

# **BEYOND THE FOOD WE EAT: ANIMAL DRUGS IN LIVESTOCK PRODUCTION**

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## I. INTRODUCTION

The Dust Bowl seemed to sweep down upon an unsuspecting people from out of nowhere. Yet now, when we look back, we wonder how we could have been so foolish as to allow the reckless and ruthless plowing of so much of the Plains.<sup>1</sup>

Today, U.S. livestock production relies heavily on antimicrobials, hormones, and a variety of other pharmaceuticals. A number of concerns have been raised about these developments, including the presence of drug residues in meat and the impact of these production techniques on animal welfare. This article, however, focuses particularly on an issue that has not received attention—the potential environmental impact associated with this pervasive use of pharmaceuticals. It questions whether our use of drugs in livestock production, in combination with the concentration of production, can be likened to farmers’ naïve plowing of the Plains in the 1930’s. Like

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1. See generally TIMOTHY EGAN, *THE WORST HARD TIME: THE UNTOLD STORY OF THOSE WHO SURVIVED THE GREAT AMERICAN DUST BOWL* (Anton Mueller ed., 2006) (relating the problems of people who lived through the Great Depression’s dust bowl). Appreciation is extended to Associate Dean Don Judges for his thoughts and inspiration regarding the connections between the dust bowl disaster and issues of environmental consequence today.

those farmers, we have beneficially increased the volume of what we produce. But is our dependence on animal drugs reckless and ruthless when viewed in terms of the long-term environmental consequences? Are we on our way to creating a new and different ecological disaster? Will we look back and wonder how we could have been so foolish?

This article will set the stage by providing an overview of the U.S. livestock industry. It will emphasize how the industry has changed in the last several decades, noting the intensification of individual production facilities and the concentration of the industry in certain regions. These changes have already had significant environmental impacts and additional risks will present going forward.

The article will proceed to examine the industry's overall dependence on pharmaceuticals. There may be a passionate young movement toward antibiotic-free, hormone-free, and organic production. Nevertheless, the industry standard and the vast majority of the meat and poultry production in the United States still depends on the use of antibiotics, hormones, beta-agonists, and other drugs used to sustain production levels.<sup>2</sup> These drugs, in particular the antibiotics, enable intense confinement of animals in mega-facilities that house thousands of hogs and tens of thousands of chickens.<sup>3</sup> The two billion animals that are raised in the United States each year produce over 1 billion tons of manure—manure that contains residues of many of the drugs these animals were given.<sup>4</sup>

Following this examination, the article will describe the regulatory process in place for the approval of animal drugs and argue that this process is insufficient and ineffective. As will be shown, more robust regulation faces significant impediments,

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2. See Lauren Orrico, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria*, 27 J.L. & HEALTH 259, 263–64 (2014) (discussing that “cramped conditions [on factory farms are] ripe for bacterial epidemics” and that as a result, factory farms depend on antibiotics to combat “the spread of disease among animals kept in close quarters”).

3. See *id.* (noting how animal feed containing antibiotics, hormones, and other materials is used to maintain high concentrations of animals in small areas and in unsanitary conditions.)

4. See OCTAVIA CONERLY & LESLEY VAZQUEZ CORIANO, U.S. ENVTL. PROT. AGENCY, EPA 820-R-13-002 LITERATURE REVIEW OF CONTAMINANTS IN LIVESTOCK AND POULTRY MANURE AND IMPLICATIONS FOR WATER QUALITY 5 (2013), available at <http://water.epa.gov/scitech/cec/upload/Literature-Review-of-Contaminants-in-Livestock-and-Poultry-Manure-and-Implications-for-Water-Quality.pdf> (noting that the contaminants associated with manure can enter the environment through storage, handling, and land application).

including Congressional support for drug use in the livestock industry. This article concludes, that environmental advocates can confront these headwinds with strategies for change—by reordering industry priorities, increasing transparency, and reevaluating our means of production. These strategies can help us to prevent another ecological disaster.

## II. OVERVIEW OF U.S. LIVESTOCK PRODUCTION

According to a recent U.S. Department of Agriculture (USDA) Economic Research Service report, the livestock industry in the United States has “undergone a series of striking transformations” in recent decades.<sup>5</sup> Fifty years ago, the majority of livestock were produced on diversified independent farms—farms that were diverse in both the types of livestock and the variety of crops raised.<sup>6</sup> Today, the majority of the livestock raised in the United States are produced on large specialized farms.<sup>7</sup>

Specialization in this context may mean not only that farms are limited to a single species of animal, but that they raise that species only during a single stage of its life. Large livestock operations “increasingly specialize in a single stage of livestock production, such as hog finishing,”<sup>8</sup> with animals shifting from one specialized unit to another throughout their life cycle.<sup>9</sup> Specialization is further evident in the careful breeding of one genetic line that meets processor expectations.<sup>10</sup>

There has also been a dramatic increase in the size of livestock operations. We have more than doubled the number of livestock and poultry produced, a figure that now exceeds over 2 billion head of livestock per year. This development has coincided with an 80% decrease in the number of farms. Most livestock and poultry are no

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5. JAMES M. MACDONALD & WILLIAM D. MCBRIDE, U.S. DEP’T. AGRIC., ECON. RESEARCH SERV., EIB- 43, THE TRANSFORMATION OF U.S. LIVESTOCK AGRICULTURE: SCALE, EFFICIENCY, AND RISKS iii (2009), *available at* <http://www.ers.usda.gov/media/184977/eib43.pdf> [hereinafter TRANSFORMATION].

6. JAMES M. MACDONALD ET AL., U.S. DEP’T. AGRIC., ECON. RESEARCH SERV., ERR-152, FARM SIZE AND THE ORGANIZATION OF U.S. CROP FARMING 31 (2013), *available at* <http://www.ers.usda.gov/media/1156726/err152.pdf>.

7. *Id.*

8. TRANSFORMATION, *supra* note 5, at 1.

9. *See id.* at 8 (explaining that most market hogs come from “feeder-to-finish” operations that involves pigs cycling through all three stages of hog production).

10. *See id.* at 20 (noting that “controlling the genetics of their pigs and chicks” is one of the ways that processors assure uniformity to maintain processing efficiencies).

longer raised on pasture, but in confinement, allowing for greater control over the animals and larger numbers of animals per facility.<sup>11</sup>

The EPA's definition of a "Concentrated Animal Feeding Operation" (CAFO) for purposes of environmental regulation represents an attempt to accurately characterize these changes in the livestock industry. An "Animal Feeding Operation" (AFO) is defined to be one where animals are confined and fed for 45 days or more in any 12-month period without grazing or foraging access.<sup>12</sup> A CAFO is an AFO that has been designated as a point source for water pollution under the Clean Water Act largely because of its size, as measured by the number of animals in the facility.<sup>13</sup> The concept, as well as the regulatory definition of a CAFO, embodies the dominant approach to livestock production today. A CAFO is "a production process that concentrates large numbers of animals in relatively small and confined spaces, and that substitutes structures and equipment (for feeding, temperature controls, and manure management) for land and labor."<sup>14</sup>

This "production process"—the transformed system of livestock production in the United States—is not based solely on economies of scale. One of the technologies integral to this transformation is the use of drugs to enhance growth,<sup>15</sup> alter the animals' physiology,<sup>16</sup> and provide short-term disease prevention while animals are under stress.<sup>17</sup> This article will now look at current production practices within four of the major livestock industries—the swine industry, the poultry industry (focusing on broiler production), the dairy industry, and the beef cattle industry—to set the stage for examining drug use within these industries and the resulting environmental concerns.

### A. *The Swine Industry*

As a USDA report from 2008 noted, "[t]oday's hog sector bears little resemblance to the one that existed 15 years ago . . . . There are

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11. *See id.* at 1 (describing how livestock are fed in confined areas with automated feed milling and delivery, grouped according to certain characteristics for feed formulas).

12. 40 C.F.R. § 122.23(b)(1)(i) (2014).

13. 40 C.F.R. § 122.23(b)(2).

14. TRANSFORMATION, *supra* note 5, at 3.

15. *Id.* at 32.

16. Alberto Alemanno & Giuseppe Capodiecì, *Testing the Limits of Global Food Governance: The Case of Ractopamine*, 3 EUR. J. OF RISK REG. 2 (2012) (describing Ractopamine as causing an "increase muscle leanness by inducing a redistribution of fat to muscle tissue in certain food animal species such as pigs and cattle").

17. TRANSFORMATION, *supra* note 5, at 32.

fewer hog farms, and the average number of hogs per farm has increased substantially.”<sup>18</sup> In 1992, there were more than 240,000 farms that raised hogs. By 2004, less than 70,000 hog farms remained—a drop of over 70 percent. Yet, the overall size of the U.S. hog inventory “remained stable at about 60 million head.”<sup>19</sup>

Data from the 2012 Agricultural Census confirms the continued concentration of hog production on large farms. Hog and pig sales in 2012 totaled \$4.4 billion, up 24.6 percent from the last census in 2007.<sup>20</sup> However, “[e]ven as the value of sales went up, the number of farms with hog and pig sales declined by 25 percent.”<sup>21</sup> Farms that specialized in hog production declined by 29%.<sup>22</sup> The bottom line is that more hogs are raised on fewer, larger specialized farms.

Large hog facilities present complex manure management problems. Data from the 2007 census were used to estimate that the hog industry alone generates over 111 million tons of manure per year.<sup>23</sup>

Swine are typically housed over slatted floors, allowing manure to be washed down and routinely flushed out of the housing facility. Swine manure may be flushed to an underground pit (57% of operations), or another storage area like a manure pile (20% of operations).<sup>24</sup>

In addition to concentration into larger facilities, these hog farms are now concentrated regionally. Regional concentration exacerbates manure management problems as states contend with clusters of large confinement facilities. Iowa, the top hog producing state, was responsible for 27 percent of swine production in 2007.<sup>25</sup> Iowa hogs

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18. NIGEL KEY & WILLIAM D. MCBRIDE, U.S. DEP’T AGRIC., ECON. RESEARCH SERV., TECHNOLOGY, LARGER FARM SIZE INCREASED PRODUCTIVITY ON U.S. HOG FARMS 17, AMBER WAVES (Apr. 2008), available at <http://www.ers.usda.gov/amber-waves/2008-april/technology,-larger-farm-size-increased-productivity-on-us-hog-farms.aspx#.VRLcu8ZX80k>.

19. *Id.* at 18.

20. U.S. DEP’T. AGRIC., NAT’L AGRIC. STATISTICS SERV., ACH12–4, 2012 CENSUS HIGHLIGHTS, HOG AND PIG FARMING 1 (2014), available at [http://www.agcensus.usda.gov/Publications/2012/Online\\_Resources/Highlights/Hog\\_and\\_Pig\\_Farming/#industry](http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Hog_and_Pig_Farming/#industry) [hereinafter HOG AND PIG FARMING].

21. *Id.*

22. *Id.*

23. CONERLY & CORIANO, *supra* note 4, at 7, tbl.2-2.

24. *Id.* at 9 (citing Richard.W. Gullick et al., AWWA RESEARCH FOUND. & UNITED STATES ENVTL. PROT. AGENCY., SOURCE WATER PROTECTION FOR CONCENTRATED FEEDING OPERATIONS: A GUIDE FOR DRINKING WATER UTILITIES (2007), available at <http://waterrf.org/PublicReportLibrary/91159.pdf>).

25. *Id.* at 7, tbl.2-2.

and pigs produced over 31 million tons of manure that year.<sup>26</sup> North Carolina, the second-largest hog-producing state in the country, raised 15.5% of U.S. swine, resulting in over 17 million tons of hog manure.<sup>27</sup> The third-ranked state, Minnesota, was responsible for just over 11% of national production and contended with more than 12.7 million tons of hog manure in 2007 alone.<sup>28</sup> Farms in these three states alone “accounted for 55 percent of the value of U.S. hog and pig sales and 56 percent of the 66 million hog and pig end-of-year inventory in 2012.”<sup>29</sup> Unfortunately, concentration of production leads to a concentration of waste outputs as well. This highly-localized inundation of manure poses acute environmental risks.

### *B. The Poultry Industry*

The poultry industry follows a similar pattern. The 2012 Census of Agriculture reported that U.S. poultry and egg sales totaled \$42.8 billion in 2012.<sup>30</sup> This was a 15% increase since 2007.<sup>31</sup> Yet, the Census also showed that the number of farms with poultry and egg sales decreased by 8%.<sup>32</sup> Large, specialized farms accounted for 98% (\$42.0 billion) of sales in 2012.<sup>33</sup>

The poultry business can be divided into production categories, with chicken production dwarfing the production of other fowl such as turkey, ducks, quail, geese, and others. The 2012 Census of Agriculture estimates the U.S. inventory of chickens at 1,506,300,000.<sup>34</sup> In contrast, the turkey inventory was estimated to be just over 100 million.<sup>35</sup>

Chicken production can be further divided into subcategories based on use: broilers and other chickens raised for meat, laying hens (including both those raised to produce table eggs and those raised to produce pullets for broiler production); and pullets (young chickens

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26. *Id.*

27. *Id.*

28. *Id.*

29. HOG AND PIG FARMING, *supra* note 20, at 1.

30. USDA, NAT'L AGRIC. STATISTICS SERV., ACH12-18, 2012 CENSUS HIGHLIGHTS, POULTRY AND EGG PRODUCTION 1 (2015), available at [http://www.agcensus.usda.gov/Publications/2012/Online\\_Resources/Highlights/Poultry/Poultry\\_and\\_Egg\\_Production.pdf](http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Poultry/Poultry_and_Egg_Production.pdf) [hereinafter POULTRY AND EGG PRODUCTION].

31. *Id.*

32. *Id.* at 2.

33. *Id.*

34. *Id.*

35. *Id.*

raised to replace the layers).<sup>36</sup> A facility is typically designed to accommodate only one of these categories.<sup>37</sup>

### 1. Broiler Production

Broiler production is vertically integrated, with poultry processors controlling all aspects of production.<sup>38</sup> While diversified farms of the previous generation had “chicken coops”—i.e., small structures with access to a yard or run—in today’s commercial chicken production, housing for a broiler’s short life is typically in a 20,000 square foot rectangular building that is approximately 40 feet wide and 500 feet long.<sup>39</sup> A house this size is used to produce 115,000–135,000 birds in a year through confined growing conditions and one-flock-after-another production.<sup>40</sup> Farmers are encouraged to build these houses in pairs, doubling annual production.<sup>41</sup> Now, few growers still produce fewer than 100,000 broilers per year. In fact, the production locus has grown from 300,000 broilers in 1987 to 520,000 in 2002, to 600,000 by 2006.”<sup>42</sup>

Poultry manure accumulates inside the broiler house, mixed with whatever bedding is provided.<sup>43</sup> Broiler chickens in the United States produced over 52.7 million tons of manure in 2007.<sup>44</sup>

Broiler production is concentrated along the Atlantic coast from Delaware south to Georgia, and in the southern states of Alabama, Mississippi, and Arkansas.<sup>45</sup> Three southeastern states lead the nation—Georgia, with 14.7% of U.S. broilers, Arkansas, with 12.6%, and Alabama, with 11.1%.<sup>46</sup> As in the hog industry, this means a lot of manure concentrated in a handful of states. In 2007, Georgia was responsible for 7.7 million tons of manure, Arkansas for over 6.6 million tons, and Alabama for over 5.8 million tons.<sup>47</sup>

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36. *Id.*

37. *Id.*

38. TRANSFORMATION, *supra* note 5, at 6 fig.1.

39. *Id.* at 18.

40. *Id.*

41. *Id.* (referencing measurements from the 2006 ARMS broiler survey).

42. *Id.* at 7.

