



## Contagion Without Relief: Democratic Experimentalism and Regulating the Use of Antibiotics in Food-Producing Animals

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### ABSTRACT

We are progressing toward a post-antibiotic world: Antibiotic drugs that could once treat basic infections are losing their effectiveness at an accelerating rate. If this trend continues, common illnesses will become potentially deadly, and more complex procedures—chemotherapy, surgeries, dialysis—will carry much more significant risk. The modern industrial agricultural system may have contributed significantly to this state of affairs. The vast majority of antibiotics sold in the United States each year—an estimated 70 to 80 percent—are for use in animal agriculture. These antibiotics are primarily administered to food-producing animals at routine, low doses as a cheap method of promoting faster growth and preventing disease in crowded, unsanitary conditions. These subtherapeutic doses, however, are also the most conducive to breeding antibiotic-resistant bacteria. The resistant bacteria bred in animals are then transferred to humans through a variety of mechanisms and reduce the efficacy of antibiotic drugs. In order to address the increasing problem of antibiotic resistance in humans, it is crucial to reduce the subtherapeutic use of antibiotics in food-producing animals. How to efficiently and cost effectively reduce their use, however, remains unclear, and is not a problem traditional command-and-control legislation can solve.

Democratic experimentalist theory offers a compelling framework for addressing this problem. Under the traditional democratic experimentalist model, a central institution sets a common goal and then delegates authority to local institutions to experiment to achieve that goal. Local institutions then provide data on their performance to the central institution to pool, assess, and re-benchmark. The federal government has identified the importance of reducing antibiotic use in livestock, but beyond articulating this goal, has failed to act thus far. In its place, California has become the first state to pass a law banning the subtherapeutic use of antibiotics in food-producing animals. This legislation is an exemplar of state action with the potential to improve the food system and public health both locally and in other states, and it could do so effectively using a new, layered iteration of democratic experimentalism.

The California law is, however, subject to legal challenge under federal preemption grounds. This Article analyzes these grounds and concludes that the law may survive such a challenge because it furthers federal objectives in a number of ways and is supported by California's compelling interest in protecting the health and safety of its citizens. The Article further contends that democratic experimentalist theory also bolsters the argument against federal preemption here and more generally when addressing these


types of knowledge-intensive, scientifically uncertain policy areas where experimentation is key to problem-solving and especially where there is a threat to public health. As the only state action in this critical area, ensuring the experimentalist implementation of the California law and securing its fate against preemption are crucial to addressing the threat to public health posed by antibiotic resistance.

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## TABLE OF CONTENTS

INTRODUCTION.....	553
I. THE RISE OF ANTIBIOTIC RESISTANCE .....	557
A. Background on Antibiotics and Their Introduction	
Into Agriculture.....	557
B. The Rise and Threat of Antibiotic Resistance .....	559
1. The Link Between Agricultural Use and Resistance	
in Humans.....	562
II. DEMOCRATIC EXPERIMENTALISM .....	567
A. Introduction to Democratic Experimentalism .....	567
B. Democratic Experimentalism And Antibiotics.....	569
III. FEDERAL AND STATE ACTION IN ANTIBIOTICS REGULATION .....	570
A. History of Federal Regulation in Antibiotics .....	570
1. FDA and Judicial Action.....	570
2. Executive and Congressional (In)Action .....	576
B. State Action and the California Antibiotics Law .....	578
IV. DEMOCRATIC EXPERIMENTALISM AND CURRENT ANTIBIOTICS	
REGIMES.....	579
A. The Emergence of Layered Democratic Experimentalism .....	579
B. Challenges in Applying Democratic Experimentalism.....	583
V. FEDERAL PREEMPTION AND DEMOCRATIC EXPERIMENTALISM .....	585
A. Brief Overview of Preemption .....	586
1. Express Preemption.....	586
2. Implied Preemption.....	588
B. Democratic Experimentalist-Informed Preemption Doctrine .....	593
C. Lessons for States .....	596



1. The Ex Ante Process and the Role of Popular Opinion and Scientific Evidence .....	596
2. Substantive Law Writing .....	598
CONCLUSION .....	599

## INTRODUCTION

Antibiotics, also known as antimicrobials,<sup>1</sup> are critical to modern medicine. However, these drugs are losing their effectiveness at an accelerating rate.<sup>2</sup> If this trend continues unabated, we will lose the ability to treat even the most basic infections as we rapidly progress toward a post-antibiotic world. Common, everyday illnesses will become potentially deadly, and more complex procedures—chemotherapy, surgeries, dialysis—will carry untenable risk. This phenomenon has already placed serious burdens on our healthcare system and economy, and future forecasts are even more alarming.

