EXAMINING FOOD SAFETY FROM A FOOD SYSTEMS PERSPECTIVE: THE NEED FOR A HOLISTIC APPROACH

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INTRODUCTION

There has been an effort to shift the focus of the Food and Drug Administration's (FDA) food safety approach from reactive to preventative. The recently enacted Food Safety Modernization Act was hailed as a means to "transform the FDA from an agency that tracks down outbreaks after the fact, to an agency focused on preventing food contamination in the first place."[1] While this attempted proactivity is laudable in many respects, the United States' overall approach toward food safety remains highly compartmentalized and is seemingly unable to consider safety concerns on a systemic scale. This has resulted in actions based on narrow and immediate justification with unanticipated negative consequences. This Article considers the inherently systemic nature of our food system and the inability of the agencies involved to address it as such.

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1. Megan R. Wilson & Elise Viebeck, *Obama Administration Begins Major Overhaul of Food Safety Rules*, THE HILL (Jan. 4, 2013, 8:29 PM), http://thehill.com/blogs/healthwatch/food-safety/275691-obama-admin-releases-major-food-safety-regs.

I. THE CONCEPT OF FOOD SAFETY IN TODAY'S COMPLEX FOOD SYSTEM: "ENSURING THAT THE FOODS WE EAT . . . ARE SAFE AND DON'T CAUSE US HARM"

Most agree that providing a safe and adequate food supply is a critical responsibility of government. World history is replete with examples of the importance of food security in maintaining order and support for the government in power. Maintaining an adequate food supply implies that this food supply must be safe to consume.

In 2009, President Obama delivered a speech announcing the appointment of Dr. Margaret Hamburg as Commissioner of the FDA, the appointment of Dr. Joshua Sharfstein as the Principal Deputy Commissioner, and the creation of a new Food Safety Working Group.[2] His remarks included the following statement on the role of government in the food safety arena:

> I've often said that I don't believe government has the answer to every problem or that it can do all things for all people. We are a nation built on the strength of individual initiative. But there are certain things that we can't do on our own. There are certain things only a government can do. And one of those things is ensuring that the foods we eat, and the medicines we take, are safe and don't cause us harm. That is the mission of our Food and Drug Administration and it is a mission shared by our Department of Agriculture, and a variety of other agencies and offices at just about every level of government.[3]

This vision of the role of government was at the heart of President Obama's support for the Food Safety Modernization Act.[4] This new law, the first major change to the FDA's authority in many years, was passed with the goal of establishing a more proactive approach to food safety.[5] According to FDA Commissioner Hamburg, the law "[shifted] the focus [of government] from responding to [food] contamination to preventing

2. Barack Obama, President of the U.S., Weekly Address: President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures (Mar. 14, 2009), *available at* http://www.whitehouse.gov/the_press_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F.

3. *Id.*

4. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

5. *See id.* §§ 101–116.

it."[6] She further stated, "Preventing problems before they cause harm is not only common sense, it is the key to food safety in the 21st century."[7]

Recognized food safety advocate and food safety director at the Center for Science in the Public Interest, Caroline Smith DeWaal, agreed, issuing the following statement: "The new law should transform the FDA from an agency that tracks down outbreaks after the fact, to an agency focused on preventing food contamination in the first place."[8]

Preventing food "contamination" is indeed the main focus of the law. It seeks to prevent food from being contaminated with the kinds of pathogens that can cause foodborne illness.[9] The latest estimates from the Center for Disease Control indicate that "roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases" each year.[10]

Far more is involved, however, if we truly seek to "ensur[e] that the foods we eat . . . are safe and don't cause us harm."[11] Connecting a virulent pathogen to a food product that has caused an outbreak of foodborne illness is a very worthy and complex task. However, far more difficult safety concerns are those that involve determining the long-term safety implications inherent in our increasingly complex food safety system.

When our food system was more basic, our populations less dense, and our environment less challenged, food safety could focus on the immediate problems of adulteration and misbranding: Would a consumer become ill from eating the food that he or she purchased and is that food what it promises to be?[12]

Today, however, our food system has transcended that analysis. The complexity of this system mandates a more complex analysis. Food production and food processing each have a significant environmental impact. Through that process, a discreet food safety concern—such as pathogen contamination—may occur with devastating effects. We respond with efforts to impose "kill steps" in the process, such as antimicrobial washes or additives, but we seldom look at the system as a

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6. Wilson & Viebeck, *supra* note 1.

7. *Id.*

8. *Id.*

9. *See* FDA Food Safety Modernization Act § 101.

10. *CDC Estimates of Foodborne Illness in the United States*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last updated Apr. 22, 2013).

11. Obama, *supra* note 2.

12. These two questions and the dual concern of adulteration and misbranding form the basis for our federal regulation of food today. *See, e.g.*, The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2012) (prohibiting the adulteration or misbranding of food sold in interstate commerce).

whole to determine why it produced the pathogens or what the implications of the remedy are.

Moreover, food production may have far-reaching safety implications that transcend pathogenic contamination. All levels of food production impact the environment, with negative effects including water pollution, air pollution, and contribution to the greenhouse gases associated with climate change. Food pricing, availability, and marketing affect consumption. Food consumption, in terms of what food one eats and how much one eats, has a dramatic impact on health. All of this affects the economy, not just in terms of the food industry, but the health industry as well. Yet food safety is typically limited to the staid principles of adulteration and misbranding with few considerations of the whole integrated system.

Technology promises us the benefits of new food additives to improve our food products, new pesticides to prevent damage, new feed additives to promote growth, and new packaging materials in which to deliver our foods. Nanotechnology promises a new frontier in altering the behavior of the ingredients in food products. This is the modern food system, with both a Garden of Eden and a Pandora's Box of possibilities.

How does a government ensure that these new products and practices "don't cause us harm?" Immediate harm is relatively easy to detect, but how can long-term harm—including environmental impact—be detected while still protecting innovation?

