# OVERUSE OF ANTIBIOTICS IN CONCENTRATED ANIMAL FEEDING OPERATIONS: REGULATION AND TORT LAW

BY

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*AE request abstract DRAFT – DO NOT CITE - NOT FOR CIRCULATION*

## I. INTRODUCTION

The development and proliferation of antibiotic resistant bacteria has increased the risk that humans will develop infections that are resistant to treatment by antibiotics. The Food and Drug Administration (FDA) has been aware of this public health risk for decades, but it's only effort to regulate came in June 2015 and then it only partially addressed the risk. Since there are good reasons to believe that FDA's regulatory effort will fall short of protecting the public, this essay explores the potential of the civil justice system to fill this gap in public health protection.

The outburst of health, safety and environmental legislation in the 1960s and 1970s was in significant part a response to the failure the failure of tort law adequately to protect people and the environment.[1] The need for federal regulation arose because the civil justice system is constrained by a number of aspects of tort law that limit its effectiveness in protecting the public. These same limitations are likely to constrain tort law in deterring the overuse of antibiotics in animal-food production, but these hurdles are not insurmountable. This essay examines the potential success of a product liability lawsuit by someone who becomes ill after eating pork or poultry contaminated with antibiotic resistant bacteria.

More broadly, the essay explores the roles of regulation and tort law in protecting the public from antibiotic resistant bacterial infections in four steps. Section I describes the risk to the public of the use of antibiotics in animal production. Section II considers the reasons why, as a general matter, it is preferable to use regulation to address public health risks. The tort system,

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[1] *See* SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 1-2 (2003).

however, can be an important backup to regulation when, as here, it appears that regulators have failed to address a public health risk adequately. Section III describes and evaluates FDA's response to the development and proliferation of antibiotic resistant bacteria. This section explains why FDA's efforts are likely to be insufficient to protect the public. Finally, Section IV evaluates whether this gap in protection can be reduced using product liability law. The conclusion is successful litigation will be hampered by the same limitations that make tort law a less successful way to respond to public health risks than regulation. Nevertheless, it is possible that a tort plaintiff could succeed in a products liability action.

## II. THE PUBLIC HEALTH RISK

The use of antibiotics in animal production has led to a significant increase in antibiotic resistant bacteria.[2] Although the magnitude of this problem is unknown, the most recent statistics reveal that antibiotic use in food production accounts for about 73 percent of all medically significant antibiotics sold in the United States.[3]

Antibiotics are used in agriculture because most of America's pigs and chickens are raised in artificial and extremely confined conditions known as confined animal feeding operations (CAFOs). [4] A CAFO typically keeps animals confined for a period of over 45 days, and brings feed to the animals, rather than permitting the animals to graze or forage for food.[5] A CAFO is designed fit as many animals as possible in extremely cramped conditions and to fatten

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[2] Mary J. Gilchrist, et. al., *The Potential Role of Concentrated Feed Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 ENVTL. HEALTH PERSPECTIVES 313, 313 (2007).

[3] The Pew Charitable Trusts, Record-High Antibiotic Sales for Meat and Poultry Production (July 17, 2013), available at http://www.pewtrusts.org/en/multimedia/data- visualizations/2013/recordhigh-antibiotic-sales-for-meat-and-poultry-production. See also MARGARET MELLON, CHARLES BENBROOK & KAREN LUTZ BENBROOK, HOGGING IT! ESTIMATES OF ANTIBIOTIC USE IN LIVE STOCK (2001) (report for the Union of Concerned Scientists) (estimating that the use of antibiotics in animals has been estimated to account for 40 to 87 percent of total antibiotic use), available at http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/hogging-it-estimates-of.html#.WGPMILYrJ0sl; Stuart B. Levy, G_____B. Fitzgerald, & A_____ B. Macone, *Spread of Antibiotic Resistant Plasmids from Chicken to Chicken and from Chicken to Man*, 260 NATURE 40 (1996) (estimating no more than 40 percent).

[4] CHRISTOPHER LEONARD, THE MEAT RACKET: THE SECRET TAKEOVER OF AMERICA'S FOOD BUSINESS, 5 (2014).

[5] U.S. EPA Animal Feeding Operations, https://www.epa.gov/npdes/animal-feeding-operations-afos.

[5] NATIONAL ASSOCIATION OF LOCAL BOARDS OF HEALTH, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES, 10 (2010), available at http://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf.

the animals to market weight as quickly as possible. Because the practices of industrial animal agriculture are largely non-transparent, no one knows precisely how many animals are confined on CAFOs, although it is estimated that 99 percent of all farmed animals are raised this way.[6] CAFOs are subject to disease outbreaks because of the unsanitary concentrated conditions in which the animals are raised.

The solution that the industry has used is to administer low-level doses of antibiotics (subtherapeutic doses) in the animals' food or water for long periods of time preemptively to prevent infections. FDA estimates that between 60 and 80 percent of the antibiotics sold in the United States are given to farmed animals.[7] Moreover, this practice is growing. According to FDA, antibiotic use in food-producing animals had increased 26 percent increase between 2009 and 2015.[8]

The prophylactic administration of low doses of antibiotics fosters the development of drug resistant bacteria in animals.[9] Since the antibiotics kill off the most susceptible bacteria, it allows drug resistant bacteria to replicate in an animal's gut. In turn, the public can become exposed to the drug resistant bacteria by direct contact with that waste or by contact with meat or poultry contaminated with the waste.[10]

Workers in CAFOs, for example, can become colonized with drug resistant bacteria. Those workers can then spread the bacteria into their homes and their communities after they leave their workplaces.[11] Since the trucks that carry live broiler chickens to slaughterhouses are highly contaminated with antibiotic resistant bacteria from chicken litter, people traveling on the

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[6] *See* Farm Forward, Factory Farming (estimate based on U.S. Department of Agriculture, 2012 Census of Agriculture, June 2014); available at https://farmforward.com/ending-factory-farming/#easy-footnote-bottom-.

[7] Grace Communications Foundation, Antibiotics (citing a 2009 FDA report), available at http://www.sustainabletable.org/257/antibiotics.

[8] *Id.*

[9] *See infra* notes * & accompanying text (discussing studies linking antibiotic use and the development of drug resistant pathogens in pork and chickens raised in CAFOs). et. al

[10] Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States, 2013*, (2013) 14, http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf; s*ee infra* notes __ & accompanying text (linking the use of antibiotics in animal production with antibiotic resistance in humans).

[11] A. Richter, et. al., *Prevalence of Types of Methicillin-Resistant Staphylococcus Aureus in Turkey Flocks and Personnel Attending the Animals*, 140 EPIDEMIOL INFECT. 2223, 2232 (2012).

same roads can be exposed to the bacteria through the air for a period of time after the truck passes by.[12] Drug resistant bacteria can also travel through the air, moving from a CAFO to nearby communities, motor vehicles, and individuals.[13] Even flies that come into contact with the bacteria from hog and chicken waste can expose people to this risk.[14]

Contact between humans and food containing drug resistant bacteria is another route of exposure. This can occur when people eat meat or vegetables contaminated with antibiotic resistant bacteria.[15] Slaughterhouses process animals at such high speeds that feces from the animals, which contain the drug resistant bacteria, can contaminate the meat products.[16] The drug resistant bacteria are transferred to vegetables either in the application of manure as fertilizer on vegetable crops or from water contaminated from runoff that has been contaminated by animal waste is used to water vegetable crops.[17]

Drug resistant bacteria are estimated to kill at least 23,000 people and sicken a total of two million people each year in the United States,[18] which results in $20 billion dollars in health costs.[19] The Center for Disease Control (CDC) estimates that germs from food and animals cause one in five resistant infections in humans.[20]

Scientists first warned about the threat posed by antibiotic use in animal production around 1970. In 1969, a committee of the National Academy of Sciences recommended the

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[12] A___ .M. Rule, S____L. Evans, & Ellen K. Silbergeld, *Food Animal Transport: A Potential Source of Community Exposures to Health Hazards from Industrial Farming (CAFOs)*, 1 J. INFECTION & PUBLIC HEALTH 33 (2008).