How did we reach this state of affairs? The modern industrial agricultural system may have contributed significantly. The vast majority of antibiotics sold in the United States each year—an estimated 70 to 80 percent—are for use in animal agriculture.<sup>3</sup> Although the presence of some antibiotic resistance is scientifically inevitable, the overuse and misuse of antibiotics accelerates the prevalence of these resistant bacteria. The antibiotics are primarily administered to food-producing animals at routine, low doses as a cheap method of promoting faster growth and preventing disease in crowded, unsanitary conditions. Incidentally, however, these subtherapeutic doses of antibiotics are the most conducive to breeding antibiotic-resistant bacteria. The resistant bacteria bred in animals then get transferred to humans through various mechanisms, which reduces the efficacy of antibiotic drugs in humans. This serious threat has been well recognized for decades—both by the medical community and the federal government.<sup>4</sup> In order

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1. This Article uses the terms “antibiotic” and “antimicrobial” synonymously, though by strict definition the two are not identical. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics.
  2. CDC, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 11 (2013), <http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf> [https://perma.cc/2WKR-SPZ6] [hereinafter ANTIBIOTIC RESISTANCE THREATS IN THE US].
  3. Joan A. Casey et al., *High-Density Livestock Operations, Crop Field Application of Manure, and Risk of Community-Associated Methicillin-Resistant Staphylococcus Aureus Infection in Pennsylvania*, 173 JAMA INTERNAL MED. 1980, 1980 (2013), <http://archinte.jamanetwork.com/article.aspx?articleid=1738717> [https://perma.cc/Y5UF-TL43]; Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1010–12 (2013); JOHNS HOPKINS CTR. FOR A LIVABLE FUTURE, INDUSTRIAL FOOD ANIMAL PRODUCTION IN AMERICA: EXAMINING THE IMPACT OF THE PEW COMMISSION'S PRIORITY RECOMMENDATIONS 2 (2013), [http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/\\_pdf/research/clf\\_reports/CLF-PEW-for%20Web.pdf](http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/_pdf/research/clf_reports/CLF-PEW-for%20Web.pdf) [https://perma.cc/ST97-JHH2] [hereinafter INDUSTRIAL FOOD ANIMAL PRODUCTION].
  4. See FDA, REPORT TO THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION BY THE FDA TASK FORCE IN THE USE OF ANTIBIOTICS IN ANIMAL FEEDS 3, 10 (1972), <http://hdl.handle.net/2027/coo.31924051104002> [https://perma.cc/6VZG-RLQ2].

to address the increasing problem of antibiotic resistance in humans, it is crucial to reduce the subtherapeutic use of antibiotics in food-producing animals.

Resistant strains continue to multiply, with two million illnesses and 23,000 deaths each year attributed to antibiotic-resistant infections.<sup>5</sup> Even so, and despite recognizing the threat, the federal government has been slow to act, and the action that it has taken has been ineffectual. For nearly forty years, the U.S. Food and Drug Administration (FDA) has failed to follow through on its 1970s threat to withdraw approval for subtherapeutic use of antibiotics.<sup>6</sup> For fifteen years, federal legislation that would prohibit the subtherapeutic use of antibiotics has languished in Congress.<sup>7</sup>

Some states have attempted to address the problem with their own legislation. To date, only one has succeeded. In October 2015, California passed the first and only state law prohibiting the subtherapeutic use of antibiotics in food-producing animals, both for growth promotion and disease prevention purposes.<sup>8</sup> The law, which will take effect in January 2018, represents an important step forward in the effort to reduce the problematic use of antibiotics.<sup>9</sup> In addition to banning both subtherapeutic uses of antibiotics, the California law also requires, for the first time, data collection on antibiotic use in livestock.<sup>10</sup> The FDA currently does not track the use of antibiotics in livestock or require any data collection, making it difficult to fully understand the extent of the threat of the agricultural use of antibiotics.<sup>11</sup> Scientists' uncertainty over the extent to which

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5. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 11 (“Each year in the United States, at least 2 million people acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections. At least 23,000 people die each year as a direct result of these antibiotic-resistant infections. Many more die from other conditions that were complicated by an antibiotic-resistant infection.”).

6. Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (Apr. 20, 1973) (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15 (2013)); Penicillin-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. at 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 56,264 (Oct. 21, 1977); Penicillin and Tetracycline in Animal Feeds, Notice of Hearing, 43 Fed. Reg. 53,827–28 (Nov. 17, 1978). See generally Diana R.H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA*, 90 IND. L.J. 1047 (2015).

7. Preservation of Antibiotics for Medical Treatment Act of 2015, H.R. 1552, 114th Cong. (2015), <https://www.govtrack.us/congress/bills/114/hr1552/text> [<https://perma.cc/ZQ3J-TZ4A>].