II. THE FRAGMENTATION OF AUTHORITY

The silo approach to food safety imposed by statutory authority upon the various agencies involved has been recognized as a perpetual problem for food safety.[13] The FDA has direct regulatory authority over most of our food system,[14] yet the Environmental Protection Agency (EPA) regulates the appropriate use of pesticides, including those applied to food crops.[15] The Department of Agriculture (USDA) has jurisdiction over most meat products,[16] yet the FDA approves and regulates the drugs

13. *E.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/T-RCED-99-256, FOOD SAFETY: U.S. NEEDS A SINGLE AGENCY TO ADMINISTER A UNIFIED, RISK-BASED INSPECTION SYSTEM 2 (1999), *available at* http://www.gao.gov/assets/110/108064.pdf; Timothy M. Hammonds, *It Is Time to Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427, 429 (2004); Note, *Reforming the Food Safety System: What if Consolidation Isn't Enough?*, 120 HARV. L. REV. 1345, 1345–47 (2007).

14. *E.g.*, Federal Food, Drug, and Cosmetic Act §§ 301–399(f).

15. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136(g) (2012).

16. *See* Federal Meat Inspection Act, 21 U.S.C. §§ 601–683 (2012); Poultry and Poultry Products Inspection Act, 21 U.S.C. §§ 451–472 (2012).

that can be administered to livestock.[17] The Government Accountability Office (GAO) continues to stress the problems associated with such a "fragmented" food safety system:

> For more than a decade, GAO has reported on the fragmented nature of federal food safety oversight. While the Food and Drug Administration (FDA) and U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) have primary oversight responsibilities, a total of 15 agencies collectively administer at least 30 food-related laws.[18]

According to the GAO, this results in "inconsistent oversight, ineffective coordination, and inefficient use of resources."[19] This fragmentation contributes to the inability of government to undertake a systemic food safety analysis.

The 2010 *Salmonella* outbreak traced to eggs produced in Iowa provides a telling example. That outbreak was blamed for nearly 2,000 *Salmonella* infections and resulted in a recall of over 500 million eggs.[20] FDA federal investigators eventually found unsanitary conditions at several DeCoster facilities in Iowa "including dead chickens, rodents and towers of manure."[21]

The GAO used this example to show that "fragmentation persists, with several agencies having different roles and responsibilities throughout the egg production system."[22] This fragmentation is described as follows:

> FDA is generally responsible for ensuring that eggs in their shells—referred to as shell eggs—including eggs at farms such as those where the outbreak occurred, are safe, wholesome, and properly labeled. FSIS, on the other hand, is responsible for the safety of eggs processed into egg products. In addition,

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17. 21 U.S.C. § 360b (2012).

18. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-289, FEDERAL FOOD SAFETY OVERSIGHT: FOOD SAFETY WORKING GROUP IS A POSITIVE FIRST STEP BUT GOVERNMENTWIDE PLANNING IS NEEDED TO ADDRESS FRAGMENTATION 1, (2011) [hereinafter GAO, POSITIVE FIRST STEP], *available at* http://www.gao.gov/products/GAO-11-289.

19. *Id*.

20. Dan Flynn, *Settlements for Children Injured in Egg Outbreak*, FOOD SAFETY NEWS (Nov. 17, 2011), http://www.foodsafetynews.com/2011/11/some-settlements-for-children-injured-in-egg-outbreak/#.Uu65QXddV8s.

21. *Employee at Maine Egg Farm Killed by Coworker*, FOOD SAFETY NEWS (Aug. 22, 2013), http://www.foodsafetynews.com/2013/08/employee-at-maine-egg-farm-killed-by-coworker/#.UwFN3ihjtU8.

22. GAO, POSITIVE FIRST STEP, *supra* note 18, at 1.

> USDA's Agricultural Marketing Service (AMS) sets quality and grade standards for shell eggs, such as Grade A, but does not test the eggs for bacteria such as *Salmonella*. Further, while USDA's Animal and Plant Health Inspection Service manages the program that helps ensure laying hens are free from *Salmonella* at birth, FDA oversees the safety of the feed they eat.[23]

In the Iowa *Salmonella* outbreak, AMS officials had actually visited the facilities shortly before the outbreak and performed grading services.[24] However, there was no communication with the FDA, who was in charge of the safety of the facility.[25] Fragmentation at about its worst.

In addition to the federal agency fragmentation, others have used the Iowa egg example to describe another level of inefficiency. The DeCoster facilities contracted with Iowa State University's (ISU) Veterinary Diagnostics Laboratory for *Salmonella* testing.[26] It is reported that the tests revealed that the eggs produced at the facilities "were likely contaminated with Salmonella months before more than half a billion eggs from its facility were recalled."[27]

> ISU's lab, employing 125 people with a $3.2 million budget funded annually by Iowa taxpayers, provided "third-party quality assured diagnostic services" for Austin "Jack" DeCoster's egg empire and discovered the problem long before the August 2010 recall. . . .
>
> ISU gave the results to DeCoster, but did not alert consumers. Rodger Main, operations director at the veterinary lab, said the strain involved did not have to be reported to either the state or federal government, and doing so outside of any requirement would violate confidentiality agreements the lab signs with food producers.[28]

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23. *Id.*

24. U.S. DEP'T OF AGRIC., OFFICE OF INSPECTOR GEN., AUDIT REPORT 50601-0001-23, USDA CONTROLS OVER SHELL EGG INSPECTIONS 13 n.42, 17–18 (2012) [hereinafter USDA AUDIT REPORT], *available at* http://www.usda.gov/oig/webdocs/50601-0001-23.pdf.

25. *Id.* at 12–13.

26. Dan Flynn, *DeCoster Knew about Contamination for Months before Recall*, FOOD SAFETY NEWS (June 4, 2012), http://www.foodsafetynews.com/2012/06/decoster-knew-about-contamination-for-months-before-recall/#.Uu6o-nddV8s.

27. *Id.*

28. *Id.*

Under current law, the ISU research facility owed no duty to report the problem; the conflicting loyalties between the private contract with food producers and the public good is disconcerting. The ease with which publicly funded research institutions are able to set aside their duty to taxpayers for private financial gain is a recurring problem throughout the academy. It is not one that is helpful to a systemic approach to true preventative food safety.