43. CONERLY & CORIANO, *supra* note 4, at 10.

44. *Id.* at 8.

45. *Poultry & Eggs: Background*, U.S. DEP’T. AGRIC., ECON. RESEARCH. SERV., <http://www.ers.usda.gov/topics/animal-products/poultry-eggs/background.aspx> (last updated May 28, 2012).

46. CONERLY & CORIANO, *supra* note 4, at 8.

47. *Id.*



## 2. Egg Production

The USDA National Agricultural Statistics Service estimates that the U.S. egg industry produced over 95 billion eggs in 2013.<sup>48</sup> The most recent monthly report estimates that 8.63 billion eggs were produced in the United States in December 2014 alone, an amount that is up 3% from last year.<sup>49</sup>

The egg industry has become very concentrated and operates under a corporate model. According to the American Egg Board,<sup>50</sup> in 1994, approximately 350 companies had layer flocks of 75,000 hens or more.<sup>51</sup> Today, that number has declined to 175 companies with flocks of 75,000 hens or more.<sup>52</sup> However, these 175 companies “represent about 99 percent of all the hens in the United States.”<sup>53</sup> Of these, there are “approximately 66 egg producing companies with 1 million-plus hens.”<sup>54</sup> These companies alone control approximately 87 percent of total production. Seventeen companies each have greater than 5 million hens.<sup>55</sup>

It is estimated that there were 306 million layers in the United States at the end of 2014.<sup>56</sup> Most layers are housed in elevated cages, allowing manure to accumulate below or drop onto a conveyor belt that removes manure from the building.<sup>57</sup> Manure is typically washed from the housing facility to a storage pit.<sup>58</sup> Estimates of total manure

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48. USDA NAT'L AGRIC. STATISTICS SERV., CHICKENS AND EGGS 2013 SUMMARY 7 (2014), available at <http://usda.mannlib.cornell.edu/usda/nass/ChickEgg//2010s/2014/ChickEgg-02-27-2014.pdf>.

49. USDA NAT'L AGRIC. STATISTICS SERV., CHICKENS AND EGGS DECEMBER REPORT 4 (2015), available at <http://usda.mannlib.cornell.edu/usda/nass/ChicEggs//2010s/2015/ChicEggs-01-23-2015.pdf>.

50. The American Egg Board is an organization funded through the congressionally created “checkoff” program that assesses a charge from companies with more than 75,000 layer chickens in the United States. Egg Research and Consumer Information Act, 7 U.S.C. §§ 2701–2718 (2012). The AEB is run by a board that is appointed by the Secretary of Agriculture. *About AEB*, AM. EGG BD., <http://www.aeb.org/about-aeb/about> (last visited Mar. 1, 2015).

51. *Industry Overview*, AMERICAN EGG BD., <http://www.aeb.org/farmers-and-marketers/industry-overview> (last visited Mar. 1, 2015) [hereinafter *Industry Overview*].

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. CONERLY & CORIANO, *supra* note 4, at 10 (citing RICHARD.W. GULLICK ET AL., AWWA RESEARCH FOUND. & UNITED STATES ENVTL. PROT. AGENCY., SOURCE WATER PROTECTION FOR CONCENTRATED FEEDING OPERATIONS: A GUIDE FOR DRINKING WATER UTILITIES 1 (2007), available at <http://waterrf.org/PublicReportLibrary/91159.pdf>).

58. *Id.* (referencing Zhao et al., *Hormones in Waste from Concentrated Animal Feeding Operations*, in FATE AND TRANSPORT OF PHARMACEUTICALS IN THE ENVIRONMENT AND

production associated with egg production are difficult to find. However, the USDA estimates that layer chickens produce approximately 60.5 lbs. of manure per day per 1000 lbs. of animal unit.<sup>59</sup> Like each of the previously discussed industries, egg production is regionally concentrated. Five states—Iowa, Ohio, Indiana, Pennsylvania, and Texas—represent approximately 51% of all U.S. egg production,<sup>60</sup> and thus find themselves responsible for a majority of the nation's chicken waste.

### C. *The Cattle and Dairy Industries*

The beef cattle and dairy industries are obviously related; both depend on cattle and both contribute to the supply of beef available to consumers. They are, however, profoundly different in structure and production methods.

#### 1. The Dairy Industry

The dairy industry has also exhibited a dramatic transformation with fewer farms and a production shift to farms that are significantly larger in size. The 2012 Census of Agriculture estimates that there were 9.3 million milk cows in the United States at the end of 2012.<sup>61</sup> This was down 0.2% from 2007, although the number of farms involved declined by 8% during that time period.<sup>62</sup>

This trend has been ongoing for some time. Between 1997 and 2007, dairy production remained relatively stable, while the number of dairy farms in the United States dropped by nearly 50%.<sup>63</sup> Recent USDA estimates indicate that the number of dairy farms fell by nearly 60% over the past 20 years, even as total milk production increased by one-third.<sup>64</sup> The production locus or midpoint (the measurement of the size of a farm at which half of production would

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WATER TREATMENT SYSTEMS (Diana S. Aga, ed., 2008)).

59. *Animal Manure Management*, U.S. DEP'T AGRIC., NATURAL RES. CONSERVATION SERV. (1995), [http://www.nrcs.usda.gov/wps/portal/nrcs/detail//?cid=nrcs143\\_014211#table1](http://www.nrcs.usda.gov/wps/portal/nrcs/detail//?cid=nrcs143_014211#table1).

60. *Industry Overview*, *supra* note 51.

61. USDA NAT'L. AGRIC. STATISTICS SERV., ACH12-14, 2012 CENSUS HIGHLIGHTS, DAIRY CATTLE AND MILK PRODUCTION 1 (2014), *available at* [http://www.agcensus.usda.gov/Publications/2012/Online\\_Resources/Highlights/Dairy\\_Cattle\\_Milk\\_Prod/Dairy\\_Cattle\\_and\\_Milk\\_Production\\_Highlights.pdf](http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Dairy_Cattle_Milk_Prod/Dairy_Cattle_and_Milk_Production_Highlights.pdf).

62. *Id.*

63. CONERLY & CORIANO, *supra* note 4, at 11.

64. James MacDonald & Doris Newton, *Milk Production Continues Shifting to Large-Scale Farms*, U.S. DEP'T AGRIC., ECON. RESEARCH SERV. (Dec. 1, 2014), <http://www.ers.usda.gov/amber-waves/2014-december/milk-production-continues-shifting-to-large-scale-farms.aspx#.VM7MOFXF-I1>.

come from larger farms and half from smaller) shifted dramatically from 80 cows in 1987 to 275 by 2002.<sup>65</sup> By 2012 it was 900 cows, and “farms with at least 1,000 cows accounted for 49 percent of all cows.”<sup>66</sup>

The large size and active metabolism of a lactating cow result in a tremendous volume of associated waste. It is estimated that, on average, a lactating dairy cow will generate 50 liters of manure, including urine, every single day.<sup>67</sup> The University of Wisconsin Agricultural Extension Service developed a chart for farmers to compute manure production from their herd. For one average 1400 lb. dairy cow, the chart estimates that 21.9 tons of manure per year will be produced.<sup>68</sup>

Dairy production is concentrated in California and Wisconsin; together these states account for a third of U.S. dairy sales.<sup>69</sup> The top ten states account for nearly three-fourths of sales.<sup>70</sup> Following California and Wisconsin, these states, in order of production, are New York, Idaho, Pennsylvania, Texas, Minnesota, Michigan, New Mexico, and Washington.<sup>71</sup>

## 2. The Beef Cattle Industry

The United States boasts “the world’s largest fed-cattle industry,” and is also the “world’s largest producer of beef.”<sup>72</sup> It is known for its grain-fed beef for domestic and export markets.

Feedlots provide for “finishing” and preparing cattle for slaughter. There, they are fed a high-energy ration that is 70–90% grain and protein concentrate.<sup>73</sup> They are usually in the feedlot for about 140 days, with variations between 90 and 300 days reported.<sup>74</sup> Their average weight gain is 2.5–4 pounds per day based on 6 pounds of feed per pound of gain.<sup>75</sup>

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65. TRANSFORMATION, *supra* note 5, at 5–6.

66. MacDonald & Newton, *supra* note 64.

67. CONERLY & CORIANO, *supra* note 4, at 5.

68. UNIV. OF WIS. EXTENSION SERV., HOW MUCH FERTILIZER DO YOUR ANIMALS PRODUCE? 1, available at <http://learningstore.uwex.edu/assets/pdfs/a3601.pdf> (last visited March 2, 2015).

69. U.S. DEP’T AGRIC., NAT’L. AGRIC. STATISTICS SERV., *supra* note 61, at 1.

70. *Id.*

71. *Id.*

72. *Cattle and Beef, Cattle Background*, USDA ECON. RESEARCH SERV. (May 26, 2012), <http://www.ers.usda.gov/topics/animal-products/cattle-beef/background.aspx> [hereinafter *Cattle and Beef*].

73. *Id.*

74. *Id.*

75. *Id.*

Today, feedlots represent the concentrated and the “industrialized stage” of the cattle sector.<sup>76</sup> Again, however, this is a change from prior production practices. Individual farms and small local feedlots were the norm until at least the mid-1960s. “In 1964, feedlots with capacities of less than 1,000 head handled over 60 percent of U.S. fed-cattle marketings.”<sup>77</sup>

Since that time, there has been a marked shift of the industry toward large commercial feedlots, particularly those located in the Great Plains and the West. These feedlots house tens of thousands of cattle at a time, purchase feed ingredients, maintain their own feedmills, and “employ nutritionists, veterinarians, and sales and management staff.”<sup>78</sup>

Feedlots with capacity for 1,000 head or more now market between 80 and 90% of fed cattle.<sup>79</sup> Feedlots with capacity for 32,000 head or more sell approximately 40% of the fed cattle market.<sup>80</sup> “The largest feedlots can feed 100,000 cattle at a time. Some are owned by meatpackers, some are part of larger diversified firms, and others are specialized cattle feeding businesses, sometimes with a feed production enterprise as well.”<sup>81</sup>

#### *D. Summary: Livestock Production Today*

The U.S. livestock and poultry industry produces over 2 billion animals per year.<sup>82</sup> Most of these animals are being raised in conditions and in concentrations that are relatively novel, as the industry has seen a rapid and dramatic transformation.<sup>83</sup> Within just the last fifty years, we have moved from production on diversified and dispersed smaller farms to large-scale industrial-style production that both concentrates animals in confined facilities, and that are concentrated themselves in specific regions of the country.<sup>84</sup> This can be said with regard to each major category of livestock that we produce.<sup>85</sup>

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76. TRANSFORMATION, *supra* note 5, at 12.

77. *Id.*

78. *Id.*

79. *Cattle and Beef*, *supra* note 72.

80. *Id.*

81. TRANSFORMATION, *supra* note 5, at 12.

82. CONERLY & CORIANO, *supra* note 4, at 1.

83. *Id.*

84. *Id.*

85. *Id.*

Livestock and poultry produced in the United States generate over one billion tons of manure each year.<sup>86</sup> In reasonable quantities, and applied to land appropriately, manure can improve soil quantity and provide essential nutrients for plant growth.<sup>87</sup> However, when concentrated in large quantities, manure can also degrade surface water quality, pollute the air, and spread disease.<sup>88</sup> Most concerns about concentrated livestock production and manure have focused on phosphorus and nitrate contamination associated with manure runoff and spills. Some, however, have also raised the alarm that the drugs given to the livestock and present in the manure are another cause for serious concern.<sup>89</sup>

It is not the purpose of this article to criticize the shift in agricultural production per se.<sup>90</sup> Rather, this article argues that the current use of livestock drugs—drugs that in many instances make concentrated production feasible—raises serious environmental and public health risks. The next section of this article will discuss how these drugs are used and their capacity to impact the environment.

### III. THE USE OF PHARMACEUTICALS IN LIVESTOCK PRODUCTION

The transformation of the livestock industry has been largely driven by efforts to decrease production costs. Producing more meat at a cheaper price has been the driving influence of a very competitive industry.

New technologies both support and encourage this objective. Technological innovations initially offer opportunities for expanded production and reduced costs, but then become the norm, forcing all producers to adapt or else compete at a price disadvantage.<sup>91</sup>

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86. *Id.* at 5.

87. *Id.*

88. *See id.* at 1 (identifying environmental problems caused by manure concentration).

89. *Id.*

90. This author has expressed that view previously. *See, e.g.,* Susan A. Schneider, *Reconsidering the Industrialization of Agriculture*, 26 J. ENVTL. L. & LITIG. 19 (2011) (arguing that external costs associated with large scale industrial production systems should be considered and challenging the efficiency of these systems when these costs are included). Many others have raised persuasive, passionate arguments about the broader consequences of industrial agriculture including its impact on rural communities, the environment, and the welfare of the animals raised. *See, e.g.,* Neil D. Hamilton, *Essay – Food Democracy and the Future of American Values*, 9 DRAKE J. AGRIC. L. 9 (2004) (discussing the changes in agriculture and the changes in the U.S. food system).

91. This phenomenon is referred to as the “technology treadmill.” *See* Susan A. Schneider, *FOOD, FARMING, AND SUSTAINABILITY: READINGS IN AGRICULTURAL LAW* 19 (2011) (referencing the work of Willard Cochrane).

Mechanical innovations have allowed producers to reduce labor costs, while chemical innovations have created pesticides that have decreased pest loss and increased crop yields.<sup>92</sup> Biological innovations—including breeding animals for specialized traits and using a variety of animal drugs—have had a dramatic impact on livestock production, reducing costs and increasing the volume and speed of production.

New technologies often reduce costs directly, by allowing more meat and milk to be produced for a given amount of land, feed, labor, and capital. But the new technologies also create economies of scale, which reduce costs more for larger operations. As a result, larger farms realize higher profits, on average, which provides a strong incentive for operators to grow. In turn, lower industry-wide farm costs lead to lower prices for farm commodities. Lower prices can squeeze smaller farms with higher costs, causing many to exit, grow, or explore niche markets for differentiated products.<sup>93</sup>

Unfortunately, these new technologies often create new problems, and the most common response has been the development of an additional new technology to address the problem. For example, the overuse of the pesticide Glyphosate (RoundUp) has resulted in the development of resistant “super weeds.”<sup>94</sup> In response, farmers are increasing the quantities of Glyphosate used and are using more virulent pesticides, as well.<sup>95</sup> The seed/chemical industries suggest new pesticide/genetic modification technologies, and so the treadmill continues.<sup>96</sup>

In livestock agriculture, animal science researchers have focused on developing drugs to provide greater efficiencies and/or to address the problems caused by industrial production. This has been a lucrative market for the pharmaceutical industry.<sup>97</sup>

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92. *Id.*

93. TRANSFORMATION, *supra* note 5, at 2.

94. Neil D. Hamilton, *Don't Repeat Mistakes That Led To Superweeds*, DES MOINES REG. (June 28, 2014), <http://www.desmoinesregister.com/story/opinion/columnists/iowa-view/2014/06/28/repeat-mistakes-led-superweeds/11652199/>.

