

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

BY  
SIDNEY A. SHAPIRO\*

*This Essay explores the potential role of the tort system to plug the regulatory gap created by the reluctance of the Food and Drug Administration (FDA) to reduce the use of antibiotics in animal food production despite increasing evidence that this practice increases the risk of human infections that cannot be treated by available antibiotics. This regulatory gap could be addressed if plaintiffs were able to establish that antibiotic use is a product defect, but this will be difficult because of the requirements of proof in a tort action including establishing that a defendant was the cause of the plaintiff's antibiotic-resistant infection. Despite these hurdles, a plaintiff could potentially succeed, which may be the only way to deter the risk to the public caused by the use of antibiotics in animal food production until FDA acts to protect the public.*

I.	INTRODUCTION.....	558
II.	THE PUBLIC HEALTH RISK.....	558
III.	REGULATION VERSUS TORT LAW AS A RESPONSE.....	562
IV.	THE RELUCTANT REGULATOR.....	566
V.	PRODUCTS LIABILITY LITIGATION AS AN ALTERNATIVE.....	571
	A. <i>Legal Standards of Liability</i> .....	572
	1. <i>Manufacturing Defect</i> .....	572
	2. <i>Design Defect</i> .....	573
	a. <i>Consumer Expectation Test</i> .....	574
	b. <i>Risk-Utility Test</i> .....	576
	c. <i>Hybrid Test</i> .....	578
	B. <i>Causation</i> .....	579
VI.	CONCLUSION.....	580

---

\* Frank U. Fletcher Chair of Administrative Law, Wake Forest University. This Essay is based on a project of the Center for Progressive Reform (CPR), and the author wishes to acknowledge that portions of this Essay reflect work done by Mollie Rosensweig, a CPR policy analyst.

## 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 its only effort to regulate came in June 2015,<sup>1</sup> which 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 of state law to adequately protect people and the environment.<sup>2</sup> The need for federal regulation arose in part 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, this Essay explores the roles of regulation and tort law in protecting the public from antibiotic-resistant bacterial infections in four steps. Part II describes the risk to the public of the use of antibiotics in animal production. Part III considers the reasons why, as a general matter, it is preferable to use regulation to address public health risks. The tort system, however, can be an important backup to regulation when, as here, it appears that regulators have failed to adequately address a public health risk. Part IV describes and evaluates FDA's response to the development and proliferation of antibiotic-resistant bacteria. This Part also explains why FDA's efforts are likely to be insufficient to protect the public. Finally, Part V evaluates whether this gap in protection can be reduced using product liability law. The conclusion is that 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.<sup>3</sup> Although the magnitude of this problem is unknown, the most recent statistics reveal that antibiotic use in

---

<sup>1</sup> Veterinary Feed Directive; Correction, 80 Fed. Reg. 31,708, 31,708 (June 3, 2015) (codified at 21 C.F.R. pts. 514 and 558).

<sup>2</sup> See SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, *RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH* 1–2 (2003).

<sup>3</sup> Mary J. Gilchrist et al., *The Potential Role of Concentrated Feed Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 ENVTL. HEALTH PERSP. 313, 313 (2007).

food production accounts for about 73% of all medically significant antibiotics sold in the United States.<sup>4</sup>

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).<sup>5</sup> A CAFO typically keeps animals confined for a period of over forty-five days and brings feed to the animals, rather than permitting the animals to graze or forage for food.<sup>6</sup> A CAFO is designed to fit as many animals as possible in extremely cramped conditions and to fatten 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 in CAFOs, although it is estimated that 99% of all farmed animals are raised this way.<sup>7</sup> CAFOs are subject to disease outbreaks because of the unsanitary concentrated conditions in which the animals are raised.<sup>8</sup>

The solution industry has used is to administer low-level (subtherapeutic) doses of antibiotics in the animals' food or water for long periods of time prophylactically to prevent infections.<sup>9</sup> FDA estimates that 80% of the antibiotics used in the United States are fed to farmed animals.<sup>10</sup> Moreover, this practice is growing. According to FDA, antibiotic use in food-producing animals increased 26% between 2009 and 2015.<sup>11</sup>

The prophylactic administration of low doses of antibiotics fosters the development of drug-resistant bacteria in animals.<sup>12</sup> 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 the animal's waste or by contact with meat or poultry contaminated with the waste.<sup>13</sup>

---

<sup>4</sup> *Record-High Antibiotic Sales for Meat and Poultry Production*, PEW CHARITABLE TR. (Feb. 6, 2013), <https://perma.cc/NV9E-LR68>. See also MARGARET MELLON, CHARLES BENBROOK & KAREN LUTZ BENBROOK, UNION OF CONCERNED SCIENTISTS, HOGGING IT! ESTIMATES OF ANTIBIOTIC USE IN LIVE STOCK, at xiii (2001) (estimating that the use of antibiotics in animals could be as high as 84% of total antibiotic use); but see Stuart B. Levy, *The Challenge of Antibiotic Resistance*, SCI. AM., Mar. 1998, at 46, 51 (estimating more than 40% in 1998).

<sup>5</sup> CARRIE HRIBAR, UNDERSTANDING CONCENTRATED ANIMAL FEEDING OPERATIONS AND THEIR IMPACT ON COMMUNITIES 10 (2010), <https://perma.cc/DBP8-SBPL>.

<sup>6</sup> *Id.* at 1; *Animal Feeding Operations (AFOs)*, U.S. ENVTL. PROTECTION AGENCY, <https://perma.cc/FB6Z-PV93> (last visited July 8, 2017).

<sup>7</sup> See *Ending Factory Farming*, FARM FORWARD, <https://perma.cc/84V7-YZ6X> (last visited July 8, 2017) (citing U.S. DEP'T OF AGRIC., 2012 CENSUS OF AGRICULTURE (2014)).

<sup>8</sup> HRIBAR, *supra* note 5, at 8.

<sup>9</sup> *Id.* at 10.

<sup>10</sup> *Antibiotics*, GRACE COMM. FOUND., <https://perma.cc/KY87-KZ3B> (last visited July 8, 2017) (citing FOOD & DRUG ADMIN., 2009 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 10 (2014), <https://perma.cc/W6RY-ZZVA>).

<sup>11</sup> FOOD & DRUG ADMIN., 2015 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 20 (2016), <https://perma.cc/QQ8F-BUD2> [hereinafter FDA 2015 REPORT].

<sup>12</sup> See *infra* notes 14–20 and accompanying text (discussing studies linking antibiotic use and the development of drug-resistant pathogens in pork and chickens raised in CAFOs).