Just prior to the 2010 *Salmonella* outbreak and egg recall, the FDA announced new regulatory provisions designed to limit *Salmonella* outbreaks in egg production. The new regulations were effective September 8, 2009, but had a compliance date of July 9, 2010.[29] Arguably, the regulations, if implemented sooner, should have been effective in preventing—or at least limiting—the Iowa outbreak. In this sense, the rules represent a real food safety improvement. However, some who have evaluated the implementation of the regulations suggest that lack of compliance and insufficient resources for inspection and enforcement have reduced the potential effectiveness of the rules.[30]

The USDA Office of the Inspector General (OIG) investigated the USDA's performance with regard to the outbreak and issued a critical report.[31] The report noted, however, that the agencies were attempting to address the specific problem of fragmentation. It noted that:

> USDA and FDA have updated their agreements in an effort to improve coordination and the exchange of information. In March 2011, the Agricultural Marketing Service (AMS) and FDA revised their long-standing memorandum of understanding (MOU) on information sharing and other activities relating to the inspection and grading of food products. In addition, in December 2011, the Under Secretaries representing several USDA agencies, including AMS, the Food Safety and Inspection Service (FSIS), and the Animal and Plant Health Inspection Service (APHIS), signed a new MOU with FDA to improve the sharing of information between the two Departments.[32]

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29. Prevention of Salmonella Enteritidis in Shell Eggs during Production, Storage, and Transportation, 74 Fed. Reg. 33,030, 33,030, 33,034 (July 9, 2009) (codified in 21 C.F.R. pts.16, 118).

30. Dan Flynn, *New Egg Rule Inspections Show Problems Persist*, FOOD SAFETY NEWS (Aug. 31, 2011), http://www.foodsafetynews.com/2011/08/new-egg-rule-inspections-not-looking-good-for-anybody/#.Uu66PnddV8t.

31. USDA AUDIT REPORT, *supra* note 24, at 1–4.

32. *Id.* at 1.

Nevertheless, the OIG included that "USDA agencies need to improve both their coordination of responsibilities and their communication of information in order to ensure consumer safety."[33] And, as there are still two different agencies working on related regulatory functions, the fragmentation continues.

Regardless of which agency is involved, food safety initiatives seem to focus on treating the symptoms of the problem without questioning the potential causes. A truly "preventative" approach would consider how and why *Salmonella* continues to be a problem in poultry production. For example, the new egg regulations impose testing and sanitation requirements on large-scale industrialized egg factories without questioning the actual production practices in place.[34] Given that these production practices apply to living animals, and given that the food safety concerns involve disease and infections afflicting these animals, shouldn't production practices be the first area of inquiry? This is not to suggest that improved production practices would eliminate *Salmonella* contamination, but a systemic, preventative analysis would begin with the source of the problem, not a curative treatment.

Ninety-five percent of egg production in the United States is achieved through "conventional cage systems."[35] Production practices under this system are unquestionably physically stressful for the chickens. Intense crowding within cages, unnatural living conditions, and tens of thousands of birds all within one facility with the associated air pollution from waste, all contribute to a physically challenging environment.[36] Antibiotics are often administered at sub-therapeutic levels not only to stimulate growth but to prevent infection.[37] This use of antibiotics has been linked to the development of antibiotic-resistant pathogens, such as antibiotic-resistant *Salmonella*.[38]

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33. *Id.*

34. *See* Prevention of Salmonella Enteritidis in Shell Eggs during Production, Storage, and Transportation, 74 Fed. Reg. at 33,030.

35. *Animal Welfare*, UNITED EGG PRODUCERS, http://www.unitedegg.org/AnimalWelfare/default.cfm (last visited Mar. 7, 2014).

36. *See* SARA SHIELDS & IAN J.H. DUNCAN, HUMANE SOC'Y OF THE UNITED STATES, AN HSUS REPORT: A COMPARISON OF THE WELFARE OF HENS IN BATTERY CAGES AND ALTERNATIVE SYSTEMS 1, 6 (2010), *available at* http://www.humanesociety.org/assets/pdfs/farm/hsus-a-comparison-of-the-welfare-of-hens-in-battery-cages-and-alternative-systems.pdf.

37. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-490, ANTIBIOTIC RESISTANCE: FEDERAL AGENCIES NEED TO BETTER FOCUS EFFORTS TO ADDRESS RISK TO HUMANS FROM ANTIBIOTIC USE IN ANIMALS 10 (2004), *available at* http://www.gao.gov/assets/250/242186.pdf.

38. *Salmonella and Chicken: What You Should Know and What You Can Do*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/features/salmonellachicken/ (last updated Oct. 28, 2013).

Animal welfare concerns are addressed in many other writings and are beyond the scope of this analysis. Suffice it to say that it defies common sense to focus all of our food-safety efforts on increased testing and the inspection of the cleanliness of the egg facility without considering the health and safety of the conditions within which the animals that produce the eggs are raised. A more systemic approach to food safety concerns is appropriate.

One is again struck by the difference between producing inanimate objects in a factory setting and producing live animals and their products.[39] This difference is often ignored in our food safety regime. Indeed, the issue is perhaps not just one of fragmentation but of a gap in our regulatory scheme. No federal agency regulates the process of raising chickens or producing eggs. There are no federal animal welfare standards that apply to chickens or other poultry.[40]

III. BEYOND THE FOOD WE EAT: THE EXTENDED IMPACT OF FOOD PRODUCTION PRACTICES

The industrialization of our food production methods has misled many into believing that food is simply another manufactured item. This is a dangerous misinterpretation. In reality, almost all of our food sources depend directly on the complex interaction of natural processes—our food all begins as a living thing, whether plant or animal. Because food production involves the biological or horticultural process of growing a living animal or plant, production cycles are complex and inherently interrelated. Thus, the production process is far more interactive than the manufacturing model anticipates. Regulation often fails to recognize this interconnection, attending to individual aspects without consideration of the whole. When government attempts to regulate food safety as if it were regulating product safety, it misses this critical distinction.

The use of arsenic-based compounds (arsenicals) as animal drugs in livestock production provides an illustrative example. Arsenic is naturally occurring and widely dispersed in the environment.[41] In addition, however, arsenic has had many commercial uses, particularly in

39. *See* Susan A. Schneider, *Reconsidering the Industrialization of Agriculture*, 26 J. ENVTL. L. & LITIG. 19, 21 (2011).

40. There are minimal standards applicable in some states, most significantly in California, where Proposition 2 imposed increased cage sizes in factory-style egg production. *See Proposition 2: Treatment of Farm Animals*, INST. GOV'T STUDS., UNIV. CAL., BERKELEY (Nov. 4, 2008), http://igs.berkeley.edu/library/elections/proposition-2.