[13] A_____ Chapin, et. al., *Airborne Multidrug-Resistant Bacteria Isolated from a Concentrated Swine Feeding Operation*, 113 ENVTL. HEALTH PERSPECTIVES 137 (2005).

[14] J_____ P. Graham, et. al., *Antibiotic Resistant Enterococci and Staphylococci Isolated from Flies Collected near Confined Poultry Feeding Operations*, 407 SCIENCE OF THE TOTAL ENVIRONMENT 2701 (2009).

[15] CDC Report, *supra* note 10, at 14. A consumer may be able to avoid an antibiotic infection by safe handling and adequate cooking of pork and poultry, *see infra* notes * & accompanying text (discussing safe handling of pork and poultry) or by washing vegetables.

[16] Andrea Rock, How Safe Is Your Ground Beef, CONSUMER REPORTS (Dec. 21, 2015), available at http://www.consumerreports.org/cro/food/how-safe-is-your-ground-beef.

[17] *Id.*; *see* J_____ Graham, et. al., *Fate of Antimicrobial-Resistant Enterococci and Staphylococci and Resistance Determinants in Stored Poultry Litter*, 109 ENVTL. RESEARCH 682 (2009) (typical litter storage practices do not kill bacteria so that litter used as fertilizer contains drug resistant bacteria that can be transmitted to vegetable crops).

[18] CDC Report, *supra* note 10, at 11.

[19] R___ Smith & J___ Coast, *The True Cost of Antimicrobial Resistance*, BRITISH MEDICAL JOURNAL (March, 2013), at 346:f1493.

[20] CDC, Antibiotic Resistance from the Farm to the Table, http://www.cdc.gov/ foodsafety/challenges/from-farm-to-table.html (last updated Nov. 16, 2015).

minimal use of antibiotics in food animals for growth promotion and the discontinuation of antibiotic use for disease prevention.[21] A 1970 FDA task force warned subtherapeutic use of antibiotics could "become a reservoir of antibiotic resistant pathogens that produced human infections."[22] A 1972 FDA advisory committee recommended that FDA "immediately withdraw approval for the subtherapeutic uses of penicillin, i.e., growth promotion/feed efficiency, and disease control."[23] Similarly, a 1977 Advisory Committee recommended that FDA propose to withdraw regulatory approval for most subtherapeutic uses of oxytetracycline and chlortetracycline in animal feed, and all subtherapeutic uses of penicillin in animal feed.[24]

The warnings have continued to the present day. The American Academy of Pediatrics (APP) warned in 2015 that "the overuse and misuse of antimicrobial agents in veterinary and human medicine is, in large part, responsible for the emergence of antibiotic resistance," and that children under five years old are the most susceptible to food borne pathogen infections.[25] The physicians called for ending the use of subtherapeutic use of antibiotics in food production. [26] In 2016, a coalition of medical and scientific groups called for "policy measures that will end routine antibiotic use in food animal production."[27]

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[21] NAT'L ACAD OF SCIENCES, COMM. ON SALMONELLA, AN EVALUATION OF THE SALMONELLA PROBLEM: A REPORT OF THE USDA, FDA, US DEPT. OF HEALTH, EDUCATION AND WELFARE, (1969), available at https://books.google.com/books?id=o5YrAAAAYAAJ&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false.

[22] Antibiotics and Sulfanamid Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (Apr. 20, 1973) (codified at 21 C.F.R. § 558.15). The task force also made three additional findings: (1) The prevalence of multiresistant R-factor bearing pathogenic and nonpathogenic bacteria in animals has increased and has been related to the use of antibiotics and sulfonamide drugs. (2) Organisms resistant to antibacterial agents have been found on meat and meat products. (3) There has been an increase in the prevalence of antibiotic and sulfonamide resistant bacteria in man. *Id.*

[23] Natural Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 133 (S.D.N.Y. 2012).

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

[25] American Academy of Pediatrics, *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*, 136 PEDIATRICS e1670 (June 2015) hereinafter 2015 AAP Report], available at http://pediatrics.aappublications.org/content/pediatrics/136/6/e1670.full.pdf. The 2015 report reaffirms the conclusions of a report the AAP published in 2004. See American Academy of Pediatrics, *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*, 114 PEDIATRICS 862 (Sept. 2004), http://pediatrics.aappublications.org/content/ pediatrics/114/3/862.full.pdf.

[26] 2015 AAP Report, *supra* note 25.

[27] Principles for Appropriate Livestock and Poultry Antibiotic Use (Aug. 2016), available at https://www.chausa.org/docs/default-source/environment/principles-for-appropriate-livestock-and-poultry-antibiotic-use.pdf?sfvrsn=0.

Outside of the United States, the Swann Report in the United Kingdom recognized a potential link between the use of antibiotics in agriculture and the drug resistant infections in 1969,[28] and the World Health Organization recommended against using antibiotics used by humans for growth promotion in 1973.[29] In 1999, the European Union banned the use of antibiotics for growth promotion.[30]

## III. REGULATION VERSUS TORT LAW AS A RESPONSE

The government has two ways in which it can reduce the public health risk created by antibiotic use in CAFOs. As the introduction points out, the government has relied primarily on standard setting since the 1970s to address safety and health risks. Nevertheless, tort law can deter behavior that is dangerous to the public in additional to its role of compensating individuals for harms done to them.[31]

Regulatory standard setting has a number of advantages over the civil justice system regarding the reduction of health and safety risks. First, the goal of modern regulatory agencies is to prevent harm before it occurs, using notice and comment rulemaking, monitoring, and enforcement.[32] Tort law, of course, is not activated until people are injured or killed by an unsafe product or practice, and they successfully sue the manufacturer or producer responsible. Moreover, a number of such successful lawsuits can be necessary to deter similar future behavior. Still, the threat of paying compensation to victims can also have a deterrent effect, even though this is not the primary purpose of state civil justice systems.[33] A number of industries have taken potential tort liability into account to reduce risks that they pose to others.[34]

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[28] M_____ SWANN, et. al., REPORT OF THE JOINT COMMITTEE ON THE USE OF ANTIBIOTICS IN ANIMAL HUSBANDRY AND VETERINARY MEDICINE (1969).

[29] *Id.*

[30] Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718, 722 (2011).

[31] *See See* Jean Macchiaroli Eggen, *The Synergy of Toxic Tort Law and Public Health*, 41 CONN. L. REV. 561 564-65 (2008) (recognizing that tort law has traditionally served compensatory and regulatory functions in the health and safety context); Leon Green, *Tort Law as Public Law in Disguise*, 38 TEX. L. REV. 1 (1959) (referring to tort law as a form of public regulation "in disguise").

[32] Christopher H. Schroeder, *Lost in Translation: What Environmental Regulation Does That Tort Cannot Duplicate* 41 WASH. L. REV. 583, 589 (2002)

[33] *See* Michael D. Green & Brandon Jones,*Tort Law to the Rescue*, in FUNCTIONAL OR DYSFUNCTIONAL—THE LAW AS A CURE 187, 191 *(*Lars Gorton et al. eds. 2014). ("[W]hile tort law may not be a universal deterrent—and

Second, while regulatory standard setting makes choices about public health and safety through public processes, tort law makes the same choices using private and individual decisions.[35] In addition, the regulatory system can call on its expertise when making determinations about the riskiness of a product or process.[36] The civil justice system, by comparison, relies either on lay juries or a generalist judge to make the same type of determinations.[37]

Again, however, this advantage should not be exaggerated. Although there are prominent examples of the tort system apparently mistakenly establishing liability,[38] tort law has demonstrated that lawyers are capable of educating juries and judges about the nature of the risks that they are adjudicating.[39]

Third, regulatory agencies are capable of acting in circumstances where individual tort plaintiffs may lack the evidence that they need to establish a chemical or other hazard was the cause of their illness. Comparing how regulatory agencies and tort law makes decisions concerning exposure to health risks explains this advantage.