<sup>13</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 14 (2013), <https://perma.cc/YEH5-EBWQ> [hereinafter CDC, ANTIBIOTIC

Workers in CAFOs, for example, can become colonized with drug-resistant bacteria. Those workers may then spread the bacteria into their homes and their communities after they leave their workplaces.<sup>14</sup> Since the trucks that carry live broiler chickens to slaughterhouses are highly contaminated with antibiotic-resistant bacteria from chicken litter, people traveling on the same roads can be exposed to the bacteria through the air for a period of time after the truck passes by.<sup>15</sup> Drug-resistant bacteria can also travel through the air, moving from a CAFO to nearby communities, motor vehicles, and individuals.<sup>16</sup> Even flies that come into contact with the bacteria from hog and chicken waste can subsequently expose people to this risk.<sup>17</sup>

Contact between humans and foods containing drug-resistant bacteria is another route of exposure. This can occur when people eat meat or vegetables contaminated with antibiotic-resistant bacteria.<sup>18</sup> Slaughterhouses process animals at such high speeds that feces from the animals, which contain the drug-resistant bacteria, can contaminate the meat products.<sup>19</sup> The drug-resistant bacteria are transferred to vegetables by the direct application of manure as fertilizer on vegetable crops or from runoff water that has been contaminated by animal waste that is subsequently used to water vegetable crops.<sup>20</sup>

Drug-resistant bacteria are estimated to kill at least 23,000 people and sicken a total of 2,000,000 people each year in the United States,<sup>21</sup> which results in \$20 billion dollars in health costs.<sup>22</sup> The Centers for Disease

---

RESISTANCE THREATS]; *see also infra* notes 21–23 and accompanying text (linking the use of antibiotics in animal production with antibiotic-resistant infections in humans).

<sup>14</sup> A. Richter et al., *Prevalence of Types of Methicillin-Resistant Staphylococcus aureus, in Turkey Flocks and Personnel Attending the Animals*, 140 EPIDEMIOLOGY & INFECTION 2223, 2231 (2012).

<sup>15</sup> Ana M. Rule, Sean L. Evans & Ellen K. Silbergeld, *Food Animal Transport: A Potential Source of Community Exposures to Health Hazards from Industrial Farming (CAFOs)*, 1 J. INFECTION & PUB. HEALTH 33, 37–38 (2008).

<sup>16</sup> Amy Chapin et al., *Airborne Multidrug-Resistant Bacteria Isolated from a Concentrated Swine Feeding Operation*, 113 ENVTL. HEALTH PERSP. 137, 140 (2005).

<sup>17</sup> Jay P. Graham et al., *Antibiotic Resistant Enterococci and Staphylococci Isolated from Flies Collected Near Confined Poultry Feeding Operations*, 407 SCI. TOTAL ENV'T 2701, 2709 (2009).

<sup>18</sup> CDC, ANTIBIOTIC RESISTANCE THREATS, *supra* note 13. A consumer may be able to avoid an antibiotic infection by safe handling and adequate cooking of pork and poultry or by washing vegetables. *Antibiotic Resistance and Food Safety*, CTNS. FOR DISEASE CONTROL & PREVENTION (Jan. 12, 2016), <https://perma.cc/K8BM-C756>.

<sup>19</sup> Andrea Rock, *How Safe Is Your Ground Beef?*, CONSUMER REP. (Dec. 21, 2015), <https://perma.cc/5NS4-YQ3W>.

<sup>20</sup> Jay Graham et al., *Fate of Antimicrobial-Resistant Enterococci and Staphylococci and Resistance Determinants in Stored Poultry Litter*, 109 ENVTL. RES. 682, 688 (2009).

<sup>21</sup> CDC, ANTIBIOTIC RESISTANCE THREATS, *supra* note 13, at 11.

<sup>22</sup> Richard Smith & Joanna Coast, *The True Cost of Antimicrobial Resistance*, BRIT. MED. J., Mar. 11, 2013, at f1493, f1493.

Control and Prevention (CDC) estimates that germs from food and animals cause one in five drug-resistant infections in humans.<sup>23</sup>

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 minimal use of antibiotics in food animals for growth promotion and the discontinuation of antibiotic use for disease prevention.<sup>24</sup> A 1970 FDA task force warned subtherapeutic use of antibiotics could become “a reservoir of antibiotic resistant pathogens” that “can produce human infections.”<sup>25</sup> A 1977 FDA advisory committee recommended that FDA “immediately withdraw approval for the subtherapeutic uses of penicillin, i.e., growth promotion/feed efficiency, and disease control.”<sup>26</sup> The advisory committee also 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.<sup>27</sup>

The warnings have continued to the present day. In 2015, the American Academy of Pediatrics warned 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.<sup>28</sup> The physicians called for ending the use of subtherapeutic use of antibiotics in food production.<sup>29</sup> In 2016, a coalition of medical and scientific groups called for “principles for appropriate livestock and poultry antibiotic use.”<sup>30</sup>

---

<sup>23</sup> *Antibiotic Resistance from the Farm to the Table*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 16, 2015), <https://perma.cc/R6NF-EEAZ>.

<sup>24</sup> E. M. FOSTER ET AL., NAT. ACAD. OF SCIS., AN EVALUATION OF THE SALMONELLA PROBLEM 18 (1969).

<sup>25</sup> Antibiotics and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444, 2445 (Feb. 1, 1972) (to be codified at 21 C.F.R. pt. 135). 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.*

<sup>26</sup> Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 884 F. Supp. 2d 127, 133 (S.D.N.Y. 2012) (citation omitted).

<sup>27</sup> 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, 43,774 (Aug. 30, 1977).

<sup>28</sup> Jerome A. Paulson & Theoklis E. Zaoutis, *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*, 136 PEDIATRICS e1670, e1670–73 (2015) [hereinafter *2015 AAP Report*]. The 2015 report reaffirms the conclusions of a report the AAP published in 2004. Katherine M. Shea, *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*, 114 PEDIATRICS 862, 862–64, (2004).

<sup>29</sup> *2015 AAP Report*, *supra* note 28, at e1674.

<sup>30</sup> *Principles for Appropriate Livestock and Poultry Antibiotic Use*, CATH. HEALTH ASS'N U.S., <https://perma.cc/78CU-K6Y5> (last visited July 8, 2017).

Outside of the United States, in 1969, the Swann Report in the United Kingdom recognized a potential link between the use of antibiotics in agriculture and the drug-resistant infections,<sup>31</sup> and the World Health Organization recommended against using antibiotics used by humans for growth promotion in 1973.<sup>32</sup> In 1999, the European Union banned the use of antibiotics for growth promotion.<sup>33</sup>

### 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 addition to its role of compensating individuals for harms done to them.<sup>34</sup>

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.<sup>35</sup> The incentive effects of tort law can also prevent harm from occurring, just like a regulation, although tort law is not activated until after people are injured or killed by an unsafe product or practice and then they successfully sue the manufacturer or producer responsible. A number of such successful lawsuits may therefore be necessary to deter similar future behavior. Still, the threat of paying compensation to victims can have a deterrent effect.<sup>36</sup> A number of industries have taken potential tort liability into account to reduce risks that they pose to others.<sup>37</sup>

---

<sup>31</sup> See generally MICHAEL SWANN ET. AL., JOINT COMMITTEE ON THE USE OF ANTIBIOTICS IN ANIMAL HUSBANDRY AND VETERINARY MEDICINE (1969).