41. *See Facts on Arsenic*, DARTMOUTH TOXIC METALS SUPERFUND RES. PROGRAM, http://www.dartmouth.edu/~toxmetal/arsenic/facts-on-arsenic.html (last updated Nov. 1, 2012).

agriculture, that have contributed significantly to environmental contamination.

> Arsenic has a long history as a poison—a rodent poison in particular—and great lore as a homicidal agent. Humans have exploited its toxic properties in weed killers, fungicides and insecticides, especially in vineyards, apple orchards, and cotton and tobacco fields. Arsenic has also been used as an embalming agent, to preserve specimens in taxidermy and to defoliate cotton for harvesting.[42]

The regulation of arsenic levels is both complex and important. Commercial use contributes to naturally occurring levels with the origin sometimes difficult to determine. Moreover, there are two primary forms of arsenic: inorganic and organic, with inorganic arsenic much more toxic than the organic forms.[43] While the full effect of arsenic on human health at various levels of exposure is not fully understood,[44] there is increasing and well-documented evidence of the link between long-term arsenic exposure and serious health problems, including cancer.[45]

Consistent with international norms expressed by the World Health Organization (WHO),[46] the EPA reports that:

> Non-cancer effects can include thickening and discoloration of the skin, stomach pain, nausea, vomiting; diarrhea; numbness in hands and feet; partial paralysis; and blindness. Arsenic has been linked to cancer of the bladder, lungs, skin, kidney, nasal passages, liver, and prostate.[47]

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42. V.P. SINGH, METAL TOXICITY AND TOLERANCE IN PLANTS AND ANIMALS 142 (2005). For additional history on the use of arsenic-derived pesticides, see Francis J. Peryea, *Historical Use of Lead Arsenate Insecticides, Resulting Soil Contamination and Implications for Soil Remediation*, *in* PROCEEDINGS, 16TH WORLD CONGRESS OF SOIL SCIENCE (CD-ROM, 1998), *available at* http://soils.tfrec.wsu.edu/leadhistory.htm.

43. *Arsenic in Your Food: Our Findings Show a Real Need for Federal Standards for This Toxin*, CONSUMERREPORTS.ORG (Nov. 2012), *available at* http://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm.

44. SINGH, *supra* note 42, at 144–48.

45. *See* WORLD HEALTH ORG., EXPOSURE TO ARSENIC: A MAJOR PUBLIC HEALTH CONCERN (2010), *available at* http://www.who.int/ipcs/features/arsenic.pdf.

46. *Arsenic Factsheet*, WORLD HEALTH ORG. (2012), http://www.who.int/mediacentre/factsheets/fs372/en/.

47. *Arsenic in Drinking Water*, ENVTL. PROTECTION AGENCY, http://water.epa.gov/lawsregs/rulesregs/sdwa/arsenic/index.cfm (last updated Sept. 17, 2013).

The International Agency for Research on Cancer (IARC) ranks inorganic arsenic as "one of more than 100 substances that are Group 1 carcinogens."[48]

Arsenic levels in groundwater have been a concern worldwide for some time, with U.S. contamination prompting the EPA to establish a maximum tolerance of 10 parts per billion (ppb) pursuant to the Safe Drinking Water Act.[49] Extensive remediation campaigns target contaminated water sources through public programs[50] and private companies.[51]

Recognizing the risk of groundwater contamination, soil contamination, and arsenic residue on food crops, the use of arsenic-based compounds as agricultural pesticides was deemed problematic as early as 1919, and efforts to restrict their use and develop substitutes has been ongoing.[52]

However, as the EPA increased its regulation of arsenicals as pesticides and attempted to eliminate their use,[53] the FDA allowed their increasing use in the livestock industry. Arsenicals, like antibiotics, are

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48. *Arsenic in Your Food: Our Findings Show a Read Need for Federal Standards for This Toxin*, *supra* note 43.

49. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976, 6980–81 (Jan. 22, 2001) (affecting 40 C.F.R. pts. 9, 141, 142). Environmental groups and the National Academy of Sciences supported a lower tolerance level. *See* Press Release, Nat'l Resources Def. Council, EPA Issues an Arsenic-in-Tap-Water Standard Higher than That Recommended by Public Health Advocates (Oct. 31, 2001), *available at* http://www.nrdc.org/bushrecord/articles/br_483.asp?t=t.

50. *See, e.g.*, *EPA Arsenic Removal Technology Demonstration Program*, ENVTL. PROTECTION AGENCY, http://www.epa.gov/nrmrl/wswrd/dw/arsenic/where.html (last updated Aug. 16, 2012).

51. *See, e.g.*, *Arsenic Removal from Drinking Water*, EVOQUA WATER TECHS., http://www.water.siemens.com/en/applications/drinking_water_treatment/arsenic-removal/Pages/default.aspx (last visited Mar. 7, 2014) (marketing arsenic removal technologies).

52. Peryea, *supra* note 42.

> The search for substitutes for [Lead arsenate] began in earnest when it was discovered in 1919 that contemporary practices for washing produce were failing to adequately remove [Arsenic] residues. Unfortunately, all of the tested alternative materials were found to provide less effective insect control or were more toxic to plants and animals. No adequate substitutes were found until 1947, when the synthetic organic insecticide dichlorodiphenyltrichloroethane (DDT) was introduced.

Id. (citation omitted).

53. Christopher Darrell Amy, In-Situ Stabilization of Arsenic in Florida Soils Amended with Water Treatment Residuals: An Incubation Study 6–7 (Aug. 2008) (unpublished M.S. thesis, Univ. of Tex. at San Antonio).

effective in promoting rapid growth, increased weight gain, and improved feed efficiency.[54]

Although the use of arsenicals was initially approved in 1944, its approval status was confirmed and renewed repeatedly (most recently in 2009) as companies proposed new compounds and new drug combinations.[55] And its use increased dramatically. A report estimated that in 2006, "[t]he vast majority of the 8.7 billion broiler chickens produced annually in the U.S. are given feed containing arsenic compounds at some point in their brief lives."[56] Although no public data is available, it was estimated that this use translated to over 2 million pounds of the most popular arsenical, roxarsone, being given to chickens annually.[57]

For years, consumer organizations publicized the use of arsenicals.[58] They complained to the FDA, filed a formal petition requesting withdrawal of the approval for these drugs,[59] and eventually filed a lawsuit to compel the agency to respond to their petition.[60] Some companies publicly announced that they were no longer using arsenicals, although because feed ingredients are generally proprietary information, it is difficult to verify these claims so long as the drugs are approved and available for use.[61] Several drug companies voluntarily suspended

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54. New Animal Drugs for Use in Animal Feeds; Roxarsone, 46 Fed. Reg. 52,330, 52,331 (Oct. 27, 1981) (affecting 21 C.F.R. 558).