95. *Id.*

96. *Id.*

97. “The 2007 U.S. Census of Manufacturing reports that total U.S. revenues from veterinary pharmaceuticals are over \$5.41 billion.” Brian L. Buhr et al., *Health Competition in the Animal Health Industry*, CHOICES, <http://www.choicesmagazine.org/magazine/article.php?>

This article will next discuss the most common categories of drugs used in livestock production and the extent of their use. Throughout this discussion, however, only estimates are provided, sometimes expressed within a relatively wide range. This is because there is no publicly available accurate data for drug use in the livestock industry. Moreover, such information is generally not even available to the government agency that regulates its use. Most livestock drugs are sold “over-the-counter” without a prescription. On-farm reporting is not required; most drugs are available without veterinary supervision; and both feed recipes and drug use may be considered proprietary information by industry.<sup>98</sup> Pharmaceutical companies are now required to provide the Food and Drug Administration (FDA) with some data on the total sales of certain antibiotics sold for use in food animals. However, this data does not reveal the animal species related to the purchase; the geographic region of use; the purpose of the use (whether for disease prevention, treatment, or growth promotion); nor the actual use or dosage.<sup>99</sup>

#### A. Antimicrobials

It is estimated that between 60 and 80% of all livestock and poultry produced in the United States routinely receive antimicrobials of one type or another, most often at “sub-therapeutic” levels.<sup>100</sup> The majority of this use is estimated to be for

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article=164 (last visited Mar. 31, 2015).

98. See CONERLY & CORIANO, *supra* note 4, at 28 (discussing antimicrobials); *Id.* at 40 (discussing hormones); see also U. S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-490, ANTIBIOTIC RESISTANCE: FEDERAL AGENCIES NEED TO BETTER FOCUS EFFORTS TO ADDRESS RISKS TO HUMANS FROM ANTIBIOTIC USE IN ANIMALS (2004) (calling upon the USDA and the HHS to develop strategies for data collection on use in the livestock industry).

99. The FDA recently proposed a rule that would take a first step to collect additional data. The rule would require animal drug manufacturers to track the sale of antibiotics by particular species, allowing FDA to determine which are sold for use in chicken, cattle, pigs, turkeys, and other food-producing animal production. The rule would not reveal specific on-farm usage. Antimicrobial Animal Drug Sales and Distribution Reporting, 80 Fed. Reg. 28,863 (proposed May 20, 2015) (to be codified at 21 C.F.R. pt. 514); see also ANTIBIOTIC USE IN ANIMALS, GAO-04-490 at 92 (FDA response to GAO recommendation that more data on usage should be sought and maintained).

100. This refers to a dosage that would generally be insufficient for medicinal therapy to treat an active infection but that provides other benefits to production, e.g., growth promotion and possible disease prevention. While this term has been used extensively, the FDA now prefers the term “production use” as it views the terms “nontherapeutic” and “subtherapeutic” as “terms that we believe lack sufficient clarity.” FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 4 n.3 (Apr. 13, 2012), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM21>

the purpose of enhancing growth and increasing feed conversion ratios rather than for medicinal reasons.<sup>101</sup> In 2010, over 29 million pounds of antimicrobials were sold for livestock production use, an amount that is estimated to be “3–4 times the amount used by humans.”<sup>102</sup> Ninety percent of these antimicrobials are estimated to be delivered through the animals’ feed or water, and so provided to all of the animals at once, en masse.<sup>103</sup>

The routine use of antibiotics in livestock and poultry production has been increasingly controversial, as the connection between overuse in the livestock industry and the development of antibiotic resistance has been confirmed.<sup>104</sup> Antibiotic resistance is considered to be one of the major public health concerns worldwide. According to the World Health Organization, “[a]ntimicrobial resistance (AMR) threatens the effective prevention and treatment of an ever-expanding range of infections caused by bacteria, parasites, viruses, and fungi. It is an increasingly serious threat to global public health that requires action across all government sectors and society.”<sup>105</sup> The connection between agricultural use of antibiotics and antibiotic resistance was first publically acknowledged in the landmark *Report of the Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine*, more commonly known as the Swann Report, published in Great Britain in 1969.<sup>106</sup> This Report concluded that “the administration of antibiotics to farm livestock, particularly at sub-therapeutic levels, poses certain hazards to human and animal health;” and that it has led to resistant bacteria that can be transferred from animals to man.<sup>107</sup>

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6936.pdf [hereinafter JUDICIOUS USE].

101. CONERLY & CORIANO, *supra* note 4, at 27.

102. *Id.*

103. Meghan F. Davis & Lainie Rutkow, *Regulatory Strategies to Combat Antimicrobial Resistance of Animal Origin: Recommendations For a Science-Based Approach*, 25 TUL. ENVTL. L.J. 327, 331 (2012).

104. See JUDICIOUS USE, *supra* note 100, at 4 (finding that antimicrobial resistance is a “public health problem of global significance”).

105. *Antibiotic Resistance*, WORLD HEALTH ORG. (Apr. 2014), <http://www.who.int/mediacentre/factsheets/fs194/en/>.

106. M.M. SWANN, ET AL., REPORT OF THE JOINT COMMITTEE ON THE USE OF ANTIBIOTICS IN ANIMAL HUSBANDRY AND VETERINARY MEDICINE, HMSO, London (1969). This Joint Committee was appointed by the Health and Agriculture Ministers in Great Britain in July 1968, and it was chaired by Professor M. M. Swann. The committee’s report was issued in November 1969. Its findings are still cited today, and they formed the basis for the eventual withdrawal of the approval for livestock use of many antimicrobials throughout Europe.

107. House of Lords, Session 1997-98, Science and Technology Committee Reports: Science and Technology--Seventh Report, *Ch. 3 Prudent Use In Animals*, available at



In the United States, there has been a series of research studies and commission reports that have warned about the connections between antibiotic use in livestock production and antibiotic resistance.<sup>108</sup> While there are clearly other causes of resistance, the link between the extensive use of antimicrobials in the livestock industry and the development of antibiotic resistance with respect to the specific drugs used, cannot reasonably be disputed.<sup>109</sup> For example, in 2014, the President's Council of Advisors on Science and Technology confirmed the link in its report to President Obama. Since retail meat can be a source of microbes, those antibiotic-resistant microbes can be transmitted to consumers. Even more alarming is the fact that "antibiotic resistance can spread between microbes (through the transfer of DNA elements, such as plasmids, between species) and antibiotic-resistant microbes can spread from animals to people who come into contact or close proximity with them."<sup>110</sup>

Nevertheless, the extensive use of antibiotics continues today in the livestock industry. Recent FDA data shows an increase rather than a decrease in usage. In September of 2014, the FDA issued its 2012 summary report on the volume of antimicrobials sold for use in livestock. It revealed that from 2009 to 2012, "[t]he total quantity of antimicrobial active ingredients sold or distributed for use in food-producing animals increased by 16%."<sup>111</sup> It is estimated that as many

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<http://www.parliament.the-stationery-office.co.uk/pa/ld199798/ldselect/ldsctech/081vii/st0706.htm>. It is telling to note that some of the specific antibiotics singled out by the Swann Report as "unsuitable" for animal use in 1969 are still in use today in livestock production in the United States.

108. See, e.g., JENNY LI & DAVID WALLINGA, INST. FOR AGRIC. AND TRADE POL'Y, NO TIME TO LOSE: 147 STUDIES SUPPORTING PUBLIC HEALTH ACTION TO REDUCE ANTIBIOTIC OVERUSE IN FOOD ANIMALS (2012), available at [http://www.iatp.org/files/2012\\_11\\_08\\_AntibioticsBibliography\\_DW\\_JL\\_long\\_hyperlinks.pdf](http://www.iatp.org/files/2012_11_08_AntibioticsBibliography_DW_JL_long_hyperlinks.pdf) (describing the public health risks associated with antibiotic use in livestock production and providing a bibliography of studies documenting this risk).

109. See JUDICIOUS USE, *supra* note 100, at 5–17 (describing the link between the use of antimicrobials in livestock and the development of antibiotic resistance). For a cogent explanation for how antibiotic resistance can stem from the use of antibiotics in livestock production, see Davis & Rutkow, *supra* note 103, at 335–37.

110. PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, REPORT TO THE PRESIDENT ON COMBATTING ANTIBIOTIC RESISTANCE, 50–51 (Sept. 2014), available at [https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast\\_amr\\_sept\\_2014\\_final.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_amr_sept_2014_final.pdf).

111. FOOD & DRUG ADMIN., DEPT. OF HEALTH & HUMAN SERV., 2012 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 5 (Sept. 2014), available at <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM416983.pdf>.

as 55% of the types of antibiotic compounds used in the industry are also used to treat human infections.<sup>112</sup>

The resulting environmental impact of this antibiotic use is significant. There are many pathogens that are associated with livestock production; some are only adapted for a particular animal species host, and others, termed zoonotic pathogens, are adapted to produce infections in humans.<sup>113</sup> Some of these pathogens can be extremely dangerous, even aside from antibiotic resistance.<sup>114</sup> For all of these pathogens, though, antibiotic resistance complicates treatment and raises additional dangers.<sup>115</sup>

These antibiotic resistant pathogens can be found on the livestock, in their surroundings, and on the meat that is marketed to consumers; thus, it can be spread to those in contact with the animals, their surroundings, or their meat.<sup>116</sup> Both the pathogens and the antimicrobials are found in the manure that is excreted.<sup>117</sup> According to EPA:

Antimicrobials are often only partially metabolized in livestock and poultry and can be excreted virtually unchanged as the parent compound. For example, up to 80% of tetracyclines may be excreted by swine and poultry as the parent compound. Additionally, up to 67% of the macrolide tylosin, which is approved for use in beef cattle, dairy cows, swine, and poultry may be excreted by livestock and poultry when the antimicrobial is administered orally.<sup>118</sup>

After excretion, the antibiotics interact with the environment when the manure is applied to land, carried in runoff, or associated

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112. CONERLY & CORIANO, *supra* note 4, at 27.

113. *Id.* at 13.

114. See, e.g., Shiga Toxin-Producing *Escherichia coli*, 76 Fed. Reg. 58,157 (Sept. 20, 2011) (announcing the USDA Food Safety and Inspection Service's decision to declare certain Shiga toxin-producing *E. coli* (STEC) as adulterants in non-intact raw beef products because of the seriousness of the illnesses caused).

115. *Antibiotic / Antimicrobial Resistance*, CTR. FOR DISEASE CONTROL (Sept. 16, 2013), <http://www.cdc.gov/drugresistance/about.html>.

116. *Id.*; see also *The Trouble with Antibiotics* (PBS Television Broadcast Oct. 14, 2014), available at <http://www.pbs.org/wgbh/pages/frontline/trouble-with-antibiotics/> (presenting evidence of antibiotic resistant bacteria on meat and the genetic linking of the pathogens to specific infections in humans).

117. CONERLY & CORIANO, *supra* note 4, at 35.

118. *Id.*

with a spill.<sup>119</sup> The occurrence of antimicrobials in soil, surface water, and ground water has been well documented, with “antimicrobial compounds present in 67 percent of ground water and surface water samples collected near poultry operations and 31 percent of ground water and surface water sample collected near swine operations.”<sup>120</sup>

Because food-producing animals excrete 75% of the antimicrobials they consume unchanged or as active metabolites of the drug, antimicrobials not only apply selective pressure on the intestinal microbial community of the food-producing animal, but also on the microbiome of the animal's environment, such as the barn, pasture, and fields where manure is applied. Spillage of medicated feed may contaminate local soils and waters. The presence of antimicrobial drugs from these sources can influence the local microbial ecology, allowing resistant organisms to survive and to become more common in bacterial communities in and around concentrated animal feeding operations (CAFOs). Further, the CAFO environment, marked by crowding of animals in small, often indoor spaces, intensifies the spread of bacteria among animals and increases pathogen contamination of their barns or pens . . . . Residents of rural communities may be exposed to antimicrobial pollution through air and water contaminated by manure waste, and consumers nationwide (and globally) can be exposed through the retail meat, seafood, or other products they contact, such as fertilizer derived from contaminated animal products.<sup>121</sup>

A very recently published study confirms the transmission of antibiotics, bacteria, and antibiotic-resistant genetic materials by wind. The study tested areas surrounding commercial feedlots. The study found these substances not only at sites a distance from the feedlot, but also at greater levels downwind than upwind from the feedlot, confirming wind transmission.<sup>122</sup>

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119. *Id.*

120. *Id.* at 36 (citing E.R. Campgnolo et al., *Antimicrobial Residues in Animal Waste and Water Resources Proximal to Large-Scale Swine and Poultry Feeding Operations*, THE SCIENCE OF THE TOTAL ENVIRONMENT 299: 89-95 (2002)).

121. Davis & Rutkow, *supra* note 103, at 339-40.

122. ANDREW D. MCEACHRAN ET AL., ENVTL. HEALTH PERSPECTIVES, ANTIBIOTICS, BACTERIA, AND ANTIBIOTIC RESISTANCE GENES: AERIAL TRANSPORT FROM CATTLE FEED YARDS VIA PARTICULATE MATTER (Jan. 22, 2015), *available at* <http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/1/ehp.1408555.acco.pdf>.

Public health professionals around the world have been expressing grave concerns about antibiotic resistance for some time. Yet, in the United States, we are only beginning to appreciate the significance of the environmental and public health threats posed by using so many antibiotics in our livestock industry. It is time we acknowledge the risks we have created.

### *B. Hormones*

Hormones are produced naturally by animals, and the levels and kinds of hormones produced will be impacted by a variety of factors including growth, reproduction, other natural biological rhythms, and stress. Some of the most ubiquitous hormones, produced throughout life, include estrogen, progesterone, and testosterone. These natural hormones are “necessary for normal development, growth, and reproduction.”<sup>123</sup>

A variety of steroid hormone drugs that supplement natural production have been approved for use in beef cattle and sheep since the 1950s.<sup>124</sup> These approved drugs include estrogen, progesterone, and testosterone in natural and synthetic versions.<sup>125</sup> These drugs are given to animals to increase their growth rate, to increase feed conversion ratios (the rate by which the animal converts feed to weight gain for meat production), to improve meat quality, and to affect reproduction.<sup>126</sup>

According to the FDA, these drugs are typically administered in cattle and sheep as “pellets that are placed under the skin on the back side of the animal’s ear. The pellets dissolve slowly under the skin.”<sup>127</sup> Typical cattle implants contain trenbolone acetate and estradiol benzoate.<sup>128</sup> The FDA has not approved the use of exogenous steroid hormones in swine, poultry, veal calves, or dairy cows.<sup>129</sup>

In addition to the pellet delivery system, beef cattle on feedlots may also receive daily doses of synthetic hormones (melengestrol

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123. FOOD & DRUG ADMIN., *Steroid Hormone Implants Used for Growth in Food-Producing* (Oct. 14, 2014), <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055436.htm> [hereinafter *Steroid Hormone Implants*].

124. 21 C.F.R. §§ 522, 556, 558 (2014); *Steroid Hormone Implants*, *supra* note 123; CONERLY & CORIANO, *supra* note 4 at 40–41.

125. *Id.*

126. *Id.*

127. *Steroid Hormone Implants*, *supra* note 123.

128. CONERLY & CORIANO, *supra* note 4, at 40.

129. *See Steroid Hormone Implants*, *supra* note 123 (“No steroid hormones are approved for growth purposes in dairy cattle, veal calves, pigs, or poultry.”).

acetate) in their feed.<sup>130</sup> Dairy cows often receive “intravaginal controlled internal drug release (CIDR) inserts” of progesterone “to control estrous (menstrual cycle), or to treat anestrous (non-menstruating) females and females with cystic ovaries.”<sup>131</sup>

Dairy cows may receive the genetically engineered hormone, recombinant bovine somatotropin (rBST), often referred to as recombinant bovine growth hormone (rBGH), to increase milk production.<sup>132</sup> There are no public reports on the use of rBGH in dairy production as reporting is not required. Consumer demand has led to a vibrant market for “rBGH free” milk despite a skeptical FDA, and labeling rules that generally mandate a disclaimer that states that “[n]o significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.”<sup>133</sup>

According to the FDA, “[a]ll of the steroid hormone growth-promoting drugs are available for over-the-counter purchase in the United States and are generally given by the livestock producer at specific stages of the animals’ growth.”<sup>134</sup> Because these drugs are available for direct purchase, and because there are no USDA or FDA reporting requirements, the full extent of hormone use in U.S. livestock is not known.