<sup>32</sup> See generally WORLD HEALTH ORG., WORKING GROUP ON THE PUBLIC HEALTH ASPECTS OF ANTIBIOTICS IN FEEDSTUFFS (1974).

<sup>33</sup> Council Regulation 2821/98, art. 1, 1998 O.J. (L 351) 4 (1998); see also Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REV. 718, 722 (2011).

<sup>34</sup> See Jean Macchiaroli Eggen, *The Synergy of Toxic Tort Law and Public Health: Lessons from a Century of Cigarettes*, 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 Public Law in Disguise*, 38 TEX. L. REV. 1, 1 (1959) (referring to tort law as a form of public regulation “in disguise”).

<sup>35</sup> Christopher H. Schroeder, *Lost in Translation: What Environmental Regulation Does That Tort Cannot Duplicate*, 41 WASHBURN L.J. 583, 589 (2002).

<sup>36</sup> 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 therefore effective in across-the-board regulation—in most spheres at least, that ineffectiveness should not be over-generalized.”).

<sup>37</sup> See Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 408–09, 418 (1994) (discussing employers in different industries changing their practices to reduce potential liability).

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.<sup>38</sup> In addition, the regulatory system can call on its expertise when making determinations about the riskiness of a product or process.<sup>39</sup> The civil justice system, by comparison, relies either on lay juries or a generalist judge to make the same type of determinations.<sup>40</sup>

Again, however, this advantage should not be exaggerated. Although there are prominent examples of the tort system apparently establishing mistaken liability,<sup>41</sup> tort law has demonstrated that lawyers are capable of educating juries and judges about the nature of the risks that they are adjudicating, aided by expert witnesses.

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 that individual's illness. Comparing how regulatory agencies and tort law make decisions concerning exposure to health risks explains this advantage.

Health regulation takes places in two steps.<sup>42</sup> The first step for an agency is to determine if available scientific information meets the requirements established by Congress to trigger the regulatory process.<sup>43</sup> This is an issue of "general causation"<sup>44</sup> 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 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 risk.<sup>45</sup> The Clean Air Act,<sup>46</sup> 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."<sup>47</sup>

A plaintiff suing in a toxic tort case 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

---

<sup>38</sup> Schroeder, *supra* note 35, at 598.

<sup>39</sup> Sidney A. Shapiro, *The Failure to Understand Expertise in Administrative Law: The Problem and the Consequences*, 50 WAKE FOREST L. REV. 1097, 1099–110 (2015).

<sup>40</sup> Green & Jones, *supra* note 36, at 200.

<sup>41</sup> See, e.g., *id.*, *supra* note 36, at 200–01 (discussing the Bendectin litigation).

<sup>42</sup> See SHAPIRO & GLICKSMAN, *supra* note 2, at 31 (discussing in detail "statutory triggers" and "statutory standards").

<sup>43</sup> *Id.* at 31–32.

<sup>44</sup> RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 28 cmt. c(3) (AM. LAW INST. 2010).

<sup>45</sup> SHAPIRO & GLICKSMAN, *supra* note 2, at 31.

<sup>46</sup> 42 U.S.C. §§ 7401–7671q (2012).

<sup>47</sup> *Id.* § 7411(b)(1)(A).

of people.<sup>48</sup> But tort law employs a different burden of proof at this stage: a plaintiff must prove general causation by a preponderance of the evidence.<sup>49</sup> 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.<sup>50</sup>

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.<sup>51</sup> 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 Safe Drinking Water Act Amendments of 1996,<sup>52</sup> for example, instructs EPA to establish a maximum contaminant level at a level requisite to protect public health with “an adequate margin of safety.”<sup>53</sup>

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 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.<sup>54</sup>

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 Supreme Court of the United States recognized for much of the 20th century, state civil justice systems serve as an invaluable complement to federal and state positive law by compensating those harmed by unreasonably dangerous products or activities.<sup>55</sup>

---

<sup>48</sup> See Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 14 (1993) (“General causation asks whether exposure to a substance causes harm to anyone.”).

<sup>49</sup> RESTATEMENT (THIRD) OF TORTS § 28 cmt. c(1).

<sup>50</sup> See *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34, 36 (1983) (concluding that the National Highway Traffic Safety Administration acted arbitrarily and capriciously when rescinding a rule requiring passive restraints in vehicles). This difference reflects Congress’s 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, 55 (explaining that regulation is more advantageous in certain areas of the law, including toxic torts). As mentioned, the impetus for most regulatory statutes was the failure of tort law to protect people sufficiently. See *supra* note 2 and accompanying text.

<sup>51</sup> SHAPIRO & GLICKSMAN, *supra* note 2, at 35.

<sup>52</sup> Pub. L. No. 104-182, 110 Stat. 1613 (1996).

<sup>53</sup> SHAPIRO & GLICKSMAN, *supra* note 2, at 37.

<sup>54</sup> RESTATEMENT (THIRD) OF TORTS § 28 cmt. c(1).

<sup>55</sup> See *United Constr. Workers, Affiliated with United Mine Workers of Am. v. Laburnum Constr. Corp.*, 347 U.S. 656, 657, 669 (1954) (“If Virginia is denied jurisdiction in this case, it will mean that where the federal preventive administrative procedures are impotent or inadequate,



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.<sup>56</sup> Similarly, tort suits were an important component of the early civil rights movement<sup>57</sup> and the movement against sexual harassment before Congress adopted laws to address these issues.<sup>58</sup>

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.<sup>59</sup> 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 both a regulatory agency and a significant (or less) portion of the state courts. For this reason, the civil justice system 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.<sup>60</sup> 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 alleviate some of its negative consequences.

---

the offenders . . . may destroy property without liability for the damage done.”). *See also* Int'l Union, United Auto., Aircraft & Agric. Implement Workers of Am. v. Russell, 356 U.S. 634, 645–46 (1958) (recognizing that state courts, unlike the National Labor Relations Board, can award punitive damages and permit recovery for “medical expenses, pain and suffering, and property damages”), *reh'g denied*, 357 U.S. 634 (1958); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 240, 258 (1984) (holding that a “state-authorized award of punitive damages” is not preempted by federal law), *rehearing denied by*, 465 U.S. 1074 (1984); *English v. Gen. Elec. Co.*, 496 U.S. 72, 89 (1990) (“[W]e cannot conclude that Congress intended to pre-empt all state actions that permit the recovery of exemplary damages.”), *remanded to*, 765 F. Supp. 293 (E.D.N.C. 1991).

<sup>56</sup> *See, e.g.*, Benedict A. Schuck III, *Air Pollution as a Private Nuisance*, 3 NAT. RESOURCES LAW. 475, 481–82 (1970) (describing actions for air pollution as private nuisance dating back to 1611).