55. *Questions and Answers Regarding 3-Nitro (Roxarsone)*, FOOD & DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm258313.htm (last updated Jun. 8, 2011).

56. DAVID WALLINGA, INST. FOR AGRIC. & TRADE POLICY, PLAYING CHICKEN: AVOIDING ARSENIC IN YOUR MEAT 13 (2006), *available at* http://www.iatp.org/files/421_2_80529.pdf.

57. *Id.*

58. *See, e.g.*, *Id.* at 13; *They Eat What? The Reality of Feed at Animal Factories*, UNION CONCERNED SCIENTISTS, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/they-eat-what-the-reality-of.html (last updated Aug. 8, 2006) (describing the livestock feed in use on most industrial farms, including the use of animal drugs in the feed and water).

59. Center for Food Safety, *Citizen Petition Seeking Withdrawal of Approval of Roxarsone and Certain Other Arsenical Additives in Animal Feed* (FDA Dec. 8, 2009), *available at* http://www.centerforfoodsafety.org/files/arsenic-petition-12-8-09-final_67875.pdf.

60. Complaint for Declaratory and Injunctive Relief at 4, *Ctr. for Food Safety v. Sebelius*, No. CV 13-1975 (N.D. Cal. Apr. 30, 2013), *available at* http://www.centerforfoodsafety.org/files/2013-04-30-arsenic-complaint-with-exhibits-filed_65303.pdf.

61. It is 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/

marketing arsenicals to the U.S. livestock industry, but the common use of the most common arsenical, roxarsone, continued.[62]

The FDA took no action to limit or discourage the use of the arsenicals until 2011.[63] In 2009, it began to research claims that the most toxic form of arsenic, inorganic arsenic, was detected in chicken tissue.[64] It concluded its research with a positive finding in 2011; its studies found small levels of inorganic arsenic in the livers of chickens fed arsenicals.[65] However, rather than immediately rescinding approval, the FDA contacted the drug manufacturer, Pfizer, to advise them of the finding.[66] In response, Pfizer voluntarily suspended the sale of roxarsone, in 2011.[67] The FDA was sued by a collection of consumer advocacy groups in April 2013.[68] Finally, in October 2013, the FDA announced that approval would be withdrawn for three of the four arsenical compounds on the market.[69]

Concerns about the FDA's role in assuring the safety of chicken produced and consumed in the United States is the most obvious issue. The arsenical drug debacle, however, reflects an even more significant problem with our approach to food safety: the failure to adopt a systemic review of production practices and their environmental impact.

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health-science/maryland-set-to-ban-arsenic-containing-drug-in-chicken-feed/2012/05/20/gIQAFoIodU_story.html. On the issue of verification, however, the drug residues of banned substances have been found in chicken feathers, indicating improper use by some producers. *See* Nicholas Kristof, *Arsenic in Our Chicken?*, N.Y. TIMES, Apr. 4, 2012, http://www.nytimes.com/2012/04/05/opinion/kristof-arsenic-in-our-chicken.html?_r=0. And, arsenicals are still used in turkey production. *See* Allison Aubrey, *How Trace Amounts of Arsenic End Up in Grocery Store Meat*, NAT'L PUB. RADIO (May 16, 2013, 1:15 PM), http://www.npr.org/blogs/thesalt/2013/05/15/184261664/how-trace-amounts-of-arsenic-end-up-in-grocery-store-meat.

62. *See* Letter from Michael Taylor, Deputy Comm'r for Foods & Veterinary Med., to Paige M. Tomaselli, Staff Attorney, Ctr. for Food Safety, & David Wallinga, Dir., Food & Health Div. of Inst. for Agric. & Trade Policy 5 (Sept. 30, 2013), *available at* http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM370570.pdf (denying the Center for Food Safety petition).

63. *Id.* at 6.

64. *Id.* at 5.

65. *Id.* at 5–6.

66. *Id.* at 6.

67. *Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55.

68. Complaint for Declaratory and Injunctive Relief, *Ctr. for Food Safety v. Sebelius*, No. CV 13-1975 (N.D. Cal. Apr. 30, 2013), *available at* http://www.centerforfoodsafety.org/files/2013-04-30-arsenic-complaint-with-exhibits-filed_65303.pdf.

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

The FDA undertook a narrow approach, considering only the issue of whether the food produced from the treated animals would be safe for human consumption. In fact, the arsenic used in the livestock feed had a far more pervasive environmental impact. It has been found in the poultry feathers that are used in livestock and pet food as well as fertilizer;[70] it is in the manure that is spread throughout the country on cropland, contributing to recent concerns about arsenic levels in rice,[71] and it has been detected in the dust in rural communities near poultry operations.[72]

The regulation of arsenicals illustrates the narrow approach embodied in the statutory and regulatory food safety regime, and it also illustrates the FDA's unwillingness (or inability) to take aggressive action against the economic interests of the pharmaceutical and livestock industries.

The FDA's regulatory authority stems from the Federal Food, Drug, and Cosmetic Act (FDCA).[73] Section 512(a)(1) of the Act, as codified in 21 U.S.C. Section 360b, gives the FDA the authority to approve new animal drugs—including drugs used for livestock.[74] It provides that any new animal drug "shall . . . be deemed unsafe"—and as a result adulterated—unless it is approved, conditionally approved, or index-listed by the FDA.[75] The FDA has stated that it "will not find a new animal drug intended for use in food-producing animals to be safe unless the sponsor demonstrates that there is a reasonable certainty of no harm to human health with respect to the food produced from treated animals under the intended conditions of use."[76]

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70. K.E. Nachman et al., *Arsenic Species in Poultry Feather Meal*, 417–18 SCI. TOTAL ENV'T 183, 183–84 (2012).

