* at 3-4; *see also* Joanne Chen, *Meaty Confusion, Clarified,* HEALTH, Apr. 2006, at 161, *available at* http://www.keepantibioticsworking.com/new/KAW files/64_2_80789.pdf, Gosia Wozniacka, *Food Labels Confuse Consumers As 'Eco-Label' Options Multiply,* HUFFINGTON POST, Nov. 11, 2012, http://www.huffington post.fr/2012/11/12/food-labels-confusing_n_2116609.html.

88. Am. Veterinary Med. Ass'n, *supra* note 69.

89. Product Labeling: Use of the Animal Raising Claims in the Labeling of Meat and Poultry Products, 73 Fed. Reg. 60,228 (Oct. 10, 2008); FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., *supra* note 75, at slides 24-30; Transcript, *supra* note 83, at 16-17.

90. *See generally* Transcript, *supra* note 83.

91. *See generally id.*

auditors.[92] Participants in the meeting were clear that both producers and consumers suffer when false or confusing claims are put forth in the marketplace.[93]

We have seen that consumer demand affects supply in the context of antibiotic use. When a purchaser, such as McDonalds or Bon Appetit, adopts a policy precluding or restricting antibiotics usage, then their suppliers will follow suit.[94] Large purchasers have the leverage to negotiate requirements in supply contracts not only regarding how product is produced, but also rights to audit production facilities or take other steps to ensure compliance. Consumers, however, do not have these options. They are handicapped by a lack of adequate, trustworthy information to make the purchasing decision before them. The issue is complex, as consumers do not understand the potential risks and the tradeoffs, companies control information about production methods, and there is no way for consumers to verify claims being made.

The Tyson case highlights these dilemmas: Are ionophores antibiotics or not and why are they used? What is meant by "raised" without antibiotics"? Do other poultry companies use antibiotics? Which antibiotics impact antibiotic resistance in humans? Are there other risks associated with using antibiotics? Without an understanding of the scientific issues raised by these questions or the information about the production practices of the various producers offering products in the marketplace, consumers are unable to evaluate the superiority of a product. They cannot determine whether additional value is present (e.g., whether the differentiating factor really does make the product safer) or trust that the product is what it purports to be (i.e., that the company is telling the truth about its unique production practices). As a result of this "asymmetrical information," the consumer will not be willing to pay a premium for specially labeled products.[95] In turn, if consumers are

92. *Id.*

93. *Id.*

94. Weise, *supra* note 14.

95. *See generally* George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism,* 84 Q. J. ECON. 488 (1970). George A. Akerlof was awarded the Nobel Prize in Economics in 2001 jointly with A. Michael Spence and Joseph E. Stiglitz "for their analyses of markets with asymmetric information." *See* THE SVERIGES RIKSBANK PRIZE IN ECONOMIC SCIENCES IN MEMORY OF ALFRED NOBEL 2001, http://www.nobelprize.org/nobel_prizes/economics /laureates/2001/ (last visited Jan. 10, 2014). Akerlof's work was set forth in this article exploring the effect of asymmetrical information on markets in the context of the market for used cars. *See generally* Akerlof, *supra.* He noted that though some used cars were high quality and other used cars were "lemons," only sellers had access to the information needed to evaluate the quality of a given used car. *Id.* at 489. As a result,

unwilling to buy any "no antibiotic" products because their trust has been compromised, then companies will not choose to incur added expense to change production methods.[96]

The USDA has developed new guidance on such labeling, currently in the process of being cleared for release to the public, which will establish the minimum requirements for a "no antibiotics" label.[97] However, it will allow producers to make such a claim on a time limited basis, such as "within X days of finish."[98] Claims will not be required to be verified by third party certification.[99]

It remains to be seen what the new guidance will actually be. However, what has been suggested does not look promising. While it would establish a minimum standard for a "no antibiotics claim," it would not ensure such claims were verified, and would allow for the possibility of different versions of similar claims, some of which may not be meaningful in terms of having an appreciable difference in combating the spread of antibiotic resistance (for example, as to the number of days prior to finish that antibiotic usage is withdrawn). Likewise, no allowance seems to have been made for appropriate and beneficial uses of antibiotics supporting food safety or animal welfare, such as the use of antibiotics to treat diagnosed disease outbreaks under the supervision of a veterinarian.