USDA surveys can provide a window into common practices, however. One survey reported that “[a]pproximately 39% of steers and heifers weighing less than 700 pounds and 82% of those weighing 700 pounds or more received at least one hormonal implant in 1999.”<sup>135</sup> Larger livestock operations (8,000 cattle or more) were more likely to use hormone implants than smaller operations.<sup>136</sup> Another survey reported that approximately 33% of dairy operations used CIDR inserts in 2007.<sup>137</sup> A 2007 Dairy Survey reported that “rBGH is the most common production enhancement injection used

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130. CONERLY & CORIANO, *supra* note 4, at 40.

131. *Id.*

132. See Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6279 (Feb. 10, 1994) (stating that lactating dairy cows are given rBST to “increase the production of marketable milk”).

133. *Id.* at 6280. Note, that the “no significant difference” claim was called into question in the case of *Int’l Dairy Foods Assoc. v. Boggs*, 622 F.3d 628, 637 (6th Cir. 2010).

134. *Id.*; see also CONERLY & CORIANO, *supra* note 4, at 39 (stating that natural and synthetic hormones are administered to cattle to promote growth).

135. CONERLY & CORIANO, *supra* note 4, at 40.

136. *Id.*

137. *Id.*

in dairy operations.”<sup>138</sup>

It is impossible to measure the total amounts of hormones excreted in the manure produced in the livestock industry. However, one well-regarded estimate indicates that in the year 2000 alone, 722,852 pounds of estrogens, androgens, and progestogens—not including synthetic versions of these hormones—were excreted.<sup>139</sup> Although there is some indication that manure storage prior to land application may allow hormones to degrade to inactive levels, research indicates that many hormones are active even at low levels and can still be considered endocrine disruptors.<sup>140</sup>

### C. Beta-agonists: Ractopamine and Zilmax

A third category of pharmaceutical, beta agonists, has been introduced more recently to the livestock industry. This category of drugs affects animals’ metabolic systems, shifting dietary energy toward muscle growth as opposed to fat deposition.<sup>141</sup> It promises faster growth and faster muscle mass accumulation.<sup>142</sup>

Ractopamine is a beta agonist that has been approved for use in medicated feed for swine since 1999.<sup>143</sup> It was approved for use in cattle in 2003<sup>144</sup> and turkeys in 2008.<sup>145</sup> It is now estimated that 60–80% of hogs produced in the United States are given ractopamine in feed, often in combination with antibiotics such as Tylosin and Monensin.<sup>146</sup> Its use in turkeys and cattle is thought to be extensive, but no public data is available for confirmation. In 2013, Merck estimated that approximately 70% of U.S. beef cattle received either

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138. *Id.*

139. *Id.* at 41.

140. *See id.* at 45 (“[w]hile hormones are typically detected at low concentrations, such chemicals are biologically active at low levels and are classified as endocrine disruptors”).

141. *See* Donald H. Beerman et al., Council for Agric. Sci. & Tech., *Animal Agriculture’s Future Though Biotechnology Part 3: Metabolic Modifiers For Use In Animal Production*, 30 ISSUE PAPER 1 (July 2005), available at <http://www.cast-science.org/download.cfm?PublicationID=2911&File=f0304b7365a7496a189a30694d7f4b617c4f> (“[t]hese commercial products enhance carcass lean content and feed efficiency”).

142. *See id.* at 5 (stating that beta agonists stimulate muscle growth).

143. *See generally* 65 Fed. Reg. 4111 (Jan. 26, 2000) (final rule announcing the approval of ractopamine hydrochloride for use in swine feed and announcing the tolerance level for residues of ractopamine in edible tissues of treated swine). This final rule indicates that the drug was approved for use as of December 22, 1999 “for approved feed efficiency and increased carcass leanness.” *Id.* at 4111.

144. Approved as Optaflexx.

145. Approved as Topmax.

146. *See* 21 C.F.R. § 558.500 (2014) (listing acceptable combinations of ractopamine, Tylosin, and Monensin).

Optaflexx, Eli Lilly's brand of ractopamine in their feed, or Zilmax (a competing beta agonist).<sup>147</sup>

Ractopamine use is controversial. All countries in the European Union, Russia, Taiwan and China have severely limited or restricted ractopamine, citing food safety concerns; although it is allowed in the United States, Canada, and Brazil.<sup>148</sup> European Union concerns include very limited testing of effects on humans and reports of adverse human reactions to the drug, including restlessness, anxiety, and a fast heart rate.<sup>149</sup> The U.S. pork industry, however, argues that ractopamine is safe and that countries that have banned its use are merely protecting their domestic pork industry.<sup>150</sup>

There is no mandatory withdrawal period in the United States for ractopamine, meaning animals can receive it up to slaughter with a tolerance level expressed as the maximum residue limit (MRLs) of 50 ppb for pork and 30 ppb for beef.<sup>151</sup> In 2012, Codex Alimentarius Commission adopted a 10 ppb MRL for both beef and pork.<sup>152</sup> A 2012 study conducted by Consumer Reports tested 240 pork samples and found that about 20% of samples were positive for low levels of the drug, but the levels were reported to be below both the United States and Codex MRLs.<sup>153</sup>

Animal welfare concerns have been widely raised. In 2002, the FDA Center for Veterinary Medicine Office of Surveillance and Compliance accused Elanco (a division of Eli Lilly) of withholding information about reports of "adverse animal drug experiences" and the "safety and effectiveness" of the drug.<sup>154</sup> A warning label was

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147. Kelsey Gee, *Merck Suspends Sales of Cattle-Feed Additive Zilmax in U.S., Canada*, WALL ST. J. (Aug. 16, 2013), <http://www.wsj.com/articles/SB10001424127887324139404579016654038679072>.

148. See Helena Bottemiller, *FDA Petitioned to Lower Ractopamine Limits for Meat, Review Health Impacts*, FOOD SAFETY NEWS (Dec. 21, 2012), <http://www.foodsafetynews.com/2012/12/fda-petitioned-to-lower-ractopamine-limits-for-meat-review-animal-health-impact/#.VNFRFPF-10> (describing different countries' approaches to regulating ractopamine).

149. *What's in that pork?*, CONSUMER REPORTS MAGAZINE (Jan, 2013) <http://www.consumerreports.org/cro/magazine/2013/01/what-s-in-that-pork/index.htm>.

150. *Id.*

151. 21 U.S.C. § 556.570 (2014).

152. Helena Bottemiller, *Codex Adopts Ractopamine Limits for Beef and Pork*, FOOD SAFETY NEWS (July 6, 2012), <http://www.foodsafetynews.com/2012/07/codex-votes-69-67-to-advance-ractopamine-limits-for-beef-and-pork/#.VPcj0PnF98E>.

153. *Id.*

154. Warning Letter from Gloria J. Dunnavan, Director, Division of Compliance, Center for Veterinary Medicine, Office of Surveillance and Compliance, Food and Drug Administration, to Patrick C. James, President Elanco Animal Health, A Division of Eli Lilly and Company (Sept. 12, 2002) (on file with author).

mandated, stating that “Ractopamine may increase the number of injured and/or fatigued pigs during marketing.”<sup>155</sup>

Opponents claim that ractopamine has been the subject of more adverse report incidents in pigs than any other animal drug on the market, citing reports to the FDA that include “trembling, lameness, inability to walk or rise, reluctance to move, stiffness, hyperactivity, hoof disorder, difficulty breathing, collapse, and death.”<sup>156</sup> Pigs that were administered ractopamine in a research barn squealed when they took steps, as if in pain, and refused to leave their pens despite proper handling; the pain was even more noticeable when they were being shipped.<sup>157</sup>

The debate over ractopamine is heightened due to the dramatic problems associated with the competing beta agonist, Zilmax, manufactured by Merck and approved for use in cattle since 2007. Zilmax contains a different active ingredient, zilpaterol hydrochloride, and is approved for use in commercial feedlots with a withdrawal period of 3 days prior to slaughter.<sup>158</sup>

The economic advantages of using Zilmax are enticing to the industry. Merck’s Zilmax website promises gains “from 24 to 33 pounds of additional carcass weight” per animal.<sup>159</sup> Accordingly, Merck reported \$159 million in Zilmax sales in the United States and Canada in 2012. Estimates are that Zilmax was fed to more than 25 million cattle. Significant animal health problems were reported, and these reports culminated with the shocking presentation of cattle for slaughter at a Tyson Plant in Washington. “[H]eifers and steers hobbled down the ramps on August 5, barely able to walk. The reason: The animals had lost their hooves.”<sup>160</sup> The common factor among all of the animals was that they had been fed Merck & Co Inc’s feed additive, Zilmax.<sup>161</sup>

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155. 21 C.F.R. 558.500 (2014); *see also* 67 Fed. Reg. 71,820 (Dec. 3, 2002) (providing notice of the new labeling requirement).

156. Complaint at 9, Ctr. for Food Safety et al. v. Margaret A. Hamburg et al., No. 3:14-cv-4932 (N.D. Cal. Nov. 6, 2014), *available at* [http://www.biologicaldiversity.org/campaigns/toxics\\_and\\_endangered\\_species/pdfs/2014-11-6\\_Ractopamine\\_Complaint.pdf](http://www.biologicaldiversity.org/campaigns/toxics_and_endangered_species/pdfs/2014-11-6_Ractopamine_Complaint.pdf).

157. *Id.*

158. 21 C.F.R. § 558.665 (2014).

159. Zilmax Information Center, MERCK, <http://www.merck-animal-health-usa.com/products/zilmax/overview.aspx> (last visited Mar. 25, 2015).

160. P.J. Huffstutter & Tom Polansek, *Special Report: Lost Hooves, Dead Cattle Before Merck Halted Zilmax Sales*, REUTERS (Dec. 30, 2013, 5:19 PM), <http://www.reuters.com/article/2013/12/30/us-zilmax-merck-cattle-special-report-idUSBRE9BT0NV20131230> [hereinafter *Lost Hooves*].

161. *Id.*



The day after the hoofless animals were euthanized on August 6, Tyson told its feedlot customers it would stop accepting Zilmax-fed cattle. After Reuters reported the existence of a videotape of apparently lame Zilmax-fed animals, Merck itself temporarily suspended sales of the drug in the United States and Canada. The rest of the nation's leading meatpackers soon followed Tyson, the largest U.S. meat processor.<sup>162</sup>

The FDA did not take any adverse action with regard to Zilmax's approval status. Its active ingredient, zipaterol hydrochloride remains an approved animal drug for use in feed,<sup>163</sup> and Zilmax's new drug application and approval is still available on the FDA's website per its prior approval.<sup>164</sup> Merck is currently seeking to re-launch Zilmax at a lower dosage.<sup>165</sup> The FDA approved Merck's Supplemental New Drug Application in October 2014 providing for a lower dosage of Zilmax to be sold for use in cattle fed in confinement for slaughter.<sup>166</sup> Merck is currently working to convince a still-skeptical beef industry that it should resume use.<sup>167</sup> Meanwhile, use of competing ractopamine products in the cattle

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162. *Id.*; see also, Kelsey Gee, *Merck Suspends Sales of Cattle-Feed Additive Zilmax in U.S., Canada*, WALL ST. J. (Aug. 16, 2013, 12:01 PM), <http://www.wsj.com/articles/SB10001424127887324139404579016654038679072> (detailing Merck's decision to suspend its sales of feed with the Zilmax additive).

163. 21 C.F.R. § 558.665 (2014).

164. FOOD & DRUG ADMIN., FREEDOM OF INFORMATION SUMMARY, ORIGINAL NEW ANIMAL DRUG APPLICATION NADA 141-258 41 (2006) (approving Zilmax as "safe and effective"); see also ZILMAX, <http://www.zilmax.com> (last visited Feb. 24, 2015) (stating that "Zilmax is an FDA-approved feed supplement.").

165. P.J. Huffstutter & Tom Polansek, *Exclusive: Merck Funds Tests of Lower Zilmax Doses As Seen Seeking Way to Resume Sales*, REUTERS (Jan. 19, 2015, 8:02 AM), <http://www.reuters.com/article/2015/01/19/us-merck-co-zilmax-idUSKBN0KS18020150119> [hereinafter *Merck Funds*].

166. FOOD & DRUG ADMIN., FREEDOM OF INFORMATION SUMMARY, SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION NADA 141-258 (2014), available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIA/DrugSummaries/UCM421907.pdf> (requiring adding the statement "CAUTION: Not to be fed to cattle in excess of 90 mg/head/day").

167. See *Merck Funds*, *supra* note 165 (describing Merck's efforts to resume sales of Zilmax); see also Dan Charles, *Beef Packers Block Plan To Revive Growth-Promoting Drug*, NATIONAL PUBLIC RADIO: THE SALT (Jan. 27, 2015, 11:30 AM), <http://www.npr.org/blogs/thesalt/2015/01/27/381630528/beef-packers-block-plan-to-revive-growth-promoting-drug> (stating that Merck has been working on a plan to revive the use of Zilmax).

industry has soared.<sup>168</sup>

Little is known about the exact amount of beta agonists that are released into the environment from their use in the livestock industry, or about their potential impact. As an example of an industry assessment, in 1998 Elanco prepared an Environmental Assessment (EA) in conjunction with their application for approval of their ractopamine product for cattle.<sup>169</sup> This assessment confirms that the drug has the potential to impact the area surrounding the mixing facilities; the feedlot area and its surroundings; agricultural lands where manure is applied; and aquatic systems receiving runoff from animal waste storage.<sup>170</sup> The EA grossly underestimates the actual use of the drug, however, by referencing an “optimistic market penetration rate of 35 percent.”<sup>171</sup> Actual market penetration is now estimated to be between 60–80%.<sup>172</sup> The EA also describes a “typical feedlot” as one housing 200 cows, when today’s feedlots typically hold 1,000-100,000 cattle at a time.<sup>173</sup> In addition, the EA fails to consider the cumulative impact of use in multiple species.<sup>174</sup> By some estimates, “the combined population of ractopamine-drugged pigs, cattle, and turkeys may excrete over a million pounds of the drug.”<sup>175</sup> The EA also fails to consider the impact of multiple drugs released into the system as a result of competing drugs (e.g., ractopamine and Zilmax).

#### D. Environmental Effects

The potential dangers of animal drugs in manure has already been realized in the case of arsenic. Despite decades of prohibition of

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168. See Jesse Newman, *Merck Pushes to Revive Beef Drug*, WALL ST. J. (July 14, 2014, 7:32 PM), <http://www.wsj.com/articles/merck-pushes-to-revive-beef-drug-1405380749> (describing two competitors’ entrance into the growth-promoting drug market).

169. ELANCO ANIMAL HEALTH, ENVIRONMENTAL ASSESSMENT FOR THE USE OF RACTOPAMINE HYDROCHLORIDE PREMIX IN THE FEED OF CATTLE (1998), available at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/UCM303565.pdf>.

170. See *id.* at 5 (describing potential environmental impacts of the drug).

171. *Id.* at 9.

172. Complaint for Declaratory and Injunctive Relief at 16, *Humane Soc’y of the U.S. v. Hamburg*, No. 3:14-cv-04933 (N.D. Cal. Nov. 6, 2014); Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932 at 8.