Health regulation takes places in two steps.[40] The first step for an agency is to determine if available scientific information meets the requirements established by Congress to trigger the regulatory process.[41] This is an issue of "general causation" because the question is whether the activity or practice the agency is intending to regulate exposes some portion of the population to a heightened risk of becoming ill or injured. Congress establishes the agency's burden of proof at this step by specifying in the agency's legislative mandate a "risk trigger" or a statement of

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therefore effective in across-the-board regulation—in most spheres at least, that ineffectiveness should not be over-generalized.").

[34] Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 391-92, 408-09, 418 (1994).

[35] Schroeder, *supra* note 32, at 598.

[36] *See* Sidney A. Shapiro, *The Failure to Understand Expertise in Administrative Law: The Problem and the Consequences*, 51 WAKE FOREST LAW REV. 1097, ___ (2015). .

[37] Green & Jones, *supra* note 33, at 200.

[38] See, e.g., *Id*. at 200-201 (discussing the Bendectin litigation)

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[40] See SHAPIRO & GLICKSMAN, *supra* note 1, at 31-33 (2003).

[41] *Id*.

what evidence the agency must establish in order to be able to regulate. Typically, Congress has authorized regulators to act on the basis of anticipated harm.[42] The Clean Air Act, for example, authorizes the Environmental Protection Agency (EPA) to regulate new stationary sources of air pollution if they may cause or contribute to "air pollution which may reasonably be anticipated to endanger public health or welfare."[43]

A plaintiff suing in tort engages in a similar first step of proving general causation. That is, the plaintiff must also prove that a product or process causes the illness suffered by the plaintiff in some group of people.[44] But tort law employs a different burden of proof at this stage: a plaintiff must prove general causation by a preponderance of the evidence.[45] By comparison, a court will apply an "arbitrary and capricious" (or in some cases the "substantial evidence") test when it reviews the agency's proof of general causation.[46]

As a second step, an agency determines the extent to which to abate or eliminate a risk by using the "statutory standard" that Congress has established.[47] The standards vary but most are precautionary in the sense that they permit the agency to safeguard the public by erring on the side of more protection rather than less. The CAA, for example, instructs EPA to establish national primary ambient air quality standards at a level requisite to protect public health with "an adequate margin of safety."[48]

The tort system, by comparison, will not act to deter unreasonable or dangerous products or practices unless the plaintiff can prove by a preponderance of the evidence that his or her illness was caused by the defendant's product or practice. In other words, the plaintiff must

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[42] *Id.*

[43] 42 U.S.C. § 7411(b) (1) (A) (2006).

[44] S*ee* Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases,*46 STAN. L. REV. 1, 14-18 (1993).

[45] RESTATEMENT OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM §28 cmt. c(1) (2010).

[46] *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 **U.S.** ***29,*** *42*- 43(1983). This difference reflects Congress' intention to make the regulatory system more effective in regulating health risks than tort law. *See* Susan Rose-Ackerman, *Regulation and the Law of Torts,* AM. ECON. REV. May 1991, at 54. As mentioned, the impetus for most regulatory statutes was the failure of tort law to protect people sufficiently.[46] See *supra* notes __ & accompanying text

[47] Shapiro & Glicksman, *supra* note 1, at 32.

[48] *Id.* at 37.

establish that it is more likely than not that that his or her own illness would not have occurred but for the exposure to the defendant's activity.[49]

In light of these advantages, regulation generally is preferable to the civil justice system as a more effective way in which to protect the public. It is preventative, involves a decision-making process better suited to resolving issues of risk and causation, and employs a burden of proof that is easier to meet in order to establish protection. Nevertheless, we should hesitate before we put the tort system out to pasture.

First, as the U.S. Supreme Court recognized for much of the 20th century, state civil justice systems serve as an invaluable complement to federal and state positive law by compensating someone who has been harmed by an unreasonably dangerous product or activity.[50]

Second, tort law is open to reinterpretation and modification to address newly recognized wrongs. Citizens used nuisance litigation to address pollution long before EPA came into existence, for example.[51] Similarly, tort suits were an important component of the early civil rights movement[52] and the movement against sexual harassment before Congress adopted laws to address these issues.[53]

Third, the additional deterrent provided by state civil justice systems is especially important when agencies become captured or are subject to regulatory dysfunction. Regulatory capture occurs when an industry is able to exert control over an agency that has been charged with regulating it, and as a result the agency acts in the industry's interest rather than in the public interest.[54] When an agency is captured, we can expect lax regulations that inadequately protect public health and safety. By comparison, it would be difficult for an industry to capture

[49] RESTATEMENT OF TORTS, *supra* note 45, at **§28** cmt. c(1).
[50] *See* United Construction Workers v. Laburnum Construction Corp., 347 U.S. 656 (1954); Int'l Union v. Russell, 356 U.S. 634 (1958); Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984); English v. General Electric Co., 496 U.S. 72 (1990).
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[54] Sidney A. Shapiro, *Regulatory Capture: The Complexity of Diagnosis and Remediation*, 17 ROG. WILLIAMS L. REV. 101 (2012).

both a regulatory agency and even a significant portion of the state courts. The civil justice system for this reason will continue to exist as a method of deterring harmful behavior when the regulatory system fails this role.

Even if an agency is not subject to regulatory capture, agencies fall victim to regulatory dysfunction. An agency can become dysfunctional for a variety of reasons, including funding short falls, outdated authorizing statutes, political interference, and a demoralized civil service.[55] To the extent that these things hinder regulatory standard setting and enforcement, the impact of federal regulation is likely to be diminished. While it is true that state civil justice systems will not completely reverse the problem of regulatory dysfunction, tort law can help to alleviate some of its negative consequences.

Finally, state civil justice systems boost the effectiveness of federal regulatory programs by creating incentives to monitor and even create new risk regulation information.[56] The goal of a monetary recovery by plaintiffs and their lawyers can lead to civil discovery and the revelation of information that was overlooked, withheld, or not yet in existence when a regulatory decision was made earlier.[57] Regulatory agencies, by comparison, have weaker incentives to gather information about past regulatory actions because of the press of new business and limited resources.[58] Moreover, the laws under which they operate rarely require or encourage them to reexamine and reassess these past actions.[59] When information generated through tort litigation



[55] *See* RENA STEINZOR & SIDNEY SHAPIRO, THE PEOPLE'S AGENT AND THE BATTLE TO PROTECT THE AMERICAN PUBLIC ch. 1 (2010).
[56] William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1589 (2007).
[57] *Id*. at 1598-99; Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068-70 (2000).
[58] *See*, e.g. U.S. GOV'T ACCOUNTABILITY OFFICE, MEDICAL DEVICES: SHORTCOMINGS IN FDA'S PREMARKET REVIEW, POSTMARKET SURVEILLANCE, AND INSPECTIONS OF DEVICE MANUFACTURING ESTABLISHMENTS (2009) (finding FDA does not have the resources to follow up on all of the adverse events reports that they receive), *available at* http://www.gao.gov/new.items/d09370t.pdf.
[59] Thomas O. McGarity, *Some Thoughts on "Deossifying" The Rulemaking Process*, 41 DUKE L.J. 1385, 1401 (1992).

feeds back into the regulatory system, agencies hopefully can reexamine past regulatory decisions and ideally to develop better regulations.[60]

State civil justice systems also provide an incentive for manufacturers and producers continually to reevaluate risk information.[61] The desire to avoid tort liability encourages industries to monitor risk information with an eye toward reducing health and safety risks. By comparison, in the absence of an effective civil justice system, corporations have the opposite incentive since the discovery of new information might lead to the strengthening of any applicable federal standards. When this happens it is more likely that inappropriately lax regulatory standards will remain in place, putting consumer health and safety at unreasonable risk.