<sup>57</sup> *See, e.g.*, *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388, 390, 411 (1971) (holding that an action in tort may be brought against the government by private citizens).

<sup>58</sup> *See, e.g.*, Joanna Stromberg, *Sexual Harassment: Discrimination or Tort?*, 12 UCLA WOMEN'S L.J. 317, 318 (2003) (discussing victims' use of various tort claims for relief from sexual harassment).

<sup>59</sup> Sidney A. Shapiro, *The Complexity of Regulatory Capture: Diagnosis, Causality, and Remediation*, 17 ROGER WILLIAMS U. L. REV. 221, 223–25, 256 (2012).

<sup>60</sup> *See* RENA STEINZOR & SIDNEY SHAPIRO, *THE PEOPLE'S AGENTS AND THE BATTLE TO PROTECT THE AMERICAN PUBLIC: SPECIAL INTERESTS, GOVERNMENT, AND THREATS TO HEALTH, SAFETY, AND THE ENVIRONMENT* 4–5 (2010).

Finally, state civil justice systems boost the effectiveness of federal regulatory programs by creating incentives to monitor and even create new risk regulation information.<sup>61</sup> 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.<sup>62</sup> Regulatory agencies, by comparison, have weaker incentives to gather information about past regulatory actions because of the press of new business and limited resources.<sup>63</sup> Moreover, the laws under which they operate rarely require or encourage them to reexamine and reassess these past actions.<sup>64</sup> When information generated through tort litigation feeds back into the regulatory system, agencies hopefully can reexamine past regulatory decisions and ideally develop better regulations.<sup>65</sup>

State civil justice systems also provide an incentive for manufacturers and producers to continually reevaluate risk information.<sup>66</sup> 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.<sup>67</sup> The agency cannot approve a new veterinary drug unless the pharmaceutical company that

---

<sup>61</sup> William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1589 (2007).

<sup>62</sup> *Id.* at 1599; Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068–70 (2000) (referencing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504 (1992)).

<sup>63</sup> See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-370T, MEDICAL DEVICES: SHORTCOMINGS IN FDA'S PREMARKET REVIEW, POSTMARKET SURVEILLANCE, AND INSPECTIONS OF DEVICE MANUFACTURING ESTABLISHMENTS 14–15 (2009) (finding FDA does not have the resources to follow up on all of the adverse events reports that they receive).

<sup>64</sup> Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1390 (1992).

<sup>65</sup> See Buzbee, *supra* note 61, at 1583; see generally 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 235 (William W. Buzbee ed., 2009) (describing the "feedback loop" between federal regulation and state common law).

<sup>66</sup> THOMAS O. MCGARITY, *THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES* 238 (2008).

<sup>67</sup> 21 U.S.C. § 331(a) (2012) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any food [or] drug . . . that is adulterated"); *id.* § 360b(a)(1) (providing that "[a] new animal drug shall . . . be deemed unsafe . . . unless" FDA has approved the drug); *id.* § 351(a) (providing that a drug "shall be deemed to be adulterated . . . if it is a new animal drug which is unsafe within the meaning of section 360b").

wants to sell the drug has demonstrated that its use in animals is “safe” for humans.<sup>68</sup> A use is not safe unless there is a “reasonable certainty of no harm to human health.”<sup>69</sup> 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 veterinary use.<sup>70</sup>

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.<sup>71</sup> In 1977, 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.<sup>72</sup> FDA required the pharmaceutical manufacturers of these antibiotics to produce evidence that veterinary use was safe for people,<sup>73</sup> but the agency’s efforts to withdraw approval of antibiotics stalled during the Reagan administration, probably because of the administration’s antipathy to regulation.

Beginning in 2001, FDA scientists who had expertise in fields such as veterinary medicine and microbiology reviewed whether thirty 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.<sup>74</sup> 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.<sup>75</sup> After the Natural Resources Defense Council (NRDC) obtained the results of the study by filing a Freedom of Information Act<sup>76</sup> request, the environmental group revealed that FDA scientists found eighteen of the thirty additives posed a “high risk” that humans would be exposed to antibiotic-resistant bacteria

---

<sup>68</sup> *Id.* § 360b(d)(1).

<sup>69</sup> FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 18 (2012), <https://perma.cc/6JYT-P96B> [hereinafter FDA GUIDANCE #209].

<sup>70</sup> FOOD & DRUG ADMIN., DOCKET NO. 2000N-1571, FINAL DECISION OF THE COMMISSIONER: WITHDRAWAL OF APPROVAL OF THE NEW ANIMAL DRUG APPLICATION FOR ENROFLOXACIN IN POULTRY 100 (2005).

<sup>71</sup> *See supra* notes 24–27 and accompanying text.

<sup>72</sup> Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977). *See also* Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977).

<sup>73</sup> Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 884 F. Supp. 2d 127, 133 (S.D.N.Y. 2012).

<sup>74</sup> CARMEN CARDOVA & AVINASH KAR, NAT. RES. DEF. COUNCIL, PLAYING CHICKEN WITH ANTIBIOTICS: PREVIOUSLY UNDISCLOSED FDA DOCUMENTS SHOW ANTIBIOTIC FEED ADDITIVES DON’T MEET THE AGENCY’S OWN SAFETY STANDARDS 2 (2014), <https://perma.cc/4FWD-5HNE>.

<sup>75</sup> *Id.* at 7.

<sup>76</sup> 5 U.S.C. § 552 (2012).

through the food supply.<sup>77</sup> Furthermore, the agency determined that at least twenty-six of the thirty uses of antibiotics did not even satisfy the safety criteria that the agency used in 1973.<sup>78</sup>

Despite these findings, FDA announced in December 2011 that it was ending any efforts to withdraw approval of the antibiotics.<sup>79</sup> A coalition of public interest groups sued the agency to challenge this decision,<sup>80</sup> 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.<sup>81</sup> The coalition prevailed in the Southern District of New York,<sup>82</sup> but a divided panel of the Second Circuit reversed.<sup>83</sup> The court disagreed that 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.<sup>84</sup>

FDA implemented its efforts to obtain voluntary reductions in the use of antibiotics by issuing two guidance documents. In 2012, FDA recommended two voluntary "principles" for the use of antibiotics that are important to human health in food-producing animals.<sup>85</sup> The first recommended these antibiotics be limited to uses "considered necessary for

---

<sup>77</sup> CARDOVA & KAR, *supra* note 74, at 2.

<sup>78</sup> *Id.*

<sup>79</sup> Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697, 79,700-01 (Dec. 22, 2011).

<sup>80</sup> Brief for Petitioner at 23, Nat. Res. Def. Council, Citizen Petition to Withdraw Approval of the Use of Medically Important Antibiotics in Livestock and Poultry, No. FDA-2016-P-2737 (Food & Drug Admin., 2016), <https://perma.cc/LGM9-AZCP> [hereinafter NRDC Petition] (describing the lawsuit),

<sup>81</sup> *Id.*

<sup>82</sup> *Nat. Res. Def. Council, Inc.*, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012); *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 321 (S.D.N.Y. 2012).