It appears that FSIS will be proposing clear requirements for what "no antibiotics" means and that standard will likely specify that there be no *in ovo* injections of antibiotics and no usage of ionophores in raising poultry.[100] If this standard is adopted, it will be a step forward from the current state of the law. It will most likely be used by smaller operations that are set up to employ the husbandry and management practices conducive to protecting animal welfare and food safety at a premium price

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because buyers could not tell a "lemon" from a high-quality used car, they would be unwilling to pay a price representative of the value of the quality cars for fear that they might, in fact, be over-paying for a lemon. *Id.* As a result, sellers of good cars would be unlikely to sell in a market where they could not command a fair price and, eventually, the market would be made up entirely of lemons. *Id.* at 490. Akerlof saw government regulation mandating disclosure as one possible method for allowing buyers and sellers to reach the equilibrium of information necessary to allow the market to function properly. *Id.* at 488.

96. *See generally* Akerlof, *supra* note 95.

97. Letter from Thomas J. Vilsack, Secretary, U.S. Dep't of Agric., to Urvashi Rangan, Director of Consumer Safety and Sustainability, Consumer Reports (July 6, 2012), *available at* http://www.consumersunion.org/pdf/USDA_meat_ antibiotics _Ltr_712.pdf.

98. *Id.*

99. *Id.*

100. *Id.*

as well as larger producers who can dedicate a portion of their operations to these practices. For larger producers, if antibiotic treatment becomes necessary to respond appropriately to disease outbreaks, they have the option to re-direct treated flocks to conventional markets.

Nevertheless, verification is essential. As FSIS's experience with Tyson illustrates, relying on company-provided information to establish the appropriateness of a claim is insufficient. Whether this inability is as a result of intentional misrepresentation by an applicant or more benign causes, FSIS will not always be able to determine whether a claim is, in fact, truthful and not misleading. There may be confusion arising from a lack of standardized terms, or from a failure by FSIS to ask for additional information or clarification regarding an applicant's practices or procedures. In any case, onsite verification is needed to overcome this problem. Currently, FSIS does not have the authority to compel companies to obtain third-party verification nor the jurisdiction to conduct such verification procedures directly. Accordingly, legislative action would be required to enact this requirement. However, obtaining approval from Congress for such regulatory authority may well be easier than obtaining the approval of more sweeping legislation dealing with antibiotic resistance, such as PAMTA. PAMTA would immediately restrict the production practices of the majority of meat and poultry producers, potentially having an adverse impact on the cost of consumer products with a corresponding effect on sales, production levels, jobs, and grower contracts, as well as, ultimately, company profits and share prices. By contrast, authorizing FSIS to require verification of animal raising claims would involve merely an additional regulatory burden on companies choosing to adopt a voluntary marketing label on their products. This should make it more palatable to members of Congress and, therefore, more likely to be enacted. In addition, a similar program has already been successfully put into practice in the National Organic Program, allowing companies to use either third party certification or the AMS "Process Verified" program.[101]

In addition, the diversity of language that is likely to arise as a result of FSIS evaluating and approving claims on a case-by-case basis, means that the confusion associated with labeling will remain, as well as the potential for misleading claims and misinformation. As with Tyson, labeling that indicates a distinction that is not scientifically meaningful or

101. 7 C.F.R. § 205; AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC., NATIONAL ORGANIC PROGRAM, http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPNationalOrganicProgramHome&acct=AMSPW (last visited Jan. 10, 2014).

advertises a practice that does not differ materially from that of the industry in general are or have the potential to be misleading. By way of example, is there scientific evidence that treating food producing animals with antibiotics for a portion of their lives but then removing them from the drugs for a specified period before processing would make an appreciable difference in the levels of antibiotic-resistant microorganisms such animals carried? By law, food producing animals are already required to be removed from antibiotics for a mandated withdrawal period sufficient to ensure no antibiotic drug residue remains in their tissues, so a label highlighting such a practice must not imply that the purpose of such extended time period is related to residues, or suggest that this practice is superior to that of competitors in removing residues.[102] If there is no evidence that fewer antibiotic-resistant microorganisms are present in such animals than in others which are merely removed from antibiotics for the mandatory withdrawal period, then the claim would be misleading in implying superiority in this respect as well.