## IV. THE RELUCTANT REGULATOR

A pharmaceutical company cannot sell veterinary antibiotics (or any other veterinary drug) until it has FDA approval.[62] The agency cannot approve a new veterinary drug unless the pharmaceutical company that wants to sell the drug has demonstrated that its use in animals is "safe" for humans.[63] A use is not safe unless there is a "reasonable certainty of no harm to human health."[64] FDA must withdraw its prior approval of a veterinary drug if there is no longer a "reasonable certainty of no harm to human health" from is veterinary use.[65]

As described earlier, various FDA advisory committees recommended during the 1970s that FDA withdraw its approval of the subtherapeutic use of three types of antibiotics.[66] In 1977,

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[60] Buzbee, *supra* note 56, at 1583; Thomas O. McGarity, *The Regulation-Common Law Feedback Loop in Non-Preemptive Regimes*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION, ch.11 (William W. Buzbee ed., 2009).

[61] THOMAS O. MCGARITY, THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES 238 (2008).

[62] 21 U.S.C. § 331(a) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food [or] drug . . . that is adulterated"); 21 U.S.C.
§ 360b(a)(1) (providing that "[a] new animal drug shall . . . be deemed unsafe . . . unless" FDA has approved the drug); 21 U.S.C. § 351(a) (providing that a drug "shall be deemed to be adulterated . . . (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title").

[63] 21 U.S.C. § 360b(d)(1).

[64] Guidance No. 209 at 18.

[65] FDA, Final Decision of the Commissioner, Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry, Docket No. 2000N-1571, at 100 (July 27, 2005).

[66] See *supra* notes __ & accompanying text.

the Director of FDA's Bureau of Veterinary Medicine (now known as the Center for Veterinary Medicine) concluded that the subtherapeutic use of penicillin and tetracyclines for growth promotion and disease prevention "are not shown to be safe under the conditions of use prescribed, recommended or suggested in the labeling" of the antibiotics.[67] FDA required the pharmaceutical manufacturers of these antibiotics to produce evidence that veterinary use was safe for people,[68] but the agency's efforts to withdraw approval of antibiotics stalled during the Regan administration.

Beginning in 2001, FDA scientists who had expertise in fields such as veterinary medicine and microbiology reviewed whether 30 penicillin and tetracycline antibiotic feed additives previously approved for "nontherapeutic use" in livestock and poultry could still be approved using its current guidelines concerning the safe use of animal drugs.[69] Among other considerations, they evaluated whether the subtherapeutic use of these antibiotics was likely to promote the emergence of antibiotic-resistant bacteria, the likelihood of individual exposure to those bacteria, and the risk to human health of that exposure, among other factors.[70] After NRDC obtained the results of the study by filing a Freedom of Information Act request, the environmental group revealed that the FDA scientists found 18 of the 30 additives posed a "high risk" that humans would be exposed to antibiotic-resistant bacteria through the food supply.[71] Further the agency determined that at least 26 of the 30 uses of antibiotics did not even satisfy the safety criteria that the agency used in 1973.[72]

Despite these findings, FDA announced in May 2011 that it was ending any efforts to withdraw approval of any antibiotic.[73] A coalition of public interest groups sued the agency to

[67] Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977).
[68] Natural Resources Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 133 (S.D.N.Y. 2012).
[69] NRDC, Playing Chicken with Antibiotics 2 (2014), available at https://www.nrdc.org/sites/default/files/antibiotic-feed-fda-documents-IB.pdf.
[70] *Id.* at 7.
[71] *Id.* at 2.
[72] *Id.*
[73] 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).

challenge this decision,[74] and the same coalition subsequently challenged FDA's denial of two citizen petitions seeking the withdrawal of approval of several additional uses of antibiotics in livestock production.[75] The coalition prevailed in the Southern District of New York,[76] but a divided panel of the Second Circuit reversed.[77] The court disagreed the existing scientific evidence required FDA to start withdrawal proceedings, and it accepted FDA's justification for its denial of the citizen petitions, which was that a program of voluntary compliance offered the best option for immediate and significant reductions in the use of animal antibiotic use.[78]

FDA implemented its efforts to obtain voluntary reductions in the use of antibiotics by issuing two guidance documents. In 2013, FDA recommended two voluntary "principles" for the use of antibiotics that are important to human health in food-producing animals.[79] The first recommended these antibiotics be limited to uses considered necessary for addressing animal health.[80] The second principle was the use of such drugs should be limited to uses that include

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[74] National Resources Defense Council, Center for Science in the Public Interest Research Group, and California Public Interest Research Group, Citizen Petition To Withdraw Approval of the Use of Medically Important Antibiotics in Livestock and Poultry (Sept. 13, 2016), at 23 (describing the lawsuit) [hereinafter NRDC Petition], available at https://www.nrdc.org/sites/default/files/fda-antibiotics-petition-20160913.pdf.

[75] *Id.*

[76] *NRDC v. FDA*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012); *NRDC v. FDA*, 872 F. Supp. 2d 318 (S.D.N.Y. 2012).

[77] *NRDC v. FDA*, 760 F.3d 151 (2d Cir. 2014).

[78] 760 F.3d at 175. The agency has explained that withdrawal proceedings would be unduly time and resource consuming because Congress required FDA to use formal adjudication for a withdrawal Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697, 79,699, 79,700 n8 (Dec. 22, 2011); Letter from Lesley Kux, Acting Assistant Comm'r for Policy, Food & Drug Admin., to Sarah Klein, Food Safety Program, Center for Science in the Public Interest (Nov. 7, 2011), at 2 (denying the Center for Science in the Public Interest's petition to rescind FDA-approved uses of antibiotics in livestock feed), available at http://www.regulations.gov/ #!documentDetail;D=FDA-1999-P-1286-0014; Letter from Lesley Kux, Acting Assistant Comm'r for Policy, Food & Drug Admin., to Andrew Maguire, Vice President of Envlt Health, Envtl. Defense Fund (Nov. 7, 2011), at 2 (denying the Environmental Defense Fund's petition to withdraw FDA's approval of use of antibiotics in livestock feed), available at http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0007-0007.

According to administrative case law, however, the agency is not required to hold a formal evidentiary hearing to decide whether to withdraw prior approval of an antibiotic because it is not "safe" within the meaning of its statutory mandate. *See* Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VERMONT L. REV. 1007 (2013) (reviewing case law and concluding that FDA does not have to hold formal hearings); see also NRDC Petition, *supra* note 74, at 38-39.

[79] Food & Drug Admin., Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals (APR. 13, 2012), available at http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf.

[80] *Id.* at 21.

veterinary oversight or consultation.[81] In December 2013, a second guidance document recommended that pharmaceutical companies voluntarily change the labeling of veterinary drugs that are medically important in human health to no longer allow the sale of such drugs without the oversight of a licensed veterinarian.[82]

The agency's voluntary approach was criticized on several grounds.[83] First, the idea of voluntary compliance appeared to be "somewhat fanciful, if not naïve" in light of the decades of almost completely unregulated antibiotic use, intense competition in the agricultural and pharmaceutical industries, and the large financial interest at stake.[84] Second, since the FDA guidance did not eliminate the use of antibiotics to reduce infections, critics pointed out that it was unlikely that overall use would significantly decline because using antibiotics to reduce infections is both widespread and "virtually inseparable" from using antibiotics to promote growth.[85] Third, although FDA recommended that antibiotic use be under the supervision of a veterinarian, the recommendation would be ineffective because many of the drugs used to prevent specific diseases are sold over the counter.[86]

Finally, the recommendation that a veterinarian be in charge of antibiotic use was unlikely to decrease the use of antibiotics because the guidance gave veterinarians "extremely broad discretion" in administering antibiotics for prevention purposes.[87] It was anticipated that this would be a loophole because veterinarians are less regulated than physicians and have "close

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[81] *Id*. at 22.