173. ELANCO, *supra* note 169.

174. See *supra* notes 79–81 and accompanying text.

175. Complaint, *Humane Soc’y of the U.S.*, No. 3:14-cv-04933 at 16; see also Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932 at 11, (“[a]lmost all ractopamine fed to cattle, pigs, and turkey is excreted into their manure.”).

the use of arsenicals as pesticides by the EPA, the FDA continued to allow the arsenical roxarsone in poultry production.<sup>176</sup> It was used to promote rapid growth, increased weight gain, and improved feed efficiency.<sup>177</sup> A report estimated that in 2006, the vast majority of the broiler chickens produced in the United States were given feed containing arsenic compounds at some point in their lives.<sup>178</sup> Although no public data is available, estimates suggest that over 2 million pounds of roxarsone was given to chickens annually.<sup>179</sup> Consumer concerns led to industry pulling back on its use,<sup>180</sup> and the production of roxarsone was suspended following a 2011 FDA finding of traces of inorganic arsenic in poultry tissue.<sup>181</sup> However, beyond the direct food safety issue associated with chicken products, arsenic has been found in poultry feathers, poultry bedding, and in the manure that is spread on cropland—contributing to high levels of arsenic in rice produced on that land.<sup>182</sup>

As evidenced by the problems with the arsenic use in poultry production, there is a persuasive argument that each of the categories of pharmaceuticals used in the livestock industry—antimicrobials, hormones, beta agonists, and others not addressed in this article—

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176. See Susan A. Schneider, *Examining Food Safety From a Food Systems Perspective: The Need for a Holistic Approach*, 2014 WISC. L. REV. 397 (2014) (“[t]he FDA’s approval led to the widespread use of roxarsone”).

177. New Animal Drugs for Use in Animal Feeds: Roxarsone, 46 Fed. Reg. 52,330, 52,331 (Oct. 27, 1981) (affecting 21 CFR 558). [46 FR 52330-02]

178. DAVID WALLINGA, INST. FOR AGRIC. & TRADE POL’Y, PLAYING CHICKEN: AVOIDING ARSENIC IN YOUR MEAT 13 (2006), available at [http://www.iatp.org/files/421\\_2\\_80529.pdf](http://www.iatp.org/files/421_2_80529.pdf).

179. *Id.*

180. It was reported that Tyson Foods stopped using arsenicals in its chickens in 2004. Marian Burros, *Chicken with Arsenic? Is That O.K.?*, N.Y. TIMES (Apr. 5, 2006), <http://www.nytimes.com/2006/04/05/dining/05well.html>. Perdue said it stopped using arsenicals in 2007. Darryl Fears, *Maryland Set To Ban Arsenic-Containing Drug in Chicken Feed*, WASH. POST (May 20, 2012), [http://www.washingtonpost.com/national/health-science/maryland-set-to-ban-arsenic-containing-drug-in-chicken-feed/2012/05/20/gIQAfoIodU\\_story.html](http://www.washingtonpost.com/national/health-science/maryland-set-to-ban-arsenic-containing-drug-in-chicken-feed/2012/05/20/gIQAfoIodU_story.html).

181. See Letter from Michael Taylor, Deputy Comm’r for Foods & Veterinary Medicine, to Paige M. Tomaselli, Staff Attorney, Ctr. for Food Safety, and David Wallinga, Director, Food & Health Division of Inst. for Agr. and Trade Pol’y 5 (Sept. 30, 2013), available at <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM370570.pdf> (denying the Center for Food Safety petition).

182. See Susan A. Schneider, *Examining Food Safety From a Food Systems Perspective: The Need for a Holistic Approach*, 2014 WISC. L. REV. 397 (2014) (citing Fu-Min Wang, Zhang-Liu Chen, Lu Zhang, Yan-Ling Gao, & Yong-Xue Sun, *Arsenic Uptake and Accumulation in Rice (*Oryza sativa* L.) at Different Growth Stages Following Soil Incorporation of Roxarsone and Arsanilic Acid*, 285 PLANT & SOIL 359 (July 2006) (concluding that rice could accumulate arsenic “from contaminated soil (roxarsone or arsanilic acid), which may be transferred to human beings via the food chain”).

should be more carefully reviewed for the environmental impacts associated with their use. Numerous scientific studies performed on each of the individual categories and/or on individual pharmaceuticals support this argument.<sup>183</sup> Adverse environmental impacts are not being adequately considered in our evaluation and approval of the use of these drugs.<sup>184</sup>

There is an even more persuasive argument that we have no concept, indeed no way to adequately measure, the cumulative impact of the millions of pounds of different drugs used in the livestock industry. Much of those drugs are then excreted in the 1.1 billion tons of manure produced each year.

#### IV. THE REGULATION OF DRUGS ADMINISTERED TO LIVESTOCK

The United States Department of Agriculture is the federal agency involved in most matters involving livestock production, including the prevention of livestock disease<sup>185</sup> and the regulation of livestock markets.<sup>186</sup> The USDA is also responsible for the labeling and safety regulations applicable to most meat products.<sup>187</sup> Nevertheless, as described below, the regulation of animal drugs is controlled by the FDA.

##### *A. The Regulation of Animal Drugs Under the Food, Drug, and Cosmetic Act*

The Food, Drug, and Cosmetic Act (FDCA) governs the approval of animal drugs and gives regulatory authority to the Secretary of the Department of Health and Human Services (HHS).<sup>188</sup>

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183. See, e.g., Alistair B. A. Boxall et al., *Are Veterinary Medicines Causing Environmental Risks?*, 37 ENVTL. SCI. & TECH. 286A (2003) (discussing the likelihood of various veterinary medicines entering into the environment, and concluding that “too little is known about the effects of these compounds”).

184. CONERLY & CORIANO, *supra* note 4, at v–vi (stating that environmental impacts of antimicrobial use in livestock are “poorly understood,” and “would benefit from further research”).

185. The USDA Animal & Plant Health Inspection Service (APHIS) “works in a variety of ways to protect and improve the health, quality, and marketability of our nation’s animals (including various wildlife), animal products, and veterinary biologics.” U.S. DEP’T OF AGRIC., *Animal & Plant Health Inspection Serv.*, <http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth> (last visited Feb. 24, 2015).

186. The USDA administers the Packers and Stockyards Act, 7 U.S.C. §§ 181–229b (2012), through the Grain Inspection and Packers and Stockyards Administration (GIPSA).

187. The USDA Food Safety and Inspection Service (FSIS) is responsible for meat regulation as authorized under the Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2012), and the Poultry Products Inspection Act, 21 U.S.C. §§ 451–472.

188. The definition of “drug” contained in the statute includes “articles intended for use in

The Secretary has delegated this authority to the Commissioner of the Food and Drug Administration (FDA).<sup>189</sup> The statute provides that a new animal drug “shall be deemed unsafe” unless the manufacturer has obtained FDA “approval,” a “conditional approval,” or an allowed “index listing” of the drug for use in “minor species.”<sup>190</sup> Animal feed that contains a new animal drug is similarly regulated.<sup>191</sup>

The phrase “new animal drug” is broadly defined and extends far beyond the literal creation of a new drug. The FDCA states that “[t]he term ‘new animal drug’ means any drug intended for use for animals other than man.”<sup>192</sup> The regulations clarify that it includes all new uses for existing drugs, new combinations of drugs, the use of the drug in a new species, and other changes in usage, composition, or labeling.<sup>193</sup>

The approval process for any new animal drug is outlined in FDCA section 360b(b). The drug’s sponsor is required to submit an application that includes “full reports of investigations which have been made to show whether or not such drug is safe and effective for use.”<sup>194</sup> According to the statute, the application must also include a “full statement of the composition” of the drug; a description of the manufacturing process; samples of the drug, the feed it might be used in, and edible portions of the animal to which it will be given (“as the Secretary may require”); examples of the proposed labeling; a description of the “practicable methods for determining the quantity, if any, of such drug in or on food . . . because of its use;” and the “proposed tolerance level or withdrawal period or other use restrictions” necessary to render the drug’s use “safe.”<sup>195</sup>

There are special provisions in the statute that exempt the

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the diagnosis, cure, mitigation, treatment, or prevention of disease in man *or other animals*; and articles (other than food) intended to affect the structure or any function of the body of man *or other animals*.” 21 U.S.C. § 321(g)(1)(B)–(C) (emphasis added).

189. FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDES, VOLUME II—DELEGATIONS OF AUTHORITY: REGULATORY DELEGATIONS OF AUTHORITY TO THE COMMISSIONER FOOD AND DRUGS 1 (2014), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf>.

190. 21 U.S.C. § 360b(a)(1)(A)–(C) (2012).

191. See 21 U.S.C. § 360b(a)(2)(A)(i)–(iii) (deeming animal feed containing new animal drugs unsafe unless granted an approval, a conditioned approval, or an index listing).

192. 21 U.S.C. § 321(v) (2012).

193. 21 C.F.R. § 510.3(i) (2007).

194. 21 U.S.C. § 360b(b)(1).

195. *Id.*

“investigational use” of drugs from this process.<sup>196</sup> For some drugs, a more streamlined process exists, using an “abbreviated application.”<sup>197</sup> An abbreviated application is appropriate if there has been a drug with the same active ingredients approved previously for the same use.<sup>198</sup>

Support for the pharmaceutical and agricultural industries is conspicuous throughout section 360b. Although drugs may be considered unsafe if they do not comply with the defined approval processes, the section includes numerous directives that prohibit the agency from finding a drug unsafe.<sup>199</sup> Indeed, the latest amendment to section 360b and the animal drug review process, in general, was passed as the Animal Drug Availability Act.<sup>200</sup> The Congressional findings contained in this bill when it was first proposed, provide an informative window into Congressional attitudes about drug use in the livestock industry. The findings are as follows:

Congress finds that—

(1) the new animal drug approval process has been proceeding too slowly, with the result that necessary and useful drug therapies are being kept from the marketplace;

(2) the lack of drug approvals for new animal drugs places the health and well-being of animals at risk;

(3) the expense and delays caused by effectiveness testing for new animal drugs have begun to outweigh the benefits of such testing;

(4) the overreliance on field investigations to establish the effectiveness of new animal drugs is a primary reason the new animal drug approval process has become so burdensome;

(5) there are not sufficient approved animal drugs available to treat every specific disease or condition found in each species of animal;

(6) it would benefit the public health and safety to have many additional animal drugs reviewed and approved by the Food and

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196. 21 U.S.C. §§ 360b(a)(3), (j).

197. 21 U.S.C. § 360b(b)(2). The requirements for approval under the abbreviated process are set forth in 21 U.S.C. § 360b(n).

198. 21 U.S.C. § 360b(n)(1)(B)(i).

199. *See, e.g.*, 21 U.S.C. § 360b(a)(4)–(6) (prohibiting the agency from finding an animal drug unsafe for specified reasons).

200. The Animal Drug Availability Act of 1996, Pub. L. No. 104-250, 110 Stat. 3151 (codified as amended at 21 U.S.C. §§ 301, 331, 353, 354, 360b (2012)).

Drug Administration;

(7) economic and regulatory incentives are necessary to encourage manufacturers of animal drugs to convert unlabeled uses of the drugs to approved, labeled uses; and

(8) it is important that the Center for Veterinary Medicine of the Food and Drug Administration promptly implement the recently developed mission, vision, and guiding principles of the Center so that the Food and Drug Administration is a global leader as a public health organization that enables the marketing of safe and effective products.<sup>201</sup>

These findings clearly reflect Congress' interest in expanding the use of animal drugs in the livestock industry, although it rather curiously justifies this interest as furthering the "the health and well-being of animals" and "public health and safety."<sup>202</sup> By 1995, when these findings were reported, public health officials worldwide were expressing serious concerns about the adverse public health consequences associated with the overuse of antibiotics in the livestock industry.<sup>203</sup> Congress's motivations were likely expressed more honestly in earlier findings:

In the past 15 years the animal feed industry in the United States has been virtually revolutionized through the use of drugs and other additives in the feed of animals. Drugs are used to promote growth and combat disease, and as a result of the increasing use, animals today add more meat per pound to feed in a much shorter time than has ever been true in the past.<sup>204</sup>

Congress recognized that the livestock industry had become dependent on using animal drugs to lower production costs. This factor places new animal drugs in sharp contrast to human drugs. For individuals suffering from a disease or other medical condition, the rapid approval of a new drug to treat that condition, provided that the drug is safe, may have a dramatic and positive impact on public health. Streamlining the approval process can be justified for

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201. S. 773, 104th Cong. § 2 (1995), available at <https://www.congress.gov/104/bills/s773/BILLS-104s773is.pdf>.

202. See *id.* (expressing a desire to expedite and expand the approval process, and identifying animal health and well-being and public health and safety as motivating factors).

203. For a listing of such studies, see JUDICIOUS USE, *supra* note 100, at 5–17.

204. H.R. REP. NO. 90-875, at 2 (1967).

humanitarian reasons, provided it remains safe. In contrast, the purpose of many new animal drugs is not to treat disease but to reduce production costs. This reduction may occur through increased feed conversion rates or through prophylactic use to allow for increased concentration without increasing disease rates. These are economic objectives, not public health objectives, and certainly not animal welfare objectives. Thus, they do not deserve the same treatment.

Despite Congress' interest in streamlining the approval of new animal drugs, the statute does require a showing that a new animal drug be "safe and effective."<sup>205</sup> Effectiveness refers to whether the drug works as promised.<sup>206</sup> The FDCA defines "safe" as having "reference to the health of man or animal."<sup>207</sup>

The notion of new animal drug safety in terms of the health of the animal sits awkwardly next to competing economic considerations. Many of the drugs approved are not good for the animals' health, particularly in the long run.<sup>208</sup> Rapid growth, increased milk and egg production and related goals often run completely counter to the animals' long-term health.<sup>209</sup> For meat producing animals, a shorter life span may actually be the economic production goal associated with the drug. For example, steroids are given with the express purpose of increasing the growth rate of the animal.<sup>210</sup> In an animal raised for slaughter, this means an earlier death. For product-producing animals such as dairy cows and chickens raised for egg production, the shorter period of production may be outweighed economically by increased output early in life.<sup>211</sup>

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205. 21 U.S.C. § 360b(b)(1)(A) (2012).

206. 21 C.F.R. § 514.4(a) (2014).

207. 21 U.S.C. § 301(u) (2012).

208. *See, e.g., supra* footnotes 159–176 and accompanying text (animal well being problems resulting from the use of Zilmax (noting severe health problems associated with the use of the drug)).

209. *See, e.g.,* HUMANE SOC'Y OF THE U. S., AN HSUS REPORT: WELFARE ISSUES WITH SELECTIVE BREEDING FOR RAPID GROWTH IN BROILER CHICKENS AND TURKEYS 2–3 (May 2014), *available at* [http://www.humanesociety.org/assets/pdfs/farm/welfiss\\_breeding\\_chickens\\_turkeys.pdf](http://www.humanesociety.org/assets/pdfs/farm/welfiss_breeding_chickens_turkeys.pdf) (describing the adverse health impact of rapid growth in poultry production and providing an extensive bibliography of animal welfare research); HUMANE SOC'Y INT'L, AN HSI REPORT: THE WELFARE OF ANIMALS IN THE PIG INDUSTRY 6 (2014), *available at* [http://www.hsi.org/assets/pdfs/hsi-fa-white-papers/welfare\\_of\\_animals\\_in\\_the\\_pig.pdf](http://www.hsi.org/assets/pdfs/hsi-fa-white-papers/welfare_of_animals_in_the_pig.pdf) (describing animal health problems associated with industrialized hog production and feed additives and providing an extensive bibliography of animal welfare research).

210. *Steroid Hormone Implants, supra* note 123.

211. For example, cows that are treated with the hormone Bovine Somatotropin (rBST) produce more milk during peak production periods, but have other health problems including



In determining whether the livestock drug is safe with “reference to the health of man” the statute calls for a consideration of (1) whether there will be drug residues found in a human food product, and (2) if so, what level of those residues FDA determines will be safe.<sup>212</sup> Approval will likely involve setting a “tolerance” for the drug, i.e., an allowed amount of drug residue found in the human food products obtained from the animal that has received the drug.<sup>213</sup> Human exposure via the environment is not mentioned.