In the Tyson case, the court found, based on consumer survey data provided by the plaintiff, that "[p]laintiffs have demonstrated that consumers are in fact misled by [Tyson's] advertisements," even the qualified version stating "raised without antibiotics that impact antibiotic resistance in humans."[103] Given the difficulty with this language, other

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102. The FDA is responsible for establishing tolerances for animal drugs under the Federal Food, Drug, and Cosmetic Act. Under the authority of the Poultry Products Inspection Act, as well as the Federal Meat Inspection Act and the Egg Products Inspection Act, and as spelled out in the National Residue Program, FSIS monitors chemical residues in poultry, meat, and egg products to ensure they fall within the FDA-established tolerances. *See generally* FOOD SAFETY & INSPECTION SERV., U.S. DEP'T OF AGRIC., NATIONAL RESIDUE PROGRAM 2010 SCHEDULED SAMPLING PLANS (2011), *available at* http://www.fsis.usda.gov/PDF/2010_blue_book.pdf; OFFICE OF PUB. HEALTH SCI., U.S. DEP'T OF AGRIC., 2008 FSIS NATIONAL RESIDUE PROGRAM DATA (2009), *available at* http://www.fsis.usda.gov/PDF/2008_Red_Book.pdf.

103. Sanderson Farms, Inc. v. Tyson Foods, 547 F. Supp. 2d 491, 503 (D. Md. Apr. 22, 2008). Plaintiff's expert, Professor Mazis, conducted a consumer survey regarding the advertising language (which mirrored the labeling) used by Tyson in its new product line. *Id.* at 498-99. Based on the survey results, he reached the following conclusions:

> First, the individuals that participated in the survey largely responded the same way to the qualified "Raised Without Antibiotics that impact antibiotic resistance in humans" claim as they did to the unqualified "Raised Without Antibiotics" claim. Second, participants viewed both the unqualified and qualified claims as implying that Tyson's chicken is safer and healthier than competitors' chicken. *Id.* at 499.

qualifications or nuanced distinctions are likely to be similarly confusing, if not misleading. Terms like subtherapeutic, therapeutic, growth promotion, prevention, prophylaxis, or control do not have standard definitions and there is disagreement even within the industry and scientific community as to how to define and monitor the use and purpose of antibiotics. For example, in the poultry industry, would it be possible to assert that antibiotics are used solely for therapeutic uses given the practice of treating an entire flock when an outbreak is detected in some birds? Some birds within a flock may be treated for disease while the rest of the flock is considered at risk and treated as well. Would such use necessarily be both therapeutic and preventative? How would such a determination be made? Without an in depth understanding of husbandry practices, the consumer would not be able to appreciate the issues surrounding such use. Therefore, any use of these terms in labeling should not be permitted.

Clearly, evaluating differing claims regarding antibiotics requires a knowledge and understanding of complex scientific issues with respect to which the scientific community is, as yet, unable to agree. Accordingly, case-by-case approval of claims should give way to a limited set of acceptable claims, designed to convey information and allow consumers to choose between reasonable alternatives.

One of those alternatives should take into account the issue of animal welfare and allow consumers to support the continued move to more responsible uses of antibiotics in the industry that is beginning to take place, with the assurance that animal welfare and food safety issues will not be compromised during the transition. Certainly, the industry is implementing improvements to husbandry and management practices that make routine use of antibiotics for disease prevention less necessary.[104] However, in the context of large-scale animal production, it is not possible to completely eliminate disease outbreaks and alternative therapies are not widely available, if at all.[105] If companies were unable to market products

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In addition, the court noted that, based on a series of open-ended questions asked to consumers about the advertising, covering both the original "Raised Without Antibiotics" claim and the later, qualified, "Raised Without Antibiotics That Impact Antibiotic Resistance in Humans" claim, "consumers process [both] messages in the same fashion. In short, consumers believe that there are no antibiotics given to Tyson's chickens." *Id.* at 499-500.