[82] FDA, New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209, at 7 (Dec. 2013), available at http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf.

[83] Lisa Heinzerling, *The FDA's Continuing Incapacity On Livestock Antibiotics*, 33 STAN. ENVTL. J. 325, 325 (2014).

[84] Susan A. Schneider, *Beyond the Food We Eat: Animal Drugs in Livestock Production*, 21 DUKE ENVT'L L & POL. FORUM 227, 265 (2015). The problem is that unless the entire poultry and pork industry goes along with the voluntary guidance, there will be pressure not to comply because competitors who do not comply may gain a competitive advantage. *Id*. at 23. When Denmark voluntary eliminated the use of antibiotics for growth promotion, the entire industry agreed to comply. See *supra* notes __ & accompanying text.

[85] Schneider, *supra* note 84, at 266.

[86] *Id*. at 267.

[87] Heinzerling, *supra* note 83, at 331.

ties with or receive financial benefits from the pharmaceutical industry" or are employed by the livestock industry.[88]

In September 2016, the Natural Resources Defense Council and two other public interest groups filed a petition requesting that FDA withdraw approval of seven antibiotics for animal use that are important to human health.[89] Among other arguments, the public interest groups noted that antibiotic use in livestock had increased since FDA had started its voluntary compliance efforts including a three percent increase in 2014 alone.[90] In December 2016, a later FDA report revealed that antibiotic use had continued to increase.[91]

It is not clear whether the increase was related to the failure of FDA's voluntary approach, to an increase in the production of chickens and poultry, or both.[92] For its part, however, FDA decided stronger action was necessary. In June 2015, the agency promulgated a regulation, named the Veterinary Feed Directive, which addressed some of the limitations of the two guidance documents mentioned earlier.[93] The regulation ends the over-the-counter sale of medically important antibiotics and requires the supervision of a licensed veterinarian in the use of the drugs.[94] It also requires that a veterinarian only allow the use of these antibiotics for uses allowed on the drug's label.[95] As the reader may recall, FDA asked pharmaceutical companies voluntarily to remove growth promotion from the list of permissible uses on their label.[96] Since the pharmaceutical companies agreed with this request,[97] this second requirement is intended to prevent veterinarians from ignoring this restriction.

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[88] Schnieder, *supra* note 84, at 267; Heinzerling, *supra* note 83, at 332.
[89] NRDC Petition, *supra* note 74, at 4.
[90] *Id.* at 7.
[91] *Id.*
[92] Helen Branswell, *Tightened Rules for Antibiotics in Livestock Go Into Effect*, STAT (Jan. 3, 2017), available at https://www.statnews.com/2017/01/03/fda-livestock-antibiotics/.
[93] FDA, Veterinary Feed Directive, 80 FED. REG. 31708 (2015).
[94] *Id.* at 31733.
[95] *Id.* at 31734.
[96] See *supra* notes __ & accompanying text.
[97] FDA, FDA Update on Animal Pharmaceutical Industry Response to Guidance #213, available at http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390738.htm.

Finally, FDA prohibited veterinarians from allowing the use of these antibiotics unless certain conditions were met. These include that a veterinarian is licensed to practice medicine in the area in which he or she is acting, the veterinarian complies with all applicable state licensing requirements, any antibiotic use is in compliance with the drug label, and there is an ongoing veterinarian-client relationship involved.[98]

The fate of the new regulation in the Trump administration is not known at this time. But even assuming that Congress does not prevent the regulation from going into effect and FDA retains it, the regulation may not significantly decrease the use of medically important antibiotics in animal food production.

The reason is that the use of antibiotics for growth promotion is a relatively small percentage of the total use. An FDA official has conceded that growth promotion is responsible for only 10 to 15 percent of the overall use of veterinary antibiotics.[99] A representative of a pharmaceutical industry trade association, the Animal Health Institute (AHI), agrees with that estimate.[100] Further, since "[g]rowth uses of medically important antibiotics represent only a small percentage of overall use," the AHI predicted in 2013 that it is unlikely that overall use will be greatly affected by banning the use of antibiotics for growth promotion.[101]

Finally, FDA has not yet addressed a loophole in its regulations. Although veterinarians have to restrict the use of antibiotics to the conditions of use indicated in a drug's label, about one-third of existing drug labels are not consistent with FDA's voluntary guidance on the use of such antibiotics.[102] Among the defects, many labels do not limit the duration of antibiotic use for

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[98] Veterinary Feed Directive, *supra* note 93, at 31734.
[99] NRDC Petition, *supra* note 74, at, at 35.
[100] Beth Hoffman, *New FDA "Rules" Not Likely to Reduce Antibiotic Use on Farm*, FORBES (Dec. 13, 2013) available at http://www.forbes.com/sites/bethhoffman/2013/12/13/new-fda-rules-will-not-reduce-antibiotic-use-on-farm/#cdcc2d62dd9f.
[101] Animal Health Institute, Q&A: Final Guidance 213 and VFD, available at http://www.ahi.org/wp-content/uploads/2013/12/Final-213-AHI-QA.pdf.
http://www.ahi.org/ wp-content/uploads/2013/12/Final-213-AHI-QA.pdf (last visited July 15, 2016).
[102] PEW Charitable Trusts, Judicious Animal Antibiotic Use Requires Drug Label Refinements: Analysis shows more than 1 in 3 labels will not fully meet judicious use standards after implementation of FDA policy (Oct. 4, 2106), available at http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2016/10/judicious-animal-antibiotic-use-requires-drug-label-refinements.

disease prevention.[103] The agency has asked for public comments on whether it should restrict the duration of use for disease prevention purposes.[104]

## V. Products Liability Litigation As An Alternative

FDA's efforts to address the public health risk created by the use of antibiotics in animal food production may be too little and too late. The agency has only prohibited the use of antibiotics for growth promotion, but most of the subtherapeutic use of antibiotics is for disease prevention. Moreover, it is unclear whether FDA in the Trump administration will retreat from even this effort to reduce antibiotic use. As explained earlier, an important function of the civil justice system is plug gaps in the regulatory system such as this one.[105] But, as also mentioned, tort law may be a less nimble regulatory tool in these instances because of differences such as the burden of proof regarding causation.[106]

This section evaluates the potential of a lawsuit by someone who is infected after eating contaminated pork or poultry. As explained, slaughterhouses process animals at such high speeds that feces from the animals, which contain the drug resistant bacteria, can contaminate pork and poultry products.[107] If a consumer becomes ill from antibiotic resistant bacteria, he or she may be able to establish liability on the ground that the meat product contained a design defect. As will be explained, the poultry or pork producer may be liable for a design defects under certain circumstances even if there was no negligence on the part of the defendant.

This would be an innovative use of existing products liability law. Accordingly, little on point case law exists but at the same time existing case law does not foreclose such a suit. While a detailed consideration of the tort law on design defect is beyond the scope of this essay, the

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[103] *See* FDA, FDA Seeks Public Input on Next Steps to Help Ensure Judicious Use of Antimicrobials in Animal Agriculture (Sept. 12, 2016) (noting that "approximately 32% of therapeutic products [defined by FDA to include disease prevention] affected by" Guidance No. 213 currently have "no defined duration of use"), available at http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm520110.htm.
[104] FDA, Establishing Appropriate Durations of Therapeutic Administration, 81 Fed. Reg. 63187 (Dec. 13, 2016).
[105] *See supra* note * & accompanying text.
[106] *See supra* note * & accompanying text.
[107] *See supra* note * & accompanying text.

intention is to show that a successful products liability lawsuit is possible, although any plaintiff faces a stiff challenge in establishing liability.