71. Fu-Min Wang et al., *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, 359 (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").

72. *See, e.g.*, WALLINGA, *supra* note 56, at 5 ("In the chicken-producing town of Prairie Grove, Ark., house dust in every one of 31 homes examined was found to contain at least two kinds of arsenic also found in chicken litter.").

73. *See* 21 U.S.C. §§ 301, 393 (2012).

74. 21 U.S.C. § 360b (2012).

75. § 360b(a)(1). Note that "index-listing" refers to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. This is a list of new animal drugs that are generally intended for use in nonfood producing minor species that have been evaluated through an alternative, less rigorous FDA review process. *See* §§ 360ccc-1, 360ccc-2; New Animal Drugs for Minor Use and Minor Species, 21 C.F.R. §§ 516.11–.171 (2013).

76. *See* Letter from Michael Taylor, *supra* note 62, at 2.

As arsenic is a recognized carcinogen, another provision also applies.[77] The FDA explained:

> Under the Delaney Clause for new animal drugs of the Federal Food, Drug, and Cosmetic Act, FDA cannot approve any compound for use in food-producing animals where the drug or its metabolites has been found to induce cancer. There is an exception, commonly referred to as the DES proviso. The DES proviso carves out an exception to the Delaney Clause allowing cancer-causing compounds (or compounds with cancer-causing metabolites) to be used in food-producing animals if 1) the drug does not harm the animal and 2) tests approved by FDA do not detect residues of the drug in any food from the animal.[78]

This is the standard applied to the initial and continued approval of roxarsone. On October 27, 1981, the FDA published a final rule in the Federal Register approving the supplemental new animal drug application (NADA) sponsored by Salsbury Laboratories for roxarsone, an arsenical manufactured as a feed additive for livestock.[79] According to the final rule, the FDA approved the drug for use as a daily feed additive in chickens and turkeys for "increased rate of weight gain, improved feed efficiency, and improved pigmentation, and for growing swine for increased rate of weight gain, improved feed efficiency, and for the treatment of swine dysentery (hemorrhagic enteritis or bloody scours)."[80]

The FDA's Bureau of Veterinary Medicine conducted an evaluation and concluded that the drug was effective for the uses described with some minor modifications on labeling negotiated with the manufacturer.[81] A cautionary labeling statement was required to state that "excessive consumption in or lack of adequate water by treated animals may result in weakness or paralysis of the legs."[82] And the label

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77. 21 U.S.C. § 360b(d)(1)(I).

78. *Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55.

79. New Animal Drugs for Use in Animal Feeds; Roxarsone, 46 Fed. Reg. 52,330 (Oct. 27, 1981) (final rule, codified at 21 C.F.R. § 558.530 (1981)). In 1989, Salsbury Laboratories, Inc., a veterinary pharmaceutical company, merged with Solvay Animal Health, Inc.; Solvay Animal Health, Inc., later became known as Fort Dodge Animal Health, which then became Wyeth. 46 Fed. Reg. 52,330 (Oct. 27, 1981). In October 2009, Wyeth was acquired by Pfizer, Inc., who is now the manufacturer of roxarsone. *Id.*; *Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55.

80. New Animal Drugs for Use in Animal Feeds; Roxarsone, 46 Fed. Reg. at 52,330–53,331.

81. *Id.* at 52,331.

82. *Id.*

was required to state "the desired oral dose per unit of animal weight per day."[83]

The FDA concurred. The Supplementary Information published with the final rule states that the evaluation "concerned only the drug's effectiveness and safety to the treated animal and did not consider the safety of food derived from treated animals."[84] However, the notice stated, in addition, that the approval would "not result in changes that will increase the risk of human exposure to residues of the drugs in edible animal tissues."[85]

The FDA dismissed any concerns about environmental contamination, stating: "The Bureau of Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared."[86] The FDA's approval led to the widespread use of roxarsone, particularly in the poultry industry.[87] It is estimated that in 2000, "approximately 70% of the broiler chickens on starter rations and approximately 74% of those on grower rations in the United States were fed roxarsone," totaling about 5.8 billion chickens in that year alone.[88]

In the face of mounting evidence that arsenicals could be dangerous in a number of ways, the FDA's stated position on its authority to withdraw its approval focused specifically on whether the drug caused cancer: "The Federal Food Drug and Cosmetic Act governs the withdrawal of approval of a new animal drug application, after due notice and an opportunity for hearing, where new evidence shows that the Delaney Clause applies."[89]

The FDA's hesitance to exercise its authority—and its tendency to define its authority very narrowly with respect to animal drug withdrawals—was recently and persuasively criticized by a food law scholar.[90] Moreover, it seems apparent that the FDA's focus was solely

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83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *See Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55 (listing the uses that roxarsone is approved for).

88. D.W. Rutherford et al., *Environmental Fate of Roxarsone in Poultry Litter. Part II. Mobility of Arsenic in Soils Amended with Poultry Litter*, 37 ENVTL. SCI. & TECH. 1515, 1515 (2003), *available at* http://www.aseanenvironment.info/Abstract/41011522.pdf.

89. *Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55.

90. Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1012–13 (2013).

on whether or not the drug is detected in the meat. This is almost ridiculously simplistic given the natural process involved.

The FDA's approval was based on the categorization of roxarsone as a form of organic arsenic, the less-toxic form of arsenic.[91] Unlike the paint applied to an auto body or another process applied to an inanimate object, however, a substance given to a live animal is processed by that animal's biological system. In the case of chickens, it has recently been determined that their digestive system can convert the organic arsenic into inorganic arsenic.[92] This inorganic and highly toxic arsenic is what was found in chicken tissue, albeit in reportedly small amounts.[93]

Moreover, early FDA approvals note that arsenicals are excreted from livestock.[94] While this fact was stated as reinforcement that it would not be retained in the meat, the agency did not take the next step to consider the impact of its presence in livestock bedding and manure. Arguably, its statutory authority did not authorize or encourage it to do so. Yet poultry bedding and manure are converted into livestock feed and used as fertilizer. This raises red flags for runoff water pollution, soil contamination, and associated indirect food contamination.[95]

The issue of arsenic in food made an abrupt entry into the mainstream media in November 2012, but the subject of the concern was not chicken; it was rice.[96] Consumer Reports issued a startling report that revealed the results of their testing of rice for levels of arsenic.[97] These tests found that "rice products on grocery shelves contain arsenic, many at worrisome levels."[98]

More than two hundred samples of rice products were tested.[99] A wide range of products were included: foods for children and infants, "iconic labels and store brands, organic products and conventional ones; some were aimed at the booming gluten-free market."[100]

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91. *Questions and Answers Regarding 3-Nitro (Roxarsone)*, *supra* note 55.