104. *Video: Poultry Insight: What Would Happen if We Stop Using Antibiotics All Together in the Poultry Industry?,* WORLD POULTRY, Nov. 13, 2012, http://www.worldpoultry.net/Home/General/2012/11/Poultry-Insight-Why-and-when-are-antibiotics-used-in-poultry-production-1104566W/ [hereinafter *Poultry Insight II*].

105. *Id.*; *see also* Michael J. Crumb, *Organic Livestock: Few U.S. Vets Trained To Treat Organic Livestock,* SALON, Jan. 4, 2012, http://www.salon.com/2012/01/04/few_us_vets_trained_to_treat_organic_livestock_2/.

from animals treated with antibiotics, the concern is that treatment would be withheld or delayed, with animal suffering or poorer food safety compliance being the result.[106] Judicious use of antibiotics for treatment, under the supervision of a veterinarian, represents a step in the right direction for purposes of combating antibiotic resistance, and companies complying with this standard should be able to inform consumers of their policies and practices. In addition, adopting this standard as an acceptable raising claim would not only help along the changes already underway in the market but would align with the process unfolding more slowing at FDA. By permitting companies to label their products "judicious use of antibiotics only," or words to that effect, companies should be able to market a product at a somewhat higher price than products unable to make this claim. This would incentivize them to adopt and comply with the voluntary principles set forth in FDA's Guidance for Industry #209, as the additional market price would compensate for the added costs associated with the more labor intensive husbandry and management practices required to comply with these principles.[107]

Consumers, in turn, would have the option of purchasing conventionally raised products at the lowest available price, products "raised without antibiotics," presumably offered at the highest price (other than organic products, which impose a variety of requirements on the raising of the animal in addition to prohibiting use of antibiotics at any time in the lifecycle), or products complying with the FDA's voluntary principles for the judicious use of antibiotics, which would presumably be offered at a price somewhere in between.

In addition to allowing for the free flow of information that should positively impact buying and selling decisions in the market, this robust, mandatory labeling scheme can also serve a consumer education role. By aligning FSIS and AMS labeling guidelines regarding antibiotics with the FDA's current thinking on judicious antibiotic usage, the agencies can present a unified message regarding the issue and better inform the public

106. *See generally* Letter from Members of the Coalition for Animal Health to Nancy Pelosi & Steny Hoyer, U.S. House of Rep. (July 20, 2009), *available at* http://www.meatami.com/ht/a/GetDocumentAction/i/51781; JOINT AVMA-FEDERATION OF VETERINARIANS OF EUROPE STATEMENT ON RESPONSIBLE AND JUDICIOUS USE OF ANTIMICROBIALS, https://www.avma.org /KB/Policies/Pages/Joint-AVMA-Federation-of-Veterinarians-of-Europe-Statement-on-Responsible-and-Judicious-Use-of-Antimicrobials.aspx (last visited Jan. 11, 2013); *Video: Poultry Insight: Why and When are Antibiotics Used in Poultry Production?,* WORLD POULTRY, Nov. 13, 2012, http://www.worldpoultry.net/Home/General /2012/11/Poultry-Insight-Why-and-when-are-antibiotics-used-in-poultry-production-1104566W/.

107. Ctr. for Veterinary Med., U.S. Dep't of Health & Human Servs., *supra* note 3, at 20.

of the different roles each agency plays in addressing the public health issues related to it.

VIII. CONCLUSION

This article has provided a brief overview of the myriad and complex issues related to the role the agricultural industry and, specifically, poultry companies and producers, play in the development of antibiotic resistant bacteria. As with any complex problem, there is no one solution—no magic pill—that will effect a cure. The FDA must protect the efficacy of antibiotics and other antimicrobial drugs on a case-by-case basis through its jurisdiction over new animal drugs. As new evidence emerges, the withdrawal of drugs or restriction of their use may be appropriate as well, but the process to do so is necessarily time consuming and demanding on the resources of the agency. As such, realistically, these changes can be instituted only at a slow pace.

Even while we wait for FDA to take action, industry may be spurred to action by the demands and preferences of the consumer, provided they are able to recoup the added cost of transition and innovation and consumers have the confidence needed in the improved product to pay more for it. If these incentives are reinforced by appropriate regulation enforced by FSIS, then before the FDA is able to reconsider all of the existing animal drug approvals, the industry's reliance on antibiotics in poultry production may have flown the coop.