To analyze the potential of a product liability lawsuit, this section first considers the potential of suing an "integrator" for such an injury. As we will be discussed, an integrator is a company that contracts with farmers to raise pork and poultry, and it then process the chickens and pigs in its own plants. The section next considers the legal standards of liability for design defects and the potential that a plaintiff who becomes ill with an antibiotic resistant infection after eating contaminated pork or poultry can successfully sue as a result of his or her illness. Finally, the analysis next evaluates whether such a plaintiff can prove causation—that that contaminated pork or poultry resulted in his or hill illness.

### *A. Suing the Integrator*

Pork and poultry are raised in this country under different arrangements.[108] If the pork of poultry process is fully integrated, one company is responsible for raising and processing the pork or chickens. Alternatively, an integrator (processor) can contract with a producer (farmer) to raise the pork or poultry. In this second arrangement, the integrator owns the pork or poultry and specifies how the producer is to feed, house, and medicate the pigs or poultry including the type and dosage of antibiotics, which are paid for and furnished by the integrator.[109]

If the plaintiff becomes ill after eating pork or chicken raised by a fully integrated company, the company is obviously in charge of the "design" of the product. If the product is raised by a farmer who contractually must use the antibiotics specified and paid for by an integrator, it would appear that the integrator is the entity that designed the product.

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[108] JAN L. FLORA, HOG CAFOS AND SUSTAINABILITY THE IMPACT ON LOCAL DEVELOPMENT AND WATER QUALITY IN IOWA 3 (Oct. 2007), available at http://www.iowapolicyproject.org/2007docs/071018-cafos.pdf.

[109] *Id*. at 4; Karla A. Raettig, *Improvements Needed in Permitting CAFOs under the Clean Water Act* (Sept. 28, 2007), at 8, available at http://www.sec.nv.gov/cafo/tab_dd.pdf; *see* NEIL D. HAMILTON, FARMER'S LEGAL GUIDE TO PRODUCTION CONTRACTS 103 (Jan. 1995) (Con-Agra (integrator) contract with producer (farmer) indicates Con-Agra will supply all medication to be used for raising pigs).

Pork and poultry integrators have insisted, however, that the producers are independent contractors.[110] Even if this is true, a court would need still need to decide whether the integrator had sufficient control of the production process that it was the integrator, not the producer, which was responsible for the subtherapuetic administration of antibiotics that led to the plaintiff's illness. A court should therefore allow a plaintiff to use discovery to reveal the exact nature of the contractual arrangements between the integrator and the producer. If the producer had no choice but to administer the antibiotics as specified by the integrator, it can hardly be said that it was the producer that was responsible for the design of the product.

### *B. Legal Standards of Liability*

There is a duty at common law not to sell defective products to consumers.[111] An actionable defect can result from a flaw during the production process or the design of the product in the first place.[112] A manufacturer may be strictly liable for a design defect. That is, the plaintiff does not need to prove that the manufacturer was negligent in causing the defect.[113] Most product liability actions involve the presence of a harmful subject in the product.[114] A plaintiff bringing an action after becoming ill from chicken or pork contaminated with an antibiotic resistant pathogen would allege the product was defective for that reason.

The law concerning product liability is complex and varies from state to state. As a general matter, the courts will take one of three approaches: a consumer expectation test, a risk utility test, or a combination of the two tests.

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[110] *See* Glenn A. Hegar, Jr., *Adhession Contracts, Debt, Law Returns, and Frustation: Can America's Independent Contract Farmer Overcome the Odds*, 22 HAMLINE L. REV. 213, 217 (1998) (discussing whether producers are independent contractors or employees of the integrator).

[111] RESTATEMENT (SECOND) OF TORTS §402 comment (a).

[112] *Id*.

[113] *Compare id*. at §282 *with* §402.

[114] *See, e.g*., Sindell v. Abbott Laboratories, 26 Cal. 3d 588 (Cal. 1980) (involving the drug DES); In Re Agency Orange Product Liability Litigation, 373 F. Supp. 2nd 7 (EDNY 2005) (involving presticides); Borel v. Fiberboard Paper Products Corp., 493 F.2d 1076 (5th Cir. 1973) (involving asbestos).

*1. Consumer Expectation Test*

The Restatement (Second) of Torts §402A recommends a seller is liable for selling a defective product if it is "unreasonable dangerous" to the user or consumer.[115] A product is "unreasonably dangerous" when the risk to the consumer is "beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."[116] Put another way, a product is defective "whenever it fails in a way that disappoints secure and reasonable expectations about product performance."[117]

Liability is imposed because "the seller, by marketing his product for use and consumption, has taken and assumed a special responsibility toward any member of the consuming public who may be injured by it."[118] As Professor Keating has explained, sellers bring responsibility upon themselves by their actions—they assume "special responsibility" by virtue of the fact that they seek to induce consumers to buy and use their products. They are not strangers to the safety of their customers. Presumptively, manufacturers are expected to market safe products.[119]

In an antibiotics case, a plaintiff could argue that feces from the animals, which contain the drug resistant bacteria, contaminated the meat product eaten by the consumer at a processing plant owned by the integrator. In other words, the plaintiff would seek to establish "(1) the product was in a defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition."[120]

[115] RESTATEMENT (SECOND) OF TORTS § 402A.
[116] Halliday v. Strum, Ruger, & Co., Inc., 368 Md. 186, 193 (Md. 2002).
[117] Gregory S. Keating, *Products Liability As Enterprise Liability* (Dec. 5, 2016), at 9.
[118] Restatement (Second) of Torts, §402A, cmt. c (1997).
[119] Keating, *supra* note 117, at 6.
[120] Nissan Motor Co. Ltd. v. Nave, 129 Md. App. 90, 118 (Md. Ct. Spec. App. 1999).

The defendant would likely raise two defenses to avoid liability. The first is that the plaintiff's illness arose from his or her misuse of the product. Consider, for example, a Maryland case, *Halliday v. Strum, Ruger & Co.*[121] in *Halliday*, the defendant gun manufacturer was not liable for the death of a child from a self-inflected gun shot because the child's father misused the weapon by failing to adhere to warnings about proper storage techniques and instead placed the gun under a mattress. According to the court, the misuse of the weapon resulted in failure to meet the elements of the consumer expectation test since the gun worked exactly as it was designed.[122]

The defendant would contend that the plaintiff's illness resulted from the plaintiff's misuse of the product—the meat the consumer ate—because the safety handling and cooking of meats are essential proper use of the product. In other words, the defendant would argue that if the plaintiff had used and cooked the meat product properly, he or she would have killed the bacteria that caused the plaintiff to become ill.

Depending upon the facts of the case, the plaintiff may be able to rebut this argument by contending that the alleged misuse was foreseeable and therefore not disqualifying.[123] An integrator that processes animals fed antibiotics is aware of the potential that a meat product might be contaminated in a manner that is different than the usual food poisoning that a consumer might suffer if the food product is contaminated by the feces of the animal during processing. Unlike in the gun case, this risk is different than the usual risks related to the use of the product. While it can be foreseen that the failure to lock up a gun might lead to an accidental shooting, a consumer would not necessarily understand that the failure to handle property a meat product would lead to a disease that cannot be readily cured by antibiotics.

As a second defense, the meat packing plant could claim that the warnings that the consumer was adequately warned to cook the meat properly because of the risk of illness. A

[121] Halliday v. Strum, Ruger & Co., 368 Md. 186 (Md. Ct. App. 2002).
[122] *Id*.
[123] Lightolier, A Div. of Genlyte Thomas Grp., LLC v. Hoon, 387 Md. 539, 553-54 (2005) ("[I]n product liability actions, misuse of a product, if proven, negates a design defect claim and occurs when the product in question is used in a manner *not* reasonably foreseeable to the manufacturer and/or seller.").

manufacture can discharge its duty to make a product non-defective by warning of the product's risks if the product unreasonably dangerous without a warning but is reasonably safe with a warning.[124] A decision in favor of a defendant based on an adequate warning is based on the idea that the consumer is in a better position than the manufacturer to take suitable precautions against the risk.[125]

In *Cotton v. Baker*, for example, the court held that the manufacturer of canisters that hold gas was not liable when the plaintiff left one of the canisters too close to a propane heater and the canister explored because some gas fumes were retained in the canister after it was emptied.[126] The defendant avoided liability because it had adequately warned consumers about this risk. The product was not defective (because it contained residual gas fumes) if it was used properly, which involved taking relatively simple precautions (keeping the canister away from heaters).