<sup>83</sup> *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 760 F.3d 151, 153 (2d Cir. 2014).

<sup>84</sup> *Id.* 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 n.8; Letter from Lesley Kux, Acting Assistant Comm'r for Policy, Food & Drug Admin., to Sarah Klein, Ctr. for Sci. in the Pub. Interest, at 2 (Nov. 7, 2011), <https://perma.cc/H48Q-374W> (denying the Center for Science in the Public Interest's petition to rescind FDA-approved uses of antibiotics in livestock feed); Letter from Lesley Kux, Acting Assistant Comm'r for Policy, Food & Drug Admin., to Andrew Maguire, Vice President of Env'tl. Health, Env'tl. Def. Fund, at 1 (Nov. 7, 2011), <https://perma.cc/JH4K-ZPQP> (denying the Environmental Defense Fund's petition to withdraw FDA's approval of use of antibiotics in livestock feed). 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 generally Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007 (2013) (reviewing case law and concluding that FDA does not have to hold formal hearings); see also NRDC Petition, *supra* note 80, at 38-39 (acknowledging FDA's authority to withdraw prior approval).

<sup>85</sup> FDA GUIDANCE #209, *supra* note 69, at 3.

assuring animal health.”<sup>86</sup> The second principle was the use of such drugs “should be limited to uses that include veterinary oversight or consultation.”<sup>87</sup> 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.<sup>88</sup>

The agency’s voluntary approach was criticized on several grounds.<sup>89</sup> First, the idea of voluntary compliance appeared to be “somewhat fanciful, if not naïve” in light of decades of almost completely unregulated antibiotic use, intense competition in the agricultural and pharmaceutical industries, and the large financial interest at stake.<sup>90</sup> Second, since 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.<sup>91</sup> 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.<sup>92</sup>

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.<sup>93</sup> It was anticipated that this would be a loophole because veterinarians are less regulated than physicians and have “close ties with or receive financial benefits from the pharmaceutical industry” or are employed by the livestock industry.<sup>94</sup>

In September 2016, NRDC and two other public interest groups filed a petition requesting that FDA withdraw approval of seven antibiotics for

---

<sup>86</sup> *Id.* at 21–22.

<sup>87</sup> *Id.* at 22.

<sup>88</sup> FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #213: NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209, at 7 (2013), <https://perma.cc/C9M8-5RKX>.

<sup>89</sup> See, e.g., Lisa Heinzerling, *The FDA’s Continuing Incapacity on Livestock Antibiotics*, 33 STAN. ENVTL. L.J. 325, 329 (2014) (criticizing FDA’s rules because they rely too much on voluntary action, and the livestock producers have no incentive to take voluntary action; they weaken veterinary oversight; and they reduce public scrutiny while FDA “works things out privately with participating drug companies”).

<sup>90</sup> Susan A. Schneider, *Beyond the Food We Eat: Animal Drugs in Livestock Production*, 25 DUKE ENVTL. L. & POL’Y. F. 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 274. However, when Denmark voluntarily eliminated the use of antibiotics for growth promotion, the entire industry agreed to comply. See *infra* notes 146–148 and accompanying text.

<sup>91</sup> Schneider, *supra* note 90, at 266.

<sup>92</sup> *Id.* at 267.

<sup>93</sup> Heinzerling, *supra* note 89, at 331.

<sup>94</sup> Schneider, *supra* note 90, at 267.

animal use that are important to human health.<sup>95</sup> 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 3% increase in 2014 alone.<sup>96</sup> In December 2016, a later FDA report revealed that antibiotic use had continued to increase.<sup>97</sup>

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.<sup>98</sup> 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.<sup>99</sup> 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.<sup>100</sup> It also requires that a veterinarian only allow the use of these antibiotics for uses allowed on the drug's label.<sup>101</sup> As the reader may recall, FDA asked pharmaceutical companies voluntarily to remove growth promotion from the list of permissible uses on their label.<sup>102</sup> Since the pharmaceutical companies agreed with this request,<sup>103</sup> this second requirement is intended to prevent veterinarians from ignoring this restriction.

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.<sup>104</sup>

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 because 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%–15% of the overall use of veterinary antibiotics.<sup>105</sup> A representative of a pharmaceutical industry trade

---

<sup>95</sup> See NRDC Petition, *supra* note 80, at 3–4 (listing macrolides, lincosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides).

<sup>96</sup> *Id.* at 7 (citing FOOD & DRUG ADMIN., 2014 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 40 (2015), <https://perma.cc/64U4-RKUX>).

<sup>97</sup> FDA 2015 REPORT, *supra* note 11, at 6.

<sup>98</sup> Helen Branswell, *Tightened Rules for Antibiotics in Livestock Go into Effect*, STAT (Jan. 3, 2017), <https://perma.cc/6JWM-J6HR>.

<sup>99</sup> Veterinary Feed Directive; Correction, 80 Fed. Reg. 31,708, 31,708 (June 3, 2015) (codified at 21 C.F.R. pts. 514 and 558).

<sup>100</sup> *Id.* at 31,708, 31,733.

<sup>101</sup> *Id.* at 31,734.

<sup>102</sup> See *supra* notes 85–88 and accompanying text.

<sup>103</sup> FDA Update on Animal Pharmaceutical Industry Response to Guidance #213, FOOD & DRUG ADMIN. (June 11, 2015), <https://perma.cc/ZJ58-G9MP>.

<sup>104</sup> Veterinary Feed Directive; Correction, 80 Fed. Reg. at 31,734.

<sup>105</sup> NRDC Petition, *supra* note 80, at 35.

association, the Animal Health Institute (AHI), agrees with that estimate.<sup>106</sup> 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.<sup>107</sup>

FDA has not yet addressed a loophole in its regulations. Although veterinarians have to restrict the use of antibiotics to the conditions of the 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.<sup>108</sup> Among the defects, many labels do not limit the duration of antibiotic use for disease prevention.<sup>109</sup> The agency has asked for public comments on whether it should restrict the duration of use for disease prevention purposes.<sup>110</sup>

#### 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 to plug gaps in the regulatory system such as this one.<sup>111</sup> 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.<sup>112</sup>

This Part evaluates the potential of a lawsuit by someone who is infected after eating contaminated pork or poultry. 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.

---

<sup>106</sup> Beth Hoffman, *New FDA ‘Rules’ Not Likely to Reduce Antibiotic Use on Farm*, FORBES (Dec. 13, 2013), <https://perma.cc/VDA3-QLF6>.

<sup>107</sup> ANIMAL HEALTH INST., Q&A: FINAL GUIDANCE 213 AND VFD 1 (2013), <https://perma.cc/59LK-XJFU>.