The drug may also be approved subject to a mandatory “withdrawal period.”<sup>214</sup> The withdrawal period is the period of time that the drug cannot be used in order to assure compliance with the set tolerance for the drug residue.<sup>215</sup> For animals marketed for meat, the withdrawal period references the time before slaughter.<sup>216</sup> For other food products such as milk and eggs, it references the period of time required between drug use and the marketing of any product from the animal for human consumption.<sup>217</sup>

Note that the tolerances set for various drugs are correlated with average consumption patterns. If daily consumption values for the meat decline, the FDA can and has raised the tolerances allowed.<sup>218</sup>

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mastitis and lameness. *See generally* I. R. Dohoo et. al., *A Meta-Analysis Review Of The Effects Of Recombinant Bovine Somatotropin*, 67 CAN. J. VET. RES. 252 (2003), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC280709/> (presenting a meta-analysis of the effects of rBST on various aspects of bovine health). Nonetheless, this hormone is considered safe with reference to the animal receiving the drug. *See* FOOD & DRUG ADMIN., *Bovine Somatotropin (BST)*, <http://www.fda.gov/animalveterinary/safetyhealth/productsafetyinformation/ucm055435.htm> (last updated July 28, 2014).

212. 21 U.S.C. § 360b(a)(6) (2012); *see also*, 21 U.S.C. § 360b(d)(1)(F) (allowing rejection of any drug with a residue beyond the determined safe tolerance level).

213. 21 U.S.C. § 360b(a)(6); 21 C.F.R. § 556 (2014).

214. 21 U.S.C. § 360b(b)(1)(H); 21 C.F.R. § 514.105(a) (2014).

215. Withdrawal periods are established as part of the new drug approval process and are published on the drug or feed label or package insert. *See*, 21 U.S.C. § 360b(b)(1) (requiring person to submit the proposed withdrawal period if it is required to ensure that the proposed use of such drug will be safe); 21 C.F.R. § 514.105 (requiring the Commissioner to forward for publication in the Federal Register a regulation prescribing the conditions for the new animal drug including the withdrawal period). For a helpful explanation, *What are Withdrawal Times (Periods) for Meat and Milk, and Where Can They be Found?*, EXTENSION FOUND. (Sept. 6, 2007), <http://www.extension.org/pages/35903/what-are-withdrawal-times-periods-for-meat-and-milk-and-where-can-they-be-found#.VPOm72PYR8w>.

216. *What are Withdrawal Times (Periods) for Meat and Milk, and Where Can They be Found?*, EXTENSION FOUND. (Sept. 6, 2007), <http://www.extension.org/pages/35903/what-are-withdrawal-times-periods-for-meat-and-milk-and-where-can-they-be-found#.VPOm72PYR8w>.

217. *Id.*

218. *See, e.g.*, 76 Fed. Reg. 57,907 (Sept. 19, 2011) (to be codified at 21 C.F.R. § 556.540) (raising the tolerance for progesterone in beef and lamb). The notice states that “Progesterone is approved for use in subcutaneous implants used for increased rate of weight gain in suckling

Alarming, there does not seem to be any practicable way for the FDA to consider the variety of drug residues that an individual might consume from different sources.

Section 360b authorizes the FDA to withdraw its approval of a new animal drug “after due notice and an opportunity for hearing” if certain conditions are met. There are six possible grounds for withdrawal:

- (1) “Experience or scientific data” shows that the drug is “unsafe for use” under the conditions for which it was approved;
- (2) “New evidence not contained in [the] application or not available” to the agency, evaluated with the prior evidence shows that the drug is “not shown to be safe;”
- (3) On the basis of new information, together with prior evidence, there is a “lack of substantial evidence” that the drug will have “the effect it purports or is represented to have;”
- (4) Required patent information is not filed;
- (5) The application is found to have contained an “untrue statement of a material fact;”
- (6) The applicant has made changes affecting safety or effectiveness beyond allowed variations and not addressed in a supplemental application.<sup>219</sup>

There is also a provision that allows withdrawal—after due notice and opportunity for a hearing—in cases where an applicant has failed to comply with recordkeeping requirements, new evidence of manufacturing problems are revealed, or new evidence of false labeling is discovered.<sup>220</sup>

There is also authority for an immediate suspension of approval, but this authority is limited to the Secretary (or acting Secretary) of Health and Human Services. Immediate suspension requires a showing of an “imminent hazard to the health of man or of the animals for which the drug is intended.”<sup>221</sup> The applicant may request

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beef calves and steers (21 CFR 522.1940) and in vaginal inserts used for management of the estrous cycle in female cattle and ewes (21 CFR 529.1940)”; *see also* Susan A. Schneider, *Hormone Levels in Beef and Lamb: Does Anyone Care*, AGRIC. L. (Oct. 15, 2011), <http://aglaw.blogspot.com/2011/10/hormone-levels-in-beef-and-lamb-does.html> (expressing concern and surprise about the increased tolerance level for progesterone in beef and lamb).

219. 21 U.S.C. § 360b(e)(1)(A)–(F) (2012).

220. 21 U.S.C. § 360b(e)(2)(A)–(C).

221. 21 U.S.C. § 360b(e)(1).

an expedited hearing.<sup>222</sup>

Despite these withdrawal and suspension authorities, the FDA has used its power sparingly, often preferring to let industry forces come to bear, as with Zilmax.<sup>223</sup> Alternatively, FDA will use its efforts to nudge the industry via guidances and voluntary recommendations.<sup>224</sup>

The “due process and notice of hearing” requirement associated with withdrawal of an application may well extend to litigation brought by a drug manufacturer that seeks to fight the withdrawal efforts. The FDA has argued that it can be more effective, produce results more quickly, and expend fewer resources by working collaboratively with industry.<sup>225</sup> This position, however, and agency’s inaction in the face of controversial drugs, has prompted third parties to litigate in order to force withdrawal. The case of *Natural Resources Defense Council, Inc. v. FDA*,<sup>226</sup> discussed below, serves as one prominent example.

### *B. Increased Concern Over the Regulation of Antibiotics: Regulation, Litigation, and “Judicious Use”*

As already noted, there is widespread concern among health professionals about the development of antibiotic resistant pathogens. The extensive use of antibiotics in livestock production, particularly of antibiotics that are important for human use, has been well established as a contributing factor. “For over thirty years the FDA has taken the position that the widespread use of certain antibiotics in livestock for purposes other than disease treatment poses a threat to

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222. *Id.*

223. *See supra* note 162 and accompanying text (describing the process through which Zilmax, an FDA-approved beta agonist, was largely boycotted by the beef industry after severe animal health problems were discovered).

224. For a current example of this approach, *see infra* notes 254–265 and the accompanying text: JUDICIOUS USE, *supra* note 101 (attempting to convince the industry to voluntarily reduce the use of medically important antimicrobials by explaining its concern); *see also* Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994, 1002 (1977) (explaining common criticisms that the FDA gives too much weight to industry interests in its drug approval process).

225. *E.g.*, FOOD & DRUG ADMIN., REPORT ON GOOD GUIDANCE PRACTICES: IMPROVING EFFICIENCY AND TRANSPARENCY (2011), available at <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf> (detailing ways in which the FDA can increase its efficiency and transparency, including making guidance documents and recommendations more easily accessible).

226. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012) [hereinafter *Natural Res. Def. Council I*].

human health.”<sup>227</sup>

In 1977, the FDA acted on this position, issuing notices of withdrawal under section 360b(e)(1)(B), seeking to withdraw approval of all subtherapeutic uses of penicillin in animal feed, and with limited exceptions, all subtherapeutic uses of oxytetracycline and chlortetracycline in animal feed.<sup>228</sup> Following the statutory procedures for withdrawal, the notices extended the opportunity for a hearing (NOOHs) to every drug manufacturer affected.<sup>229</sup> What followed is over thirty years of industry lobbying, Congressional interference, agency inaction, and eventually litigation—all giving rise to the FDA’s current policy of “judicious use.”<sup>230</sup>

Soon after the NOOHs were issued, Congress directed funds to the National Academies of Sciences so it could conduct further research on the use of antibiotics in animal feed.<sup>231</sup> “The report issued by the House Appropriations Committee included thinly veiled suggestions that the FDA not go forward with the hearing process until the research was completed.”<sup>232</sup> Two years later, Congress again expressed its interest in funding additional studies and its discouragement of FDA action until greater certainty was established.<sup>233</sup>

Industry groups concurrently petitioned the FDA to withdraw the NOOHs, but in 1983, the FDA denied their petitions and reaffirmed its concerns.<sup>234</sup> Additional studies were conducted, producing evidence of expanding antibiotic resistance and increasing concerns about livestock production, but without specifically providing a direct causal link between specific agricultural use and the

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227. *Id.* at 130.

228. Penicillin-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline) Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 56,264, 56,266 (Oct. 21, 1977).

229. *Id.*

230. *See* Withdrawal of Notices of Opportunity for a Hearing: Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697, 79,698 (Dec. 22, 2011) (recapping the FDA’s 1977 actions to withdraw uses of penicillin and tetracycline in animal feed and expressing the FDA’s new 2011 plan to focus its energy on “the promotion of the judicious use of antimicrobials in the interest of public health”).

231. *Natural Res. Def. Council, Inc. v. FDA*, 760 F.3d 151, 154 (2d Cir. 2014) [hereinafter *Natural Res. Def. Council II*].

232. *Id.* (citing H.R. REP. NO. 95-1290, at 99 (1978)).

233. *Id.* at 155 (citing S. REP. NO. 97-248, at 79 (1981)).

234. *Id.* (citing Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline) in Animal Feeds; Denial of Petitions, 48 Fed. Reg. 4544, 4556 (Feb. 1, 1983)).

specific antibiotic resistance observed.<sup>235</sup> The FDA never held the hearings and never took any further action in its efforts to withdraw the drugs noticed.<sup>236</sup>

In 1999 and again in 2005, public interest groups filed petitions with the FDA seeking withdrawal of regulatory approval for subtherapeutic livestock use of specified antibiotics, including penicillin and tetracyclines.<sup>237</sup> The FDA was still not compelled to act.<sup>238</sup>

In 2011, the National Resources Defense Council, with other public interest organizations initiated suit.<sup>239</sup> Their primary claim was that section 360b(e)(1) “compelled the FDA to hold the hearing proposed by the 1977 NOOHs and, if appropriate, withdraw approval for the antibiotic uses the NOOHs listed.”<sup>240</sup> The FDA defended vigorously, arguing that an alternative approach would be more effective than seeking withdrawal. The agency alleged that the process that was required to withdraw approval of a drug is lengthy and costly. They also alleged that new scientific findings would be required and that they would be forced proceed on a drug-by-drug basis. Accordingly, the FDA argued that the alternative course of action, pursuing voluntary measures, was preferable.<sup>241</sup>

In December 2011, the FDA formally withdrew the 1977 NOOHs.<sup>242</sup> The plaintiffs amended their complaint and moved forward.<sup>243</sup> The district court ruled in the plaintiffs’ favor, holding that section 360b(e) “requires the Secretary to issue notice and an opportunity for a hearing whenever he finds that a new animal drug is not shown to be safe. If the drug sponsor does not meet his burden of demonstrating that the drug is safe at the hearing, the Secretary must issue an order withdrawing approval of the drug.”<sup>244</sup> The district court found that the FDA’s issuance of the NOOHs in 1977 constituted a finding that that drugs were not shown to be safe.<sup>245</sup> It ordered FDA

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235. *Natural Res. Def. Council II*, 760 F.3d at 155.

236. *Id.* at 155–56.

237. *Id.*

238. *Id.* at 156.

239. *Id.*

240. *Id.*

241. *Id.* at 156–57.

242. *Withdrawal of Notices of Opportunity for a Hearing: Penicillin and Tetracycline Used in Animal Feed*, 76 Fed. Reg. 79,697 (Dec. 22, 2011).

243. *Natural Res. Def. Council II*, 760 F.3d at 157.

244. *Natural Res. Def. Council I*, 884 F. Supp. 2d at 143.

245. *Id.* at 151.

to conduct withdrawal hearings and, unless the manufacturers could rebut the finding, withdraw approval for those drug uses.<sup>246</sup>

The FDA appealed the decision, and the Court of Appeals for the Second Circuit deferred to the agency's interpretation of the statute and reversed.<sup>247</sup> The Second Circuit held that the district court erred in its reading of section 360b and that the NOOHs that were issued did not constitute a finding that mandated agency action.<sup>248</sup> The majority opinion of the Second Circuit Court provides:

The statute requires the FDA to withdraw approval of an animal drug only 'after due notice and opportunity for hearing' has been afforded, and then only 'if the Secretary finds' that the drug is not shown to be safe. 21 U.S.C. § 360B(e)(1). That language most naturally refers to a finding that is issued as a result of the hearing.<sup>249</sup>

There is a good deal of irony in this litigation. The FDA has argued against the widespread use of subtherapeutic antibiotics in the livestock industry for "over thirty years."<sup>250</sup> The plaintiffs shared the FDA's concerns about their use. Nevertheless, the FDA argued that the withdrawal process would expend resources and result in costly litigation.<sup>251</sup> Yet, in resisting the plaintiff's complaint, it ended up litigating with groups that share its concerns. In the end, it won the right to not take action.<sup>252</sup> Needless to say, this should be an unsatisfying victory in many respects.

In the midst of the litigation, the FDA issued a guidance for industry that articulated its recommended principles for the use of antibiotics in livestock production.<sup>253</sup> This guidance is an embodiment of the FDA's preferred strategy—to work with the industry and guide it to a better position rather than pursuing withdrawal. It is a non-binding statement of the FDA's favored approach to regulating the agricultural use of antibiotics considered to be medically important to

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246. *Id.* at 151–52.

247. *Natural Res. Def. Council II*, 760 F.3d at 176.

248. *Id.* at 174.

249. *Id.* at 172.

250. *Natural Res. Def. Council I*, 884 F. Supp. 2d at 130.

251. *Natural Res. Def. Council II*, 760 F.3d at 156–57.

252. *Natural Res. Def. Council II*, 760 F.3d at 176.

253. See generally JUDICIOUS USE, *supra* 100 (providing guidance on the FDA's current thinking on this topic).

humans.<sup>254</sup>

The guidance begins with an extensive description of the history of studies and reports documenting public health concerns with antibiotic resistance. The guidance then discusses the indirect, but conclusively established, connection between the extensive use of medically important antibiotics in livestock production and the increasing resistance observed.<sup>255</sup> It is an impressive argument against the use of antibiotics important to human health in livestock production.

The guidance also sets forth the FDA's two main principles for what it terms the "Judicious Use" of antibiotics:

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.

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.<sup>256</sup>

There are several weaknesses associated with the FDA's approach. First, given the financial interests at stake, the competition in both the livestock and the pharmaceutical industries, and the decades of virtually unregulated antibiotic use, a voluntary approach seems somewhat fanciful, if not naïve.

Second, the guidance contains an expansive reading of its first principle, limiting the use of medically important drugs to "those uses that are considered necessary for assuring animal health."<sup>257</sup> The FDA seeks to eliminate the use of antibiotics for "production purposes," i.e., growth enhancement and feed conversion.<sup>258</sup> It is willing to allow, however, uses that are "associated with the treatment, control, or prevention of specific diseases, including administration through feed or water."<sup>259</sup> It defines prevention as "including the administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease, in a situation

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254. *Id.* at 3.

255. *Id.* at 5–17.

256. *Id.* at 21–22.

257. *Id.* at 21.