92. *Id.*

93. *Id.*

94. *Id.*

95. *See, e.g.*, J.R. Garbarino et al., *Environmental Fate of Roxarsone in Poultry Litter. I. Degradation of Roxarsone during Composting*, 37 ENVTL. SCI. & TECH. 1509, 1513 (2003) (showing that roxarsone in poultry litter exposed to water rapidly degrades into inorganic arsenic); Rutherford et al., *supra* note 88, at 1515 (showing that when poultry litter is applied, arsenic is released into the environment and is likely to cause contamination of soil, water, and plants).

96. *Arsenic in Your Food: Our Findings Show a Real Need for Federal Standards for This Toxin*, *supra* note 43.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

> In virtually every product tested, we found measurable amounts of total arsenic in its two forms. We found significant levels of inorganic arsenic, which is a carcinogen, in almost every product category, along with organic arsenic, which is less toxic but still of concern. . . .
>
> No federal limit exists for arsenic in most foods, but the standard for drinking water is 10 parts per billion (ppb). Keep in mind: That level is twice the 5 ppb that the EPA originally proposed and that New Jersey actually established. Using the 5-ppb standard in our study, we found that a single serving of some rices could give an average adult almost one and a half times the inorganic arsenic he or she would get from a whole day's consumption of water, about 1 liter.
>
> We also discovered that some infant rice cereals, which are often a baby's first solid food, had levels of inorganic arsenic at least five times more than has been found in alternatives such as oatmeal. Given our findings, we suggest limiting the consumption of rice products.[101]

When notified of the Consumer Reports study, prior to its official release, the rice industry responded immediately and emphatically.

> Rice is a nutritious food and an important part of a healthy diet. Rice contains more than 15 vitamins and minerals that help protect against disease and ensure healthy growth during pregnancy and childhood. We are aware of concerns about the level of arsenic in food, but are not aware of any established studies directly connecting rice consumption and adverse health effects. In fact, populations with high rice consumption are associated with less overall disease rates and with better health, and scientific studies show that people who eat rice have healthier diets.[102]

The FDA took the claims seriously and undertook its own study. While it also found evidence of inorganic arsenic in the rice products tested, it did not share Consumer Report's immediate concern.[103]

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101. *Id.*

102. *Rice Is an Important, Nutritional and Safe Part of a Healthy Diet*, U.S.A. RICE FED'N (Sept. 19, 2012), https://www.usarice.com/index.php?option=com_content&view=article&id=1956:rice-is-an-important-nutritional-and-safe-part-of-a-healthy-diet&catid=87:main.

103. *FDA Statement on Testing and Analysis of Arsenic in Rice and Rice Products*, FOOD & DRUG ADMIN. (Sept. 6, 2013), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm367263.htm.

> While levels varied significantly depending on the product tested, agency scientists determined that the amount of detectable arsenic is too low in the rice and rice product samples to cause any immediate or short-term adverse health effects.
>
> This new data is the latest of the FDA's ongoing efforts to understand and manage possible arsenic-related risks associated with the consumption of these foods in the U.S. marketplace.
>
> The FDA has been monitoring arsenic levels in rice for more than 20 years and has seen no evidence of change in levels of total arsenic in rice. We now have tools that provide greater specificity about the different types of arsenic present in foods.
>
> Since rice is a life-long dietary staple for many people, the FDA's next step is to use these new tools to consider long-term exposure to very low amounts of arsenic in rice and rice products
>
> The FDA's advice for consumers, including pregnant women, infants and children, is to eat a well-balanced diet for good nutrition and to minimize potential adverse consequences from consuming an excess of any one food. This advice is consistent with the guidance of the American Academy of Pediatrics, which has long stated that parents should feed their infants and toddlers a variety of foods as part of a well-balanced diet.[104]

The issue herein is not to debate the safety of rice consumption but to use the presence of arsenic—at any level—in rice as a means of illustrating the integration of our food system.

While some arsenic is naturally occurring, it is undisputed that human activity has added to the presence of toxic inorganic arsenic to the soil. The most obvious culprit is the spraying of arsenical pesticides directly onto the soil and crops growing on it. A less obvious, but nevertheless significant, source of contamination is through the application of poultry manure containing inorganic arsenic excreted by

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104. *Id. Compare* U.S. FOOD & DRUG ADMIN., ANALYTICAL RESULTS FROM INORGANIC ARSENIC IN RICE AND RICE PRODUCTS SAMPLING (2013), *available at* http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf (the FDA's testing results), *with Arsenic in Your Food: Our Findings Show a Real Need for Federal Standards for This Toxin*, *supra* note 43 (featuring a table of the Consumer Reports' testing results). Many of the test results are consistent; the response and recommendations differ.

poultry who were fed the drug.[105] Similarly, the common use of poultry feathers, processed into a meal that is used as fertilizer, provides another source of arsenic contamination.[106]

The use of arsenicals in livestock feed may also have an impact on water quality. Runoff of fertilizer and pesticides from farm fields have long been recognized as a source of water pollution. Similarly, as was reported by a recent study, manure containing arsenic can find its way into waterways, contaminating surface water.[107]

Although soil and water residues remain, the use of arsenicals in livestock production is on the decline in the United States. Roxarsone, the most commonly used arsenical in the past, has not been marketed in the United States since 2011, when its manufacturer, Pfizer, announced the suspension of its U.S. sales.[108] In September 2013, the FDA announced that approval would be withdrawn for three of the four arsenical compounds on the market.[109] The FDA has promised to continue studying the implications of its continued approval of Nitrasone, the last remaining arsenical available for use in poultry feed in the United States.[110]

What can be learned by looking back at the process by which arsenicals came to be used and ultimately were revealed to be problematic? How we produce our food can make a significant difference in not only the food produced but also the environment that we live in. The cycle of production, with its reliance on natural processes, natural resources, and living products, is a web of interconnections and linkages. Any one variable has the potential to affect all others throughout the cycle.