<sup>108</sup> *Judicious Animal Antibiotic Use Requires Drug Label Refinements*, PEW CHARITABLE TR. (Oct. 4, 2016), <https://perma.cc/33Y5-6AWN>.

<sup>109</sup> *See FDA Seeks Public Input on Next Steps to Help Ensure Judicious Use of Antimicrobials in Animal Agriculture*, FOOD & DRUG ADMIN. (Nov. 28, 2016), <https://perma.cc/F76P-3SX5> (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”).

<sup>110</sup> *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Establishing Appropriate Durations of Therapeutic Administration; Request for Comments*, 81 Fed. Reg. 63,187 (Sept. 14, 2016).

<sup>111</sup> *See supra* note 2 and accompanying text.

<sup>112</sup> *See supra* note 54 and accompanying text.

The law concerning product liability is complex and varies from state to state. The following, therefore, is intended to provide a general description of the standards of liability for defective products and its potential use by a consumer who became ill after eating pork or poultry contaminated with antibiotic-resistant bacteria.

To analyze the potential of a product liability lawsuit, this Part first considers the legal standards of liability for defective products and whether a meat product contaminated with an antibiotic-resistant infection is defective according to these standards. It next evaluates whether such a plaintiff can prove the contaminated pork or poultry resulted in his or her illness.

### *A. Legal Standards of Liability*

There is a duty at common law not to sell defective products to consumers.<sup>113</sup> An actionable defect can result from a manufacturer defect (a flaw during the production process) or a design defect (an aspect of the design of the product).<sup>114</sup> It might be difficult to distinguish between these two types of defects when it comes to defective food products because, until there is discovery in a lawsuit, it can be unclear whether the plaintiff's harm is an unanticipated adulteration or is an inherent aspect of the product.<sup>115</sup>

#### *1. Manufacturing Defect*

A product contains a manufacturing defect when it "departs from its intended design even though all possible care was exercised in the preparation and marketing of the product."<sup>116</sup> If, for example, a glass bottle of soda explodes when it is being opened, there is a manufacturing defect if the weakness in the bottle was a departure from the product's intended design.<sup>117</sup> As explained earlier, slaughterhouses process animals at such high speeds that feces from the animals, which contain the drug-resistant bacteria, can contaminate pork and poultry products.<sup>118</sup> If the integrator meant to prevent this contamination, the presence of antibiotic-resistant bacteria on a meat product would be a departure from the product's design. That is, it would be a manufacturing defect.

The courts will use a consumer expectation test to determine if an integrator is liable for this manufacturing defect. In the case of food, a "harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the food product to contain that

---

<sup>113</sup> RESTATEMENT (SECOND) OF TORTS: LIAB. OF PERS. SUPPLYING CHATTELS FOR THE USE OF OTHERS § 402 (AM. LAW INST. 1965).

<sup>114</sup> *Id.* § 402 cmt. d.

<sup>115</sup> *Id.* § 7 cmt. b.

<sup>116</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(a) (AM. LAW INST. 1998).

<sup>117</sup> *Id.* § 2 cmt. c, illus. 1.

<sup>118</sup> *See supra* note 19 and accompanying text.



ingredient.”<sup>119</sup> It is unclear whether a reasonable consumer would expect poultry or pork to contain antibiotic-resistant bacteria. An integrator would likely argue that consumers know that pork and poultry products may contain bacteria and that they should take appropriate precautions, which would include proper cooking techniques and ensuring that no bacteria are left on work surfaces or cooking utensils.<sup>120</sup> Even if the risk of contamination is well known, it is not evident that the consumer would expect the failure to properly handle a meat product would lead to a disease that cannot be readily cured by antibiotics instead of temporary food poisoning.

## 2. Design Defect

If poultry or pork contaminated with antibiotic-resistant bacteria is not a departure from the intended design of a meat product, the contamination would constitute a design defect. The farmer who raised the pigs or poultry administered the antibiotics to the animals, but the integrator who hired the farmer to raise the animals appears to be responsible for the design of the product. To understand the integrator’s potential liability for a design defect, it is necessary to know that pork and poultry are raised in this country under different arrangements.<sup>121</sup>

If the pork or poultry process is fully integrated, one company is responsible for raising and processing the pork or chickens.<sup>122</sup> If the plaintiff becomes ill after eating pork or chicken raised by a fully integrated company, the company is obviously in charge of the product during all phases of the food production process. Alternatively, an integrator can contract with a farmer to raise the pigs or poultry. In this second arrangement, the integrator owns the animals and specifies how the producer is to raise them.<sup>123</sup> If the integrator requires the farmer to administer antibiotics to prevent diseases from spreading among the animals, a plaintiff can argue that the integrator, not the farmer, has designed the product.<sup>124</sup>

Integrators that use this second arrangement insist that the farmer is an independent contractor.<sup>125</sup> Thus, a court would have to determine whether

---

<sup>119</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 7.

<sup>120</sup> *See id.* § 7 cmt. b (“A consumer expectation test relies upon culturally defined, widely shared standards that food products ought to meet.”).

<sup>121</sup> *See generally* JAN L. FLORA ET AL., THE IOWA POLICY PROJECT, HOG CAFOS AND SUSTAINABILITY THE IMPACT ON LOCAL DEVELOPMENT AND WATER QUALITY IN IOWA (2007), <https://perma.cc/TN8Y-ZTUN>.

<sup>122</sup> *Id.* at 3.

<sup>123</sup> *Id.*; KARLA A. RAETTIG, NAT’L COMM’N ON INDUS. FARM ANIMAL PROD., IMPROVEMENTS NEEDED IN PERMITTING CAFOS UNDER THE CLEAN WATER ACT 8 (2007), <https://perma.cc/V7BD-5V8X>.

<sup>124</sup> *See, e.g.*, NEIL D. HAMILTON, FARMER’S LEGAL GUIDE TO PRODUCTION CONTRACTS 103 (1995) (providing that a Con-Agra (integrator) contract with producer (farmer) indicates Con-Agra will supply all medication to be used for raising pigs).

<sup>125</sup> *See generally* Glenn A. Hegar Jr., *Adhesion Contracts, Debt, Low Returns and Frustration—Can America’s Independent Contract Farmer Overcome the Odds?*, 22 HAMLIN L.

the use of antibiotics was required as part of the contractual arrangements between the integrator and the farmer.<sup>126</sup> A court should therefore allow a plaintiff to use discovery to reveal the exact nature of the contractual arrangements. If the farmer had no choice but to administer the antibiotics as specified by the integrator, it can hardly be said that it was the farmer who was responsible for the design of the product.

If the integrator is responsible for the design of the product—the administration of the antibiotics that caused the growth of antibiotic-resistant bacteria in the animals—the integrator’s liability depends on which of three tests a state uses for design defects. States use a consumer expectation test, a risk-utility test, or a blend of the two approaches.