The warning by a chicken or pork seller must be adequate to warn the consumer of the risks inherent in the product. It must reflect dangers that "were known to the scientific community at the it [the seller] manufactured or distributed the product."[127] Thus, merely warning the consumer that he or she might become ill if the meat product is not properly handled arguably is not sufficient.

Consider, for example, *McDonald v. Ortho Pharmaceutical*, where the court held that a warning that a medication could cause an abnormal blood clot that could be fatal was not sufficient for the company to avoid liability when a consumer suffered a disabling stroke after taking the medication. [128]The court upheld a jury verdict for the plaintiff because the jury reasonably concluded that the warning was insufficient because it did not mention heat attack or stroke, which were more "urgent" terms.[129]

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[124] Keating, *supra* note 117, at 34.
[125] *Id*.
[126] Cotton v. Buckeye Gas Prods. Co., 840 F.2d 935 (D.C. Cir. 1988).
[127] Carlin v. Superior Court, 920 P.2d 1347, 1351-52 (Cal. 1996) (Mosk, Acting C. J.).
[128] MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 71–72 (Mass. 1985).
[129] *Id.* at 71 (quoting *Seeley v. G.D. Searle & Co*., 67 Ohio St. 2d 192, 198, (1981)) ("A reasonable warning not only conveys a fair indication of the dangers involved, but also warns with degree of intensity demanded by the nature of

Likewise, a warning that a consumer could become "ill" from undercooked or improperly handled chicken or pork does not convey that the consumer's infection may not be treatable with antibiotics and hence is life threatening. In light of the risk that a consumer might accidently mishandle a meat product, consumers may well avoid meat products that may be contaminated with antibiotic resistant pathogens since these pathogens present a risk that is different and greater than the usual risks of mishandling food.

*2. Risk-Utility*

Under the Restatement of Torts (3rd), a defendant that sells or distributes a "defective product is subject to liability for harm to persons … caused by the defect."[130] A product is "defective in design when the foreseeable risks of harm posed by product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller … or a predecessor in the commercial chain of distribution …."[131]Thus, unlike the previous consumer expectation inquiry, it is not sufficient for the plaintiff to establish that the risk of harm created by the product was unexpected.[132]

To determine whether an alternative design is "reasonable," a court will balance the advantages and disadvantages of the alternative design.[133] This evaluation employs a number of criteria including the likelihood that existing design will cause injury; the probable severity of the injury; the availability of a substitute product that would meet the same need and not be as

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the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency.")

[130] RESTATEMENT (THIRD) OF TORTS §1.

[131] *Id.* §2(b).

[132] *See* RESTATEMENT (THIRD) TORTS: PRODUCTS LIABILITY § 2 Comment g. (consumer expectations do not constitute an independent standard for judging the defectiveness of product designs); *see, e.g.* Hawkeye-Security Ins. Corp. v. Ford *Motor Co.* 174 N.W.2d 672, 684 (1970) (requiring "proof of an alternative safer design that is practicable under the circumstances" in negligent design case); Hillrichs v. Avco Corp., 478 N.W.2d 70, 75 (1991) (requiring "proof of an alternative safer design" under a theory of enhanced injury caused by a design defect).

[133] Banks v. ICI, 450 S.E.2d 671, 674 (Ga. 1994) ("We conclude that the better approach is to evaluate design defectiveness under a test balancing the risks inherent in a product design against the utility of the product as designed."); Calles v. Scripto-Tokai Corp., 224 Ill.2d 247, 259 (Ill. 2007) (the same).

unsafe: and the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.[134]

In an antibiotics case, the plaintiff may be able to marshal sufficient evidence that a safe replacement was available and affordable. In 1998, the Danish poultry industry stopped using antibiotics voluntarily to promote growth and in 2000 the pork industry did the same even though Denmark is the world's largest exporter of pork.[135] Further, the country reduced its overall use of antibiotics in livestock by 60 percent by establishing a comprehensive monitoring system and limiting the amount of money veterinarians were able to earn selling antibiotics.[136] Fall from crippling pork production, production rose by 50 percent.[137]

It is not clear, however, whether the Danish situation is sufficiently comparable to that in the United States. Moreover, a defendant is only liable for risks that the consumer did not anticipate and could not avoid. Thus, as with the consumer expectation standard, the plaintiff must overcome a defense the meat product was not defective because the bacteria would have been killed if the consumer had cooked and handled the meat product properly. As the Iowa Supreme Court has explained, "A product is defective if it is 'unreasonably dangerous in a reasonably foreseeable use.' Consequently, if the misuse of the product that causes the product to become dangerous is not reasonably foreseeable, the product is not defective."

As discussed earlier, the plaintiff may be able to overcome a misuse defense on the ground that the plaintiff failed to give an adequate warning of the risk that a consumer might become infected with an antibiotic resistant pathogen.[138] A court might be (and should be) reluctant to shift the burden of prevention to a consumer unless the consumer actually

[134] The other factors are the usefulness and desirability of the product—its utility to the user and to the public as a whole; the user's ability to avoid danger by the exercise of care in the use of the product; the user's anticipated awareness of the dangers inherent in the product and their availability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and the ability of the manufacturer to spread the loss by setting the price of the product or carrying liability insurance. Calles v. Scripto-Tokai Corp, 224 Ill.2d at 259.

[135] *Pig Out: If Farmers Do Not Voluntarily Rein in the Use of Antibiotics for Livestock, People Will Be Severely Affected*, 486 NATURE 440, 440 (2012)

[136] *Id*.

[137] *Id*.

[138] See *supra* notes __ & accompanying text.

understands the extent of the risk that he or she was confronting. Faced with an adequate warning, it is plausible that consumers would not have purchased the product in the first place

*3. Hybrid Test*

The courts in a number of states follow a hybrid legal standard that employs a version of both of the first two legal standards.[139] These courts employ a consumer expectation standard that is stricter than the Restatement (Second) of Torts standard. The difference is that the plaintiff does not have to prove that a product is "unreasonably" defective, but instead needs only to establish that it was defective.[140]

Consider, for example, *Barker v. Lull Engineering.*[141] After the plaintiff sued both his employer and the manufacturer of the high-lift loader that injured the plaintiff employee while he was attempting to perform maintenance on the loader,[142] the California Supreme Court held that once a plaintiff makes a prima facie showing that a product's design proximately caused the injury, the burden shifts to the defendant to prove that the product is not defective.[143] In *Cronin v. J.B.E. Olson Corp*, the court explained that the *Restatement (Second) of Torts* § 402A placed too high a burden on the plaintiff, and only proof of a defect should be required.[144]

The hybrid version also employs a risk-utility test to protect consumers in those instances where "the consumer would not know what to expect, because he would have no idea how safe the product could be made."[145] However, this version of the risk-utility test shifts the burden of proving an alternative design to the defendant once the plaintiff establishes that he or she was harmed by a defect in the product. Since the defendant and not the plaintiff must prove the product's utility exceeds its risks, the risk utility test is employed in a manner that is more stringent that required by the Restatement (Third) of Torts.