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105. *See, e.g.*, Garbarino et al., *supra* note 95, at 1513; Chen-Wuing Liu et al., *Arsenic Accumulation by Rice Grown in Soil Treated with Roxarsone*, 172 J. PLANT NUTRITION & SOIL SCI. 550 (2009) (warning about the use of poultry fertilizer containing roxarsone residue on rice crops because of poor crop performance and rice contamination); Wang et al., *supra* note 71, at 359.

106. Nachman et al., *supra* note 70, at 183 ("Feather meal products represent a previously unrecognized source of arsenic in the food system, and may pose additional risks to humans as a result of its use as an organic fertilizer and when animal waste is managed.").

107. Clinton D. Church et al., *Occurrence of Arsenic and Phosphorus in Ditch Flow from Litter-Amended Soils and Barn Areas*, 39 J. ENVTL. QUALITY 2080 (2010), *available at* https://www.agronomy.org/publications/jeq/abstracts/39/6/2080.

108. Press Release, U.S Food & Drug Admin., Pfizer Will Voluntarily Suspend Sale of Animal Drug 3-Nitro (June 8, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258342.htm. Note that sales in foreign countries are not precluded by this decision and are outside the authority of the FDA.

109. *See* Letter from Michael Taylor, *supra* note 62, at 2, 8.

110. *Id.* at 2, 8–9.

CONCLUSION

The approval of arsenicals by the FDA and the refusal of the agency to withdraw approval—even in the face of mounting evidence of a full range of problems—tells the story of a regulatory system that is so compartmentalized that it cannot view the interconnections within our food system. It is reductionist in the way that it attempts to regulate discrete components without considering how these components interact with each other and the environment.[111]

Unfortunately, the kind of situation presented with regard to arsenicals is a situation that is replicated in other ongoing areas. For example:

- It is estimated that "60% to 80% of livestock and poultry routinely receive antimicrobials," some of which are antibiotics also used in human medicine.[112] By some estimates, this use amounts to almost 29 million pounds, perhaps four times the amount used in human medicine.[113] These antimicrobials are typically administered at sub-therapeutic levels in feed or water.[114] There is considerable concern expressed about the impact of this use on the developing problem of antibiotic resistant infections. Indeed, recent "USDA surveys reported that 74% of *Salmonella* and 62% of *Campylobacter* isolates from swine manure were resistant to two or more antimicrobials."[115]

- Hormones are produced naturally by animals, and in addition, a significant amount of artificial hormones are used in livestock production to promote growth, improve meat quality, control reproduction, and increase milk production.[116] These hormones are often excreted by the animals, and they are present in livestock manure and

111. For a discussion of the reductionist and holistic categories as applied to agricultural production systems, see FRANCIS THICKE, A NEW VISION FOR IOWA FOOD AND AGRICULTURE: SUSTAINABLE AGRICULTURE FOR THE 21ST CENTURY 18–19 (2010).

112. ENVTL. PROTECTION AGENCY, LITERATURE REVIEW OF CONTAMINANTS IN LIVESTOCK AND POULTRY MANURE AND IMPLICATIONS FOR WATER QUALITY 27 (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.

113. *Id.* at 29.

114. *Id.* at 27.

115. *Id.* at vi.

116. *Id.*

> urine.[117] By one estimate, "720,000 pounds of natural and synthetic hormones were excreted by livestock and poultry in 2000."[118] At low doses, these hormones function as endocrine disrupters. Little is known about the impact of these hormones when they are deposited in wetlands or carried in runoff.[119]

The industrialization of our food production methods has led us to think of food as a manufactured item. This is a dangerous misinterpretation. In reality, almost all of our food sources depend directly on the complex interaction of natural processes—almost all of our food is sourced from a living thing, whether plant or animal. Because food production involves biological and horticultural processes, and because they closely depend on natural processes, production cycles are complex and inherently interrelated. The production process is far more interactive than the manufacturing model anticipates. Industry and government often fail to recognize this interconnection.

With intense competition between companies competing for market share and a high stock valuation, there is an incentive to adopt whatever practices allow for production that is increased in volume, quicker, and at less (short-term) cost. This seems to be all that matters. Once one producer uses a new drug or a more intensive practice, competitors are compelled by the market to do the same. This promotes an atmosphere where attention is paid to immediate gain without consideration of the long-term effects on the whole.

Regulators follow the same path, regulating each individual factor without regard to the impact on the overall food system or any other holistic consideration. To be fair, seeking a holistic, systemic approach within the current agency construct is a difficult request. Arguably, the FDA does not have the political power, the structure, the money, or the people to perform the tasks currently under its jurisdiction. This forces it to pick battles that it believes it can win and ignore issues that are beyond its capacity. Long-term health implications and the most complex interactions are perhaps easiest to ignore. The FDA may be too strapped for resources to adequately appreciate the diversity of our food system or to adequately respond to issues with a systemic analysis.

The USDA has more resources but continues to struggle with its often conflicting mission of championing and regulating the agricultural industry. This forces it to search for areas where the missions intersect

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117. *Id.* at 41–42.
118. *Id.* at vi.
119. *See id.* at v–vi.

and to ignore problems when the solutions would be too costly (for the agricultural industry) to fix.

Both agencies seek to regulate a food system that is dominated by some of the most powerful corporations in the world and that is represented by some of the most powerful lobbyists in Washington. Both agencies are politically and administratively tied to the industries that they propose to regulate. There is, however, cause for hope, and it is in the hands of consumers—those who seek to learn more about the food they eat, who question production practices, and who demand food that meets their standards. These consumers have had, and will continue to have, a dramatic impact on the food system and the legal framework that supports it.

Incidents such as the *Salmonella* outbreak in Iowa educate consumers about the reality of modern food production, and in general, they are not pleased. Just as consumer groups and their advocates questioned the use of arsenic in livestock feed and rallied against it, consumers can question production methods and work toward a food system that recognizes a holistic, systemic approach to food production. Only then will we truly be able to develop a preventative approach to food safety—one that considers the food system as a whole, with consumers and the overall environment as integral parts of the system.