#### *a. Consumer Expectation Test*

The *Restatement (Second) of Torts* § 402A(1) recommends a seller is liable for selling a defective product if it is “unreasonably dangerous” to the user or consumer.<sup>127</sup> 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.”<sup>128</sup> Put another way, a product is defective “whenever it fails in a way that disappoints secure and reasonable expectations about product performance.”<sup>129</sup>

An integrator 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. Sturm, Ruger & Co.* In *Halliday*, the defendant gun manufacturer was held not liable for the death of a child from a self-inflicted gunshot 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.<sup>130</sup> 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.<sup>131</sup>

The defendant would contend that the plaintiff’s illness resulted from the plaintiff’s misuse of the product—the meat the consumer ate—because

---

REV. 213, 217 (1998) (discussing whether producers are independent contractors or employees of the integrator under common law).

<sup>126</sup> See *id.* (“Neither a single homogenous definition, nor a ‘bright-line’ test, exists for determining whether a grower is an employee or an independent contractor. . . . At common law the ‘right to control’ test is used to classify whether a grower is an employee or an independent contractor.”).

<sup>127</sup> RESTATEMENT (SECOND) OF TORTS: SPECIAL LIAB. OF SELLER OF PROD. FOR PHYSICAL HARM TO USER OR CONSUMER § 402A(1) (AM. LAW INST. 1965).

<sup>128</sup> *Halliday v. Sturm, Ruger & Co., Inc.*, 792 A.2d 1145, 1150 (Md. 2002).

<sup>129</sup> Gregory C. Keating, *Products Liability as Enterprise Liability* 9 (Univ. S. Cal. Gould Sch. of Law Legal Studies Research Paper, Series No. 16–38, 2016), <https://perma.cc/SDF3-7CV4>.

<sup>130</sup> *Halliday*, 792 A.2d at 1146–47.

<sup>131</sup> *Id.* at 1158.

the safe handling and cooking of meat is essential to the 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.<sup>132</sup> An integrator that processes antibiotic-fed animals 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 properly handle a meat product would lead to a disease that cannot be readily cured by antibiotics.

An integrator could also defend a lawsuit on the grounds that the consumer was adequately warned to cook the meat properly because of the risk of illness. A manufacturer can discharge its duty to make a product non-defective by warning of the product's risks—the product is unreasonably dangerous without a warning but is reasonably safe with a warning.<sup>133</sup> 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.<sup>134</sup>

In *Cotton v. Buckeye Gas Products Co.*,<sup>135</sup> for example, the court held that the manufacturer of gas holding canisters was not liable when the plaintiff left one of the canisters too close to a propane heater, and the canister exploded because some gas fumes were retained in the canister after it was emptied.<sup>136</sup> The defendant avoided liability because it had adequately warned consumers about this risk.<sup>137</sup> The product was not defective—even though it contained residual gas fumes—if 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 time [the seller] manufactured or distributed the product.”<sup>138</sup> Thus, merely warning the consumer that he or she might become ill if the meat product is not properly handled arguably is not sufficient.

---

<sup>132</sup> *Lightolier v. Hoon*, 876 A.2d 100, 109 (Md. 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.” (emphasis added) (citing *Ellsworth v. Sherne Lingerie, Inc.*, 495 A.2d 348, 355 (Md. 1985))).

<sup>133</sup> *Keating*, *supra* note 129, at 34.

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

<sup>135</sup> 840 F.2d 935 (D.C. Cir. 1988).

<sup>136</sup> *Id.* at 940.

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

<sup>138</sup> *Carlin v. Superior Court (Upjohn Co.)*, 920 P.2d 1347, 1348 (Cal. 1996).

Consider, for example, *McDonald v. Ortho Pharmaceutical*,<sup>139</sup> where the court held that a warning that a medication could cause an abnormal and potentially fatal blood clot was not sufficient for the company to avoid liability when a consumer suffered a disabling stroke after taking the medication.<sup>140</sup> The court upheld a jury verdict for the plaintiff because the jury could have reasonably concluded that the warning was insufficient because it did not mention heart attack or stroke, which were more “urgent” terms.<sup>141</sup>

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 accidentally 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.

### *b. Risk-Utility Test*

Under the *Restatement (Third) of Torts*, 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.”<sup>142</sup> Thus, unlike the previous consumer expectation inquiry, it is not sufficient or necessary for the plaintiff to establish that the risk of harm created by the product was unexpected.<sup>143</sup>

To determine whether an alternative design is “reasonable,” a court will balance the advantages and disadvantages of the alternative design.<sup>144</sup> This evaluation employs a number of criteria including:

---

<sup>139</sup> 475 N.E.2d 65 (Mass. 1985).

<sup>140</sup> *Id.* at 71–72.

<sup>141</sup> *Id.*

“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 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.”

*Id.* at 71 (quoting *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 837 (Ohio 1981)).

<sup>142</sup> RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (AM. LAW INST. 1998).

<sup>143</sup> *See id.* cmt. g. (“[C]onsumer expectations do not constitute an independent standard for judging the defectiveness of product designs.”); *see, e.g.*, *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F.3d 730, 742 (W.D. Ky. 2014) (requiring “proof of an alternative, safer design that is practicable under the circumstances” in negligent design case) (citing *McCoy v. Gen. Motors Corp.*, 47 F. Supp. 2d 838, 840 (E.D. Ky. 1998)); *Hillrichs v. Avco Corp.*, 478 N.W.2d 70, 75 (Iowa 1991) (requiring “proof of an alternative safer design” under a theory of enhanced injury caused by a design defect) (citing *Wernimont v. Int’l Harvester Corp.*, 309 N.W.2d 137, 140–41 (Iowa Ct. App. 1981)).

<sup>144</sup> *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673–74 (Ga. 1994) (“[W]e conclude that the better approach is to evaluate design defectiveness under a test balancing the risks inherent in a

the likelihood that [the existing design] will cause injury, and the probable seriousness of the injury; [t]he availability of a substitute product that would meet the same need and not be as unsafe; [and t]he manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.<sup>145</sup>

In an antibiotics case, the plaintiff may be able to marshal sufficient evidence that a safe replacement was available and affordable. In 1998, for example, 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.<sup>146</sup> Further, the country reduced its overall use of antibiotics in livestock by 60% by establishing a comprehensive monitoring system and limiting the amount of money veterinarians were able to earn selling antibiotics.<sup>147</sup> Far from crippling pork production, production rose by 50%.<sup>148</sup>

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 that 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.”<sup>149</sup>

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

---

product design against the utility of the product so designed.”); *see also* Calles v. Scripto-Tokai Corp., 864 N.E.2d 249, 257 (Ill. 2007) (applying the risk-utility analysis in a strict liability design-defect case).