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[139] *See* Keating, *supra* note 117, ("Many states have cited *Barker* and adopted its products liability regime (courts in at least 8 states have cited and followed *Barker*").
[140] *E.g*. Barker v. Lull Engineering, 20 Cal.3d 413, 417 (Cal. 1978).
[141] Barker v. Lull Engineering, 20 Cal.3d 413 (Cal. 1978).
[142] *Id.* at 417.
[143] *Id.* at 431. The Court also held that a product can be deemed defective if it meets the elements of either the consumer expectation test or a risk/utility analysis. *Id*. at 418.
[144] Cronin v. J.B.E. Olson Corp., 8 Cal.3d 121, 134-35 (Cal. 1972).
[145] Barker, 573 P.2d at 455.

An integrator would seek to meet this burden of proof by arguing that the production of affordable chicken or hogs was not possible without the subtherapeutic use of antibiotics because of the risk of infections in a CAFO. But, as discussed earlier, a plaintiff may be able to rebut the claim antibiotics are necessary in order to product chickens and hogs at affordable prices.[146]

A plaintiff suing in a jurisdiction that uses this hybrid test would therefore have two advantages. The plaintiff would not need to prove the defect was an "unreasonable" defect, and it would not need to prove the feasibility or utility of an alternative design. Nevertheless, as with the conventional versions of the consumer expectations and risk utility standards, a defendant is not liable if the consumer was warned of reasonable knowable risks at the time of distribution.[147] But as discussed earlier, existing warnings are arguably not sufficiently detailed to warn the consumer that he or she may get an infection that cannot readily be cured by antibiotics.[148]

### *C. Causation*

Whichever standard of liability is applied, the plaintiff must prove that he or she became ill from eating a contaminated meat product produced by an integrator. A plaintiff must prove both general and specific causation using expert testimony.[149]

As a matter of general causation, the plaintiff must prove by a preponderance of the evidence that that use of antibiotics in chicken and hog production increases the risk of human infections from antibiotic resistant pathogens.[150] This step requires a plaintiff to establish that it is more likely than not that the exposure to antibiotic resistant pathogens in pork or chicken causes some people to become ill with antibiotic resistant infections, taking into account the available scientific evidence and its reliability.[151]

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[146] See *supra* notes __ & accompanying text.
[147] Brown v. Superior Court, 44 Cal.3d 1049, 1069 (Cal. 1988).
[148] See *supra* notes __ & accompanying text.
[149] Thomas 0. McGarity, *Our Science is Sound Science and Their Science isjunk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities,* 52 U. KAN. L. REV. 899-900 (2004).
[150] RESTATEMENT (THIRD) OF TORTS §28 cmt. c(3) (2010).
[151] *Id.* § 28 cmt. c(4).

The increase in antibiotic resistant bacteria in farm animals and in consumer meat products is well documented, but the complexity of the production and delivery chains used in food product "make it challenging to preform controlled studies that provide unequivocal support for a direct link between antibiotic use in animals and the emergence of antibiotic resistance in food-borne bacteria associated with human disease."[152] Nevertheless, the *Review on Antimicrobial Resistance* found that 100 of 139 academic studies (72 percent) found a link between antibiotic consumption in animals and antibiotic resistance in people, while only seven (five percent) studies found no such link.[153]

As a matter of specific causation, the plaintiff must prove that his or her exposure to an antibiotic resistant pathogen in a meat product designed by the defendant caused the plaintiff to become ill from an infection related to that pathogen. This means it must be more likely than not that his or her illness would not have occurred but for the exposure to the antibiotic resistant pathogen.[154]

A plaintiff can attempt to meet this burden of proof in two ways. First, a plaintiff could attempt to tie his or her infection to the same pathogens found in the animals at a specific CAFO that originated the contaminated meat the plaintiff ate. There are studies that have linked a specific antibiotic resistant pathogen to existence of the same specific pathogen at the CAFO from which the food product came.[155] This research has been hampered by the fact that CAFO

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[152] Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718, 725, 726 (2011).

[153] Review on Antimicrobial Resistance, Antimicrobials in Agriculture and the Environment: Reducing Unnecessary Use and Waste 10 (Dec. 2015), available at http://amr-review.org/sites/default/files/Antimicrobials%20in%20agriculture% 20and%20the%20environment%20-%20Reducing%20unnecessary%20use%20and% 20waste.pdf; see also Marshall & Levy, *supra* note 152, at 718 (reporting that a number of studies "unequivocally support that use of antibiotics in feed in food animals (particularly nontherapeutic use) impacts the health of people on farms and, more distantly, via the food chain").

[154] RESTATEMENT (THIRD) OF TORTS §28 cmt. c(1).

[155] *See, e.g.* A____ C. Berge & D____ T. Griffiths, *Farm Animals As A Putative Reservoir for Vancomycin-Resistant Enterococcal Infection in Man*, 34 J. ANTIMICROB CHEMOTHER 507 (1994); ___ Davis et al., *Intermingled Klebsiella pneumoniae Populations Between Retail Meats and Human Urinary Tract Infections*, 61 CLINICAL INFECTIOUS DISEASES 892 (Sept. 15, 2015) (demonstrating that K. pneumoniae isolated from retail meat samples are genetically closely-related to K. pneumoniae isolated from human patients); ____ Vieira et al., *Association Between Antimicrobial Resistance in Escherichia coli Isolates from Food Animals and Blood Stream Isolates from Humans in Europe: An Ecological Study*, 8 FOODBORNE PATHOGENS AND DISEASE 1295 (Dec. 2011) (finding that "[r]esistance in E. coli isolates from food animals . . . was highly correlated with resistance in isolates from

operators most often do not allow researchers to gain access to the land and facilities where the antibiotics are administered. On-site testing will be a crucial element of discovery in this type of lawsuit.

A plaintiff can also seek to establish specific causation using circumstantial evidence. As mentioned earlier, a significant number of studies indicate the transmittal of antibiotic resistant pathogens to farm workers and through the food chain.[156] Whether or not this evidence is sufficient, however, depends on the strength of the evidence. For example, if there were evidence showing that exposure to an antibiotic resistant pathogen more than doubles the risk of becoming ill with a related antibiotic resistant infection, this evidence may be sufficient to establish specific causation.[157] But even if the plaintiff can present such evidence, there are other related issues including whether the plaintiff's exposure was one of comparable magnitude and duration, whether the plaintiff was exposed differentially to other causal agents for the same disease, and whether the plaintiffs individual characteristics render him or her more or less susceptible to the disease than the exposed populations in the relevant scientific studies.[158]

## V. CONCLUSION

Regulation as a way to address human health risks has the advantage over tort law of being preventative. Congress has enhanced this advantage by assigning to agencies a burden of proof that is less demanding that tort law requires. This is only one of several advantages of relying on regulation to protect the public, but regulation has none of these advantages if an agency fails to regulate pressing public health risks because of regulatory capture or dysfunction. The civil justice system is therefore a necessary and vital potential backup to the regulatory system.

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humans[, which] supports the hypothesis that a large proportion of resistant E. coli isolates causing blood stream infections in people may be derived from food sources.").

[156] *See supra* note * & accompanying text.

[157] RESTATEMENT (THIRD) OF TORTS §28 cmt. c(4).

[158] *Id*.

Despite increasing evidence that the subtherapeutic use of antibiotics in animal food production increases the risk of human infections resistant to antibiotics, FDA has been a reluctant regulator. Its only regulation to address this risk bans the use of antibiotics for growth promotion, but it allows the continued use of antibiotics to prevent the confined animals in CAFOs from becoming infected, which is by far the greater use of antibiotics in these facilities.

Potentially, this regulatory gap could be addressed if plaintiffs were able to establish that the subtherapeutic use of antibiotics is a product defect. This may prove difficult, however, because of the requirements to establish liability in a tort action and the challenge of establishing that a defendant was the cause of the plaintiff's antibiotic resistant infection.

Despite these hurdles, a plaintiff could potentially succeed, which is a good thing. Unless FDA drops its reluctance to ban the use of antibiotics for disease prevention purposes, tort law may offer the only way to deter the risk to the public caused by the use of antibiotics in animal food production.