258. *Id.*

259. *Id.*

where disease is likely to occur if the drug is not administered.”<sup>260</sup>

The problem with this approach is that the delivery of subtherapeutic levels of antibiotics to livestock for disease prevention is widespread and virtually inseparable from the use of those antibiotics as growth promotants.<sup>261</sup> The same dosage serves both purposes, regardless of how the drug is labeled. Studies have shown that in crowded confinement situations, livestock mortality is reduced by the delivery of low levels of antibiotics, even though the same result would likely be achieved from improved living conditions.<sup>262</sup> Thus, antibiotics can be used at subtherapeutic levels for disease prevention purposes as a means to adjust for the stressful production practices. Dr. Robert S. Lawrence, professor of Environmental Health Sciences, Health Policy, and International Health at the Johns Hopkins Bloomberg School of Public Health, explained this in his hard-hitting criticism of the FDA guidance:

The secret to [this production system’s] success has been, in no small part, the continuous feeding of small doses of antibiotics to food animals throughout their lives. These drugs help animals grow faster, and they also stave off infections linked to the squalid conditions in which food animals are raised. The misuse of antibiotics by the food animal industry is not just a means to make a quick buck; misusing these drugs is the lynchpin of the industrial model.

If antibiotics could no longer be used for disease prevention, the food animal production industry would be forced to reform its production practices to raise healthy animals in other ways. The preventive use of antibiotics would no longer be “necessary.” By eliding this fact in its guidance documents, the FDA has built public health policy around the needs of the industry rather than require the industry to reform itself to assure both human and

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260. *Id.* at n. 5.

261. *See, e.g.*, Bonne M. Marshall & Stuart B. Levy, *Food Animals & Antimicrobials: Impacts on Human Health*, 24 *CLIN. MICROBIOL. REV.* 718, 719 (2011), available at <http://cmr.asm.org/content/24/4/718.full> (explaining that some of the antibiotics administered to feedlot animals for non-therapeutic uses are the same ones used to treat illness in both humans and animals).

262. *See, e.g.*, JAMES M. MACDONALD & SUN-LING WANG, U.S. DEP’T OF AGRIC, ECON. RESEARCH SERV., *SUBTHERAPEUTIC ANTIBIOTICS AND U.S. BROILER PRODUCTION 3-7* (2009) available at <http://ageconsearch.umn.edu/bitstream/49198/2/AAEA%20broiler%20STA%20macdonald%20wang.pdf> (discussing the studies of subtherapeutic use of antibiotics and evaluating use in the broiler industry).



animal health.<sup>263</sup>

The FDA is relying upon a veterinarian's oversight to limit use to situations where animals are at risk for a specific disease. However, these drugs are currently sold over-the-counter.<sup>264</sup> The FDA seeks to phase-in voluntary oversight and consultation, but there is little incentive for either the livestock industry or the pharmaceutical industry to do so. Moreover, many veterinarians—who are less regulated than human doctors—have close ties with or receive financial benefits from the pharmaceutical industry.<sup>265</sup> Others are employed by the livestock industry.<sup>266</sup> Thus, the objective determination of “judicious use” may well be compromised. Finally, because the “judicious use” approach only applies to antibiotics classified as medically important, it is not likely to reduce overall antibiotic use or their impact on the environment.

### C. *The Environmental Impact of Livestock Drugs*

The FDCA does not make any apparent connections between drugs fed to animals and the overall impact on the environment, e.g., through manure excreted. Under the terms of the statutes, the requisite safety analysis appears only to consider the impact on human consumption.<sup>267</sup> However, the FDA is also subject to another federal law, the National Environmental Policy Act of 1969 (NEPA).<sup>268</sup> NEPA requires all federal agencies, including the FDA, to evaluate each major agency action to determine whether it will have a significant impact on the environment.<sup>269</sup>

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263. Robert S. Lawrence, *The FDA Did Not Do Enough to Restrict Antibiotics Use in Animals*, THE ATLANTIC (Apr. 16, 2012; 11:51 AM), <http://www.theatlantic.com/health/archive/2012/04/the-fda-did-not-do-enough-to-restrict-antibiotics-use-in-animals/255878/>.

264. JUDICIOUS USE, *supra* note 100, at 22.

265. Duff Wilson & Mimi Dwyer, *Veterinarians Face Conflicting Allegiances to Animals, Farmers—and Drug Companies*, REUTERS (Dec. 23, 2014) <http://www.reuters.com/investigates/special-report/farmaceuticals-the-drugs-fed-to-farm-animals-and-the-risks-posed-to-humans/#article-3-competing-loyalties>.

266. See generally, *Market Research Statistics—U.S. Veterinarians - 2013*, AM. VETERINARY MED. ASS'N, <https://www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-veterinarians.aspx#categories> (last visited Mar. 31, 2015) (showing 20.9 percent of veterinarians were employed in industry jobs in 2013).

267. See generally, 21 U.S.C. § 360(b) (2012) (establishing the requirements for the approval of new animal drugs).

268. 42 U.S.C. §§ 4321–4370 (2012).

269. 42 U.S.C. § 4332(C).

## 1. An Overview of NEPA

The National Environmental Policy Act (NEPA) is designed to encourage federal agencies to integrate environmental considerations into their decision making by directing them to evaluate the environmental impact of their proposed actions and, depending on that impact, to develop reasonable alternatives that have less adverse effects.<sup>270</sup> It is essentially a procedural statute. To ensure that agencies incorporate environmental impact analysis, NEPA created the Council on Environmental Quality (CEQ), and the CEQ promulgated regulations to implement NEPA procedures.<sup>271</sup> All federal agencies, including the FDA, are subject to these regulations.<sup>272</sup> However, the FDA, like most federal agencies, promulgated its own NEPA regulations which generally follow the CEQ procedures but are tailored for the specific mission and activities of the FDA.<sup>273</sup>

The requisite NEPA process provides for an evaluation of the environmental effects of any major federal action.<sup>274</sup> There are several levels of possible analysis: a categorical exclusion determination; the preparation of an Environmental Assessment (EA); a Finding Of No Significant Impact (FONSI); and the preparation of an Environmental Impact Statement (EIS).<sup>275</sup> Despite the concerns raised throughout out this article, the FDA regulations confidently state that “[t]here are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore would ordinary require the preparation of an EIS.”<sup>276</sup>

Nevertheless, instructions provided to those submitting new animal drug applications provide that drug sponsors should submit either an EA or a claim for a categorical exclusion for certain actions.<sup>277</sup> The approval of a new animal drug is included in FDA

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270. *See id.* (requiring agencies to include in recommendations or reports on legislation and action affecting the environment a statement covering the impact on the environment of that action, any adverse effect, alternatives, the relationship between short-term use of the environment and the consequences of long-term productivity, and irreversible commitments of resources involved).

271. 40 C.F.R. §§ 1500–1518 (2014).

272. 40 C.F.R. § 1500.3.

273. 21 C.F.R. § 25 (2014).

274. 40 C.F.R. § 1500.1.

275. 40 C.F.R. § 1501.4; 21 C.F.R. § 25.15.

276. 21 C.F.R. § 25.22.

277. *See* FOOD & DRUG ADMIN, *Environmental Impact Considerations*,

regulations as an action that will generally require an EA.<sup>278</sup> The EA will be prepared by the drug sponsor (the applicant) although the FDA will be “responsible for the scope and content of EAs and may include different information . . . when warranted.”<sup>279</sup> If the EA shows that the action will not significantly affect the environment, the FDA will issue a FONSI.<sup>280</sup> The FONSI is a “document prepared by a federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared.”<sup>281</sup>

The drug sponsor is thus placed in a position of assessing the environmental effects of its own request for approval. Particularly given the financial stakes at issue, it should be no surprise to find that EAs prepared in this situation find no adverse environmental impact.<sup>282</sup> If the drug sponsor were to find an adverse environmental impact, the sponsor would be expected to propose an alternative.<sup>283</sup> That alternative, whether a denial of approval or a restricted approval, would clearly work against the sponsor’s financial interests. Nonetheless, the FDA—with limited resources and little ability to generate its own environmental review—is dependent upon the research submitted by the sponsor. By all appearances, the system is designed to result in EAs that routinely support a FONSI.

If a “categorical exclusion” applies, a drug sponsor may not even have to prepare an EA. The FDA’s website explains that this exclusion applies to a “category of actions that the agency has determined, based on past experience, do not individually or cumulatively have a significant effect on the human environment.”<sup>284</sup> The FDA includes a number of types of new animal drug applications in its listing of categorical exclusions, including any new animal drug application “if the action does not increase the use of the drug.”<sup>285</sup> For example, the “[a]pproval of a drug for use in animal feeds if such

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<http://www.fda.gov/animalveterinary/developmentapprovalprocess/environmentalassessments/default.htm#top> (last updated Jul. 08, 2014) [hereinafter *Environmental Impact Considerations*].

278. 21 C.F.R. § 25.20(m).

279. 21 C.F.R. § 25.40(b).

280. 21 C.F.R. § 25.41.

281. 21 C.F.R. § 25.41(citing 40 CFR. § 1508.13).

282. See, e.g., ELANCO, *supra* note 169 (finding that the approval of ractopamine “would not be expected to have any substantial adverse effect on human health or the environment”).

283. 21 C.F.R. § 25.40(a) (providing that “[i]f potentially adverse environmental impacts are identified . . . the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action”).

284. *Environmental Impact Considerations*, *supra* note 277.

285. 21 C.F.R. § 25.33(a).

drug has been approved under § 514.2 or 514.9 of this chapter for other uses.”<sup>286</sup>

The FDA regulations provide that if an action would ordinarily be excluded, but “extraordinary circumstances indicate that a specific proposed action, may significantly affect the environment,” then an EA will be required.<sup>287</sup> Examples include “[a]ctions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment” and “actions that adversely affect a species or the critical habitat” of an endangered species.<sup>288</sup>

If the FDA anticipates that an undertaking may significantly impact the environment, or if a project is environmentally controversial, it may choose to prepare an EIS without having to first seek an EA.<sup>289</sup> This will rarely be the case.<sup>290</sup> However, if the EA is prepared and indicates that the environmental impact of the federal action may be significant, an EIS will be prepared.<sup>291</sup> Again, in part because the applicant is responsible for preparing the EA, an EIS is rarely indicated; and the FDA is extremely reluctant to order such an analysis.<sup>292</sup>

## 2. Applying NEPA to FDA Actions: Historical Context

When NEPA was first enacted, the FDA “initially took the position that [NEPA] required it to consider the environmental impact of every important action including, for example, the approval of a new drug or food additive.”<sup>293</sup> As it became clear that this

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286. 21 C.F.R. § 25.33(a)(7).

287. 21 C.F.R. §§ 25.15, 25.21.

288. 21 C.F.R. § 25.21.

289. 21 C.F.R. §§ 21.40, 21.42 (2014).

290. See 21 C.F.R. § 25.22 (describing circumstances in which preparing an EIS without an EA is appropriate).

291. *Id.*

292. FDA’s steadfast refusal to prepare an Environmental Impact Statement with regard to the very controversial new drug application that seeks the approval of genetically engineered salmon. See, e.g., FOOD & DRUG ADMIN., *Genetically Engineered Salmon*, <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm> (last visited Mar. 26, 2015); see also, HAROLD F. UPTON & TADLOCK COWAN, CONG. RESEARCH SERV., R43518, GENETICALLY ENGINEERED SALMON (Apr. 30, 2014), available at <http://www.fas.org/sfp/crs/misc/R43518.pdf> (explaining the new drug application approval process as applied to genetically engineered salmon and discussing the NEPA review).

293. PETER BARTON HUTT, RICHARD MERRILL & LEWIS GROSSMAN, FOOD AND DRUG LAW CASES AND MATERIALS 1309 (The Foundation Press, 4th ed. 2014). Note that one of the authors, Peter Barton Hutt, served as Commissioner of the FDA from 1971–1975, and another,

position was impracticable, the FDA published a Federal Register announcement declaring that the FDCA was its sole authority for the approval or rejection of any new drug or food additive.<sup>294</sup> The agency sought to “precipitate a judicial challenge that would clarify its obligations under NEPA.”<sup>295</sup>

As anticipated, the regulation was challenged and the agency’s obligations were clarified. The Federal District Court for the District of Columbia struck down the limiting regulation and held that “NEPA requires FDA to *consider* environmental factors in its decision-making process and supplements its existing authority to permit it to act on those considerations. It permits FDA to base a decision upon environmental factors, when balanced with other relevant considerations.”<sup>296</sup> FDA revoked the contested regulation soon thereafter.<sup>297</sup>

Despite NEPA’s focus on systemic environmental concerns, scholars observe that the FDA has almost never taken an action that identified environmental effects outside the risks to health as an important consideration.<sup>298</sup> And, when it has done so, it has often been unsuccessful. When it denied a food additive petition on environmental grounds, it was sued and the court reversed its decision.<sup>299</sup> Moreover, when it attempted to stay the effect of a regulation allowing the food additive selenium in animal feed because of a potential threat to aquatic fish and wildlife,<sup>300</sup> Congress forced the agency to suspend the stay.<sup>301</sup>

Over the years, there have been several unsuccessful attempts to force the FDA to file an EIS. Most prominent among these were

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Richard Merrill, served from 1975-1977, providing them with exceptional credibility in analyzing the positions of the FDA during this time period. *Id.* at x.

294. 40 Fed. Reg. 16,662 (Apr. 14, 1975). This regulation provided that the determination of an adverse environmental impact had “no legal or regulatory effect” and that the FDA Commissioner was limited in his authority to apply the law set forth in the FD&CA.

295. HUTT, MERRILL & GROSSMAN, *supra* note 293, at 1310 (referencing the notice published at 40 Fed. Reg. 16,662 (Apr. 14, 1975)). That notice included the statement that “[i]t is the Commissioner’s opinion that, since the activities of the Food and Drug Administration directly affect every person in this country, any such person has standing to obtain judicial review of this regulation in accordance with the provisions of 5 U.S.C. § 701 et seq.”

296. *Envtl. Def. Fund Inc. v. Mathews*, 410 F. Supp. 336, 338 (1976).

297. 41 Fed. Reg. 21,768 (May 28, 1976).

298. HUTT, MERRILL & GROSSMAN, *supra* note 293, at 1311.

299. *See generally* *Marshall Minerals, Inc. v. FDA*, 661 F.2d 409 (5th Cir. 1981).

300. 58 Fed. Reg. 47,962, 47,964 (Sept. 13, 1993).

301. HUTT, MERRILL & GROSSMAN, *supra* note 293, at 1311 (citing 60 Fed. Reg. 53,702 (Oct. 17, 1995) and 62 Fed. Reg. 44,892 (Aug. 25, 1997)).

efforts to object to the FDA's approval of the genetically modified drug recombinant bovine somatotropin (rBST or rBGH) marketed as Posilac.<sup>302</sup> The plaintiffs, suing as consumers of commercially produced milk, raised a number of challenges including the FDA's failure to conduct an EIS.<sup>303</sup> The FDA's FONSI determination was based on an EA prepared by the drug applicant, Monsanto.<sup>304</sup> The plaintiffs claimed that environmental harms—the socioeconomic impact on dairy farmers, health issues related to the milk produced, and health issues affecting the cows—required an EIS under NEPA.<sup>305</sup> The court disagreed, holding that FDA had met all of its requirements.<sup>306</sup> There was no allegation or discussion of any environmental impact associated with the use of the drug itself.