<sup>145</sup> Calles, 864 N.E.2d at 260 (numbering and punctuation omitted or replaced) (quoting John W. Wade, *On The Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837–38 (1973)). The other factors are:

“[t]he usefulness and desirability of the product—its utility to the user and to the public as a whole; . . . [t]he user's ability to avoid danger by the exercise of care in the use of the product; [t]he 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 t]he ability of the manufacturer to spread the loss by setting the price of the product or carrying liability insurance.”

*Id.* at 260–61 (numbering and punctuation omitted or replaced) (quoting Wade, *supra*, at 837–38).

<sup>146</sup> Editorial, *Pig Out: If Farmers Do Not Rein in the Use of Antibiotics for Livestock, People Will Be Severely Affected*, 486 NATURE 440, 440 (2012).

<sup>147</sup> *Id.*

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

<sup>149</sup> Henkel v. R & S Bottling Co., 323 N.W.2d 185, 191 (Iowa 1982) (citations omitted) (quoting Hughes v. Magic Chef, Inc., 288 N.W.2d 542, 546 (Iowa 1980)).

pathogen.<sup>150</sup> A court might be (and should be) reluctant to shift the burden of prevention to a consumer unless the consumer actually understood 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.

*c. Hybrid Test*

The courts in other states follow a hybrid legal standard that employs a version of both of the first two legal standards.<sup>151</sup> In *Barker v. Lull Engineering Co., Inc.*,<sup>152</sup> for example, the plaintiff sued both his employer and the manufacturer of the high-lift loader that injured the plaintiff employee while he was operating the loader.<sup>153</sup> 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.<sup>154</sup> If a "consumer would not know what to expect, because he would have no idea how safe the product could be made," a court would employ a risk-utility test.<sup>155</sup> Once the plaintiff establishes that he or she was harmed by a defect in the product, however, this version shifts the burden of proving an alternative design to the defendant.<sup>156</sup>

The potential outcome in a lawsuit involving antibiotic-resistant bacteria using an unreasonably dangerous or risk-utility test was discussed earlier.<sup>157</sup> A plaintiff suing in a hybrid jurisdiction, however, has a less demanding burden of proof. In terms of consumer expectation, the plaintiff need only establish that a product is defective, and not that it is unreasonably dangerous as required by the *Restatement (Second) of Torts* § 402A.<sup>158</sup> Moreover, since the defendant and not the plaintiff must prove the product's utility exceeds its risks, this risk-utility test is less demanding for a plaintiff than the version recommended in the *Restatement (Third) of Torts*.

---

<sup>150</sup> See *supra* notes 130–131 and accompanying text.

<sup>151</sup> See Keating, *supra* note 129, at 31 n.107 ("Many states have cited *Barker* and adopted its products liability regime (courts in at least 8 states have cited and followed *Barker*)."); see *infra* notes 152–156 and accompanying text (discussing *Barker v. Lull Eng'g Co., Inc.*, 573 P.2d 443 (Cal. 1978)).

<sup>152</sup> 573 P.2d 443 (Cal. 1978).

<sup>153</sup> *Id.* at 445, 447.

<sup>154</sup> *Id.* at 455. 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 455–56.

<sup>155</sup> *Id.* at 454 (quoting Wade, *supra* note 145, at 829).

<sup>156</sup> *Id.* at 456.

<sup>157</sup> See *supra* Part V.A.2.a (discussing the consumer expectation/unreasonably dangerous test); *supra* Part V.A.2.b (discussing the risk-utility test).

<sup>158</sup> See, e.g., *Barker*, 573 P.2d at 455–56 (explaining that a plaintiff may satisfy the defectiveness of product design by establishing that the product proximately caused his injury—not that "[the] product is more dangerous than contemplated by the average consumer"—when he used the product in an intended or a reasonable manner).

*B. Causation*

Whichever standard of liability is applied, the plaintiff must prove that he or she was exposed to a contaminated meat product sold by an integrator and became ill as a result of that exposure. This means a plaintiff must prove both general and specific causation using expert testimony.<sup>159</sup>

As a matter of general causation, the plaintiff must prove by a preponderance of the evidence that the use of antibiotics in chicken and hog production increases the risk of human infections from antibiotic-resistant pathogens.<sup>160</sup> 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.<sup>161</sup> 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 products “make it challenging to perform controlled studies that provide unequivocal evidence for a direct link between antibiotic use in animals and the emergence of antibiotic resistance in food-borne bacteria associated with human disease.”<sup>162</sup>

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.<sup>163</sup>

A plaintiff can attempt to meet this burden of proof in two ways. First, a plaintiff could establish that the pathogen that infected him or her had the same biological identity found in the animals at the specific CAFO that raised the contaminated meat the plaintiff ate. There are studies linking a specific antibiotic-resistant pathogen to existence of the same specific pathogen at the CAFO from which the food product came.<sup>164</sup> But, this

---

<sup>159</sup> Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 899 (2004).

<sup>160</sup> RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 28 cmt. c(3) (AM. LAW INST. 2010).

<sup>161</sup> *Id.*

<sup>162</sup> Bonnie M. Marshall & Stuart B. Levy, *Food Animals and Antimicrobials: Impacts on Human Health*, 24 CLINICAL MICROBIOLOGY REVS. 718, 726 (2011).

<sup>163</sup> RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 28 cmt. c(4).

<sup>164</sup> See, e.g., Janice Bates et al., *Farm Animals as a Putative Reservoir for Vancomycin-Resistant Enterococcal Infection in Man*, 34 J. ANTIMICROBIAL CHEMOTHERAPY 507, 509 (1994) (discussing a study that isolated vancomycin-resistant *E. faecium* from farm animals in a feedlot); see also Gregg S. Davis et al., *Intermingled Klebsiella pneumoniae Populations Between Retail Meats and Human Urinary Tract Infections*, 61 CLINICAL INFECTIOUS DISEASES 892, 894–95 (2015) (demonstrating that *K. pneumoniae* isolated from retail meat samples are genetically closely related to *K. pneumoniae* isolated from human patients); Antonio R. 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*

research has been hampered by the fact that CAFO operators commonly 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.

If the plaintiff cannot identify such a “signature” pathogen, he or she could 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.<sup>165</sup> Whether or not this evidence is sufficient, however, depends on the strength of the evidence. If the evidence on general causation reveals, for example, that persons exposed to antibiotic-resistant bacteria in pork or poultry are three times more likely to become ill from this bacteria than people who were not exposed to contaminated meat, there is an inference that the bacteria that caused the plaintiff’s illness was a result of eating the meat product. 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 plaintiff’s individual characteristics render him or her more or less susceptible to the disease than the exposed populations in the relevant scientific studies.<sup>166</sup>

## VI. 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 than 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.

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

---

PATHOGENS & DISEASE 1295, 1295 (2011) (finding that “[r]esistance in *E. coli* isolates from food animals . . . was highly correlated with resistance in isolates from 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”).

<sup>165</sup> See *supra* note 164 and accompanying text.

<sup>166</sup> See RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 28 cmt. c(4).



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.