### 3. Pending Challenges to FDA's Compliance With NEPA: Ractopamine

In November 2014, two new cases were filed against the FDA Commissioner, Margaret Hamburg, each seeking to change the FDA's casual treatment of its obligations under NEPA.<sup>307</sup> The cases challenge the FDA's approval of ractopamine for use in pigs, turkeys, and cows without conducting an appropriate environmental analysis under NEPA.<sup>308</sup>

One case was brought by the Humane Society, United Farmworkers of America, and the Animal Legal Defense Fund.<sup>309</sup> It alleges food safety risks,<sup>310</sup> worker safety risks,<sup>311</sup> a negative impact on threatened or endangered species,<sup>312</sup> and—most relevant to the discussion herein—adverse environmental impacts from ractopamine

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302. See *Stauber v. Shalala*, 895 F.Supp. 1178, 1182 (W.D. Wis. 1995) ([p]laintiffs challenge defendants' approval of intervenor-defendant Monsanto Company's new drug application for Posilac, a milk production-enhancing, synthetic bovine growth hormone drug."). See discussion of rBST, *supra*, note 132–140 and the accompanying text.

303. *Id.* at 1182.

304. *Id.* at 1186.

305. *Id.* at 1194.

306. *Id.* at 1194–96.

307. Complaint, *Humane Soc'y*, No. 3:14-cv-04933 at 30–31; Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932 at 21–22.

308. Complaint, *Humane Soc'y*, No. 3:14-cv-04933 at 2; Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932 at 1.

309. Complaint, *Humane Soc'y*, No. 3:14-cv-04933.

310. *Id.* at 10–13.

311. *Id.* at 13–14.

312. *Id.* at 17–18.

in livestock manure.<sup>313</sup> It also challenges the approval of ractopamine in combination with other drugs, Tylosin, Monensin, and Melengestrol, citing environmental risks.<sup>314</sup> The Complaint alleges that the FDA has never adequately assessed these impacts under NEPA.

The other case was brought by three organizations: the Center for Food Safety, the Center for Biological Diversity, and Sierra Club.<sup>315</sup> It alleges food safety risks;<sup>316</sup> the environmental risk of ractopamine contaminating groundwater, streams, rivers, and other surface waters;<sup>317</sup> an adverse impact on threatened or endangered species;<sup>318</sup> and environmental risks associated with the combination drugs.<sup>319</sup>

Both cases cite the extensive use of ractopamine, use that far exceeds the estimates contained in the EAs prepared by the applicant; and both assert that the FDA has failed to adequately consider the environmental impacts of such extensive use.<sup>320</sup> It remains to be seen how the court will respond to these allegations, but even the filings reflect a new awareness of the extent of drug use in livestock production and the associated risk of contaminated manure.

## V. CHARTING A PATH FORWARD

The Humane Society and the Center for Food Safety litigation may bring the issues associated with animal drug use to light, at least with respect to the specific ractopamine usage in swine, cattle, and turkeys. Unfortunately, the litigation will last some time and addresses only one drug.

The FDA's efforts to control the development of antibiotic resistance through its "Judicious Use" policy indicates both the agency's interest in confronting the problem and its hesitancy to take strong action. The FDA continues to approve new animal drugs

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313. *Id.* at 14–17.

314. *Id.* at 18–24.

315. Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932.

316. *Id.* at 8–11.

317. *Id.* at 11–12.

318. *Id.* at 12.

319. *Id.* at 13–16.

320. See generally, Complaint, *Humane Soc'y*, No. 3:14-cv-04933; Complaint, *Ctr. for Food Safety*, No. 3:14-cv-4932.

regularly,<sup>321</sup> with Freedom of Information Summaries available for each drug.<sup>322</sup> Yet, these summaries fail to include environmental risks as a category of consideration, indicating that it is unlikely to change its longstanding reliance on FONSI determinations as its sole approach to NEPA.<sup>323</sup>

Meanwhile, those at all ends of the livestock industry remain locked in a competitive struggle to produce meat at the cheapest price possible, and those in the pharmaceutical industry compete fiercely to develop and market drugs that will assist producers in achieving that goal. Both industries are on a new drug treadmill that rewards the use of more powerful drugs to achieve more dramatic results. There is no systemic analysis of the cumulative effects of these drugs' use in livestock production, and without that analysis, we proceed at our peril.

The use of drugs in the livestock industry is so pervasive, so engrained in the system, so embedded into our price structures, and so much a part of our overall food system, that it must be asked whether there is any way to retreat. Still, the seriousness of the risks presented implores us to find solutions. The following proposals provide the possibility for an interrelated way forward, employing a range of policy tools from market-based to regulatory.

#### *A. The Creation of a National Commission for the Evaluation of Drug Use in the Livestock Industry*

There are two overarching problems raised by the regulation of drug use in the livestock industry. First, there is no one who is able to see the big picture—no one who approaches the issue of livestock production with a systemic analysis. Drugs are approved on an individual basis with no follow-up mechanism to chart the extent of their eventual use. There is never any consideration of cumulative multi-drug environmental or food safety effects. Furthermore, there is no apparent thought about the systemic impact of creating a billion tons of contaminated manure and then applying it to cropland or allowing it to enter waterways. Second is the closely related problem

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321. Approvals are posted on the FDA website. *Recent Animal Drug Approvals*, FOOD & DRUG ADMIN. (Mar. 24, 2015), <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm363948.htm>.

322. See, e.g., FOOD & DRUG ADMIN., FREEDOM OF INFORMATION SUMMARY SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION: ZILMAX PLUS RUMENSIN PLUS TYLAN PLUS MGA (2015), available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/UCM433793.pdf>.

323. *Id.*



of secrecy. Even the agency charged with regulating animal drugs does not have access to how or where they are being used.

A bipartisan commission should be created to accurately evaluate the full extent of drug use in the livestock industry; the cumulative impact of this drug use; the public health and animal welfare effects; and the full range of environmental effects. The commission would further explore public and private pressures placed on FDA regulators; efforts to influence research to produce results in line with industry objectives; and efforts to prevent transparency in agricultural practices. The commission would be charged with reporting its findings to Congress, the President, and the public. Based on its findings, the commission would make recommendations to the relevant agencies involved, and to Congress if additional legislation were proposed. This commission would have wide authorities to obtain otherwise privileged information and to consult widely with a full range of affected parties.

### *B. The Expanded Use of Certification Programs for Meat Produced Without Drugs*

There are producers and retailers who would like to decrease or eliminate livestock drugs in their operations, but the current market structure places them at a disadvantage. If all meat is the same, cost of production is the only driver for economic success. Similarly, consumers who are concerned about drug use in livestock production may feel they have few options. Systems for verifiable labeling serve both interests.

Public and private certification programs should be encouraged, assisting the industry with a value-added approach to minimizing drug use. This has already begun, with successful “raised without antibiotics” market initiatives and associated certifications.<sup>324</sup> The USDA currently grades meat and poultry products and verifies some production practices,<sup>325</sup> but enhanced efforts should be made to

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324. As a current example, the “Never-Ever Process Verified Program” certifies that livestock is raised without antibiotics administered in any form; that is raised without growth hormones or other synthetic growth promotants (including natural or synthetic, estrus suppressants, beta agonists, or other drugs to promote or impact growth); and, that it is raised without being fed any mammalian and avian byproducts. See, U.S. DEP’T OF AGRIC., NEVER EVER 3 (NE3) (2009), available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5066028>.

325. E.g., U.S. DEP’T OF AGRIC., *Grading, Certification, and Verification* (Jan. 14, 2013), <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=GradingCertificationandVerification&leftNav=GradingCertificationandVerification&page=Gr>

develop a range of certification opportunities for drug-free production practices. The USDA should actively promote these efforts and encourage producers and consumers to move toward the reduced use of livestock drugs. Incentive programs to assist producers in the transition toward drug-free practices should be established.

*C. A Commitment to Transparency Throughout the Food System*

Under the current regulatory system for drugs used in livestock production, most drugs are purchased over-the-counter or in proprietary feed mixes. In this system the chemical composition of drugs and feed additives may be protected by patents and trademarks, and even regulating agencies may be unaware of industry practices. Consumers are likely to be unaware of drug use, drug residues, and potential contamination issues. The following steps would help to ensure a more transparent system.

The Department of Health and Human Services (incorporating the FDA and the CDC) should be allowed access to accurate information about what drugs are being used. This includes information about on-farm use, specific-species use, off-label use, and information about adverse impacts. This would require re-categorizing livestock drugs or establishing a new reporting system for livestock drug use.

Information on drug use that is site-specific should be available to EPA, state environmental agencies, local and tribal governments, and to environmental researchers in order for the cumulative environmental and public health effects of use to be assessed. This will not only alert agencies and governments to what is being used in their area, it will also assist in identifying the source of any contamination that may occur—be it from human or animal drug use.

Public funding and assistance should be provided to states, tribes, and communities for testing water and soil samples for drug residues. This will allow these communities to build a database of information on drug residue contamination patterns from all uses.

Additionally, meat labeling should either include mandatory reference to production practices involving significant drug use and/or information on drug use should be available to consumers on product websites. Relevant government agencies including the FDA and the

USDA should have dedicated consumer awareness programs to provide interested consumers with information about the food they eat and how it has been produced. The agencies should combat efforts to limit transparency, encouraging disclosures rather than protecting industry secrecy.

USDA residue testing should be increased, with results made available to the public. In addition, regular residue testing by meat processors should be required in conjunction with the pathogen testing now conducted under a processor's requisite HACCP system. The only exception should be for processors who obtain certifications that drugs were not used in production.<sup>326</sup>

#### *D. Requirements to Protect the Integrity of Veterinarians, Veterinary Schools, and Veterinary Associations*

Veterinarians are critical to FDA's "judicious use" approach to the use of antibiotics. Yet, currently, there is no public disclosure required for any of their financial connections with the pharmaceutical industry. Similarly, some veterinarians may be financially dependent upon a livestock integrator who seeks medical authority for drug use. Regulations should be put in place to protect the integrity of the veterinary profession.

#### *E. Increased Public Funding for Research and Higher Standards for University Agricultural Research*

Much of the animal science research now undertaken at our public land grant universities is funded by private companies with a vested interest in the outcome of the studies. Unfortunately, this can and often does influence the type of research that is done. This funding system can also taint research results, as reported in the Chronicle of Higher Education in an article about Zilmax research:

Scores of animal scientists employed by public universities have helped pharmaceutical companies persuade farmers and ranchers to use antibiotics, hormones, and drugs like Zilmax to make their cattle grow bigger ever faster. . . .

It's been a profitable venture for the drug companies, as well as for the professors and their universities. Agriculture schools

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326. HACCP refers to the Hazard Analysis Critical Control Points system of testing for and controlling pathogen contamination in meat processing. See generally *HACCP*. U.S. DEP'T OF AGRIC. (Mar. 24, 2015), <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp>.

increasingly depend on the industry for research grants . . . [a]nd many professors now add to their personal bank accounts by working for the companies as consultants and speakers. More than two-thirds of animal scientists reported in a 2005 survey that they had received money from industry in the previous five years.<sup>327</sup>

Unfortunately, schools of agriculture have “largely rejected critics’ concerns about industry cash.”<sup>328</sup> It is reported that few agriculture school administrators are willing to set limits on faculty who accept corporate money, and confidentiality rules may prevent public disclosure.<sup>329</sup>

Objective research is critical to good regulatory and policy decision making. The connection between researchers (who study the impact of new technologies) and the manufacturers (who stand to benefit from the sale of those products) must be dismantled. Public funding should be restored to prior levels, and agriculture departments at our universities should ensure that their policies demand objectivity and integrity from their professors. Strict conflict of interest provisions and limitations on private compensation should be in place at all research institutions.

#### *F. Increased Regulation*

The interpretation of the “safe and effective” test that is used to approve new animal drugs must be expanded to include an analysis of safety that incorporates environmental considerations and cumulative effects. We must develop a more systemic, holistic approach to regulating our food system. Mechanisms for tracking drug use on the farm and in all animal facilities must be in place so that the agencies can accurately evaluate the extent of use and the environmental consequences of that use. In addition, the FDA must be adequately funded so that it can perform its own environmental assessments of the impact of new drug approvals, perhaps in partnership with the EPA and publicly funded research entities.

Drugs deemed critical for human medical use should be banned in livestock production absent extraordinary circumstances, such as a

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327. Melody Petersen, *As Beef Cattle Become Behemoths, Who Are Animal Scientists Serving?*, CHRON. OF HIGHER EDUC. (Apr. 15, 2012), <http://chronicle.com/article/As-Beef-Cattle-Become/131480/> (criticizing the influence of industry funding on animal science research).

328. *Id.*

329. *Id.*

major livestock epidemic. Drug uses that increase animal suffering in any way should similarly be prohibited. Relatedly, new drug approvals should be guided by a safety analysis that truly includes consideration of the safety of the animal to which the drug is administered.

Companies and persons found to have used a drug inconsistently with label directions and approved usage should bear financial responsibility for remediating drug contamination of soil and water. Finally, the associated adverse effects on the environment should be assessed on companies marketing the drug for farm use and on anyone found to have not used the drug consistent with label directions and approved dosage.

#### *G. Campaign Finance Reform and Restrictions on Industry Lobbying*

The lack of regulation of drugs in the livestock industry is all too often traced back to Congressional pressure on an under-resourced agency. Intimately intertwined with campaign funding, this Congressional pressure all too often influences policies that should be decided on the merits. As noted herein, efforts to prevent limitations on antibiotic use in livestock production have been obvious and largely successful, despite increasing public health concerns worldwide. As long as our political system is influenced most by those with the most funds to invest in it, it will be extremely difficult to enact thoughtful, objective public policy.

### VI. CONCLUSION: A NEW VIEW OF OUR FOOD SYSTEM

The industrialization of our food production systems—namely the use of a manufacturing model for the production of food—has led many to forget that food is not just another manufactured item. Our food begins as a living thing, whether plant or animal, and it grows through natural biological processes. One process affects another, and each interacts with the environment.

Yet, our regulatory systems treat each aspect as if it were in isolation. Our system for regulating drug use seems to discount the fact that what an animal ingests will be present in that animal's system, in the products of that animal, and in the manure and urine it excretes. It ignores the fact that all of the drugs used may have a cumulative, even a synergistic effect, that far exceeds the analysis of any individual drug. Our food system is just what it claims to be—a system—and it is a system that is deeply intertwined with and dependent upon the environment. We need to stop regulating

individual components without regard for the whole.

In the end, consumers have a critical role to play. Michael Pollan's oft-quoted comment about "eating as a political act," an extension of Wendell Berry's saying that "eating is an agricultural act," remains the most realistic avenue for a change.<sup>330</sup>

Ultimately, it may be consumers' increasing interest in their food—where it comes from and how it was produced—that has the most impact on our future. Industry responds to the marketplace. Whether it is Chipotle marketing its "food with integrity,"<sup>331</sup> Tyson Foods essentially halting the use of Zilmax throughout the industry,<sup>332</sup> or efforts in the poultry industry to eliminate the use of antibiotics,<sup>333</sup> companies react to consumer interests. Assuring that consumers have the information they want and need will go a long way towards improving the food system upon which we all depend.

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330. See Joe Fassler, *The Wendell Berry Sentence That Inspired Michael Pollan's Food Obsession*, THE ATLANTIC (Apr. 13, 2013), <http://www.theatlantic.com/entertainment/archive/2013/04/the-wendell-berry-sentence-that-inspired-michael-pollans-food-obsession/275209/> (discussing how connecting the dots between the farm and the plate leads to more change in the industry).

331. *What is Food with Integrity?*, CHIPOTLE, <http://www.chipotle.com/en-US/fwi/fwi.aspx> (last visited Mar. 28, 2015).

332. *Lost Hooves*, *supra* note 160.

333. David Kesmodel et al., *Meat Companies Go Antibiotics-Free as More Consumers Demand It*, WALL ST. J. (Nov. 3, 2014), <http://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802>.