8. S.B. 27 Livestock: Use of Antimicrobial Drugs (Cal. 2015), [http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\\_id=201520160SB27](http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB27) [<https://perma.cc/X92W-R5RW>].

9. *Id.*

10. *Id.*

11. Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013, Pub. L. No. 113–14, 127 Stat. 451 (2013). See generally Qiuzhi Chang et al., *Antibiotics in Agriculture and the Risk to Human Health: How Worried Should We Be?*, 8 EVOLUTIONARY APPLICATIONS 240 (2015) (showing the lack of measures requiring data collection or tracking antibiotic use by the FDA).

agricultural antibiotic use accelerates human antibiotic resistance is due in large part to a lack of data. The data collection requirement in the California law aims to fill this large information gap and will help scientists, and ultimately policymakers, better understand the effects of agricultural antibiotic use on antibiotic resistance in humans.

Because this lack of data obscures how to efficiently and effectively reduce the overuse of antibiotics in livestock, this problem is not one for traditional command-and-control legislation to solve. Command-and-control legislation is direct regulation that clearly states what is and is not legal. Because this type of legislation makes unequivocal prescriptions, it functions well when it is clear how to solve a problem legislatively, but does not in cases like this where the right legislative answer is uncertain. Democratic experimentalist theory, however, offers a compelling framework for addressing this problem. Under the traditional democratic experimentalist model, a central institution sets a common goal and then delegates authority to experiment to achieve that goal to local institutions, which provide data on their performance to the central institution to pool and compare. The central institution assesses local performances and re-benchmarks new goals accordingly.

The federal government has identified the importance of reducing antibiotic use in livestock, but beyond this centralized goal setting, has failed to act. With the federal government having thus far neglected to address the problem of antibiotic resistance in agriculture, this Article proposes that states are uniquely positioned to fill the void in information and to provide potential solutions. California, for example, should implement its law to delegate authority to production firms to experiment with the best mechanisms to efficiently reduce antibiotic use in livestock. It should do so by collecting robust data from these firms on their approaches, pooling and comparing that data, and then benchmarking firms to improve the worst performers, and perhaps reward the best performers. What would then emerge is a new iteration of democratic experimentalism—what I term layered democratic experimentalism—that could offer great promise as a hybrid public-private mechanism for policymaking and problem-solving. In this layered democratic experimentalist approach, the federal government identifies a goal, and state governments enact an initial benchmark, serve as data collectors and poolers, and delegate authority to local firms to experiment to achieve the overarching goal. As more states enact antibiotics laws, there can also be state-level comparisons of best legislative practices to reduce antibiotic use in agriculture.

If implemented strategically and robustly and under this layered democratic experimentalist framework, California's law has groundbreaking potential. In

particular, if California effectively implements its data collection requirements, the state would become an epicenter for determining the leading mechanisms to reduce the use of antibiotics in livestock, leading the nation in this scientific and business management inquiry and also testing the contours and effectiveness of layered democratic experimentalism. California's potential to be a trailblazer in this area is particularly important given that California is a large and influential state and also a significant producer of meat.<sup>12</sup> California has the most agriculture sales of any state, accounting for nearly 11 percent of the U.S. total and has the third largest livestock industry in the country.<sup>13</sup> California has a unique opportunity to lead the way with groundbreaking experimentation, but it can only do so if the data collection component of the law is implemented well. Ensuring strategic and robust data collection will be critical to the law's success in problem-solving this threat to public health.

Although the arguments against preemption are strong, the California law may face legal challenge on preemption grounds. Because the federal and state governments have concurrent and often overlapping authority in food legislation, where federal authority ends and state authority begins is often a hazy line.<sup>14</sup> Although a state has the power to legislate to protect the health and safety of its citizens, it can only do so to the extent the state law does not conflict with federal law, whether directly or indirectly.<sup>15</sup> It is also often unclear when certain actions by the federal government, including the FDA, constitute "federal law" for the purposes of preemption.<sup>16</sup> The California law should survive a preemption challenge despite deliberately exceeding the federal scheme because it furthers federal objectives in a number of ways and is supported by California's compelling interest in protecting the health and safety of its citizens, but a court could plausibly find either way on this issue. This Article argues that democratic experimentalism can, however, bolster the argument against preemption.

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12. CAL. DEPT. OF FOOD & AGRIC., CALIFORNIA AGRICULTURE STATISTICS REVIEW, 88–98 (2015), <https://www.cdfa.ca.gov/statistics/PDFs/2015Report.pdf> [<https://perma.cc/A7FZ-8ADS>].

13. USDA, *2012 Census Highlights*, CENSUS OF AGRIC. (May 2014), [http://www.agcensus.usda.gov/Publications/2012/Online\\_Resources/Highlights/Farm\\_Economics](http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Farm_Economics) [<https://perma.cc/8WA7-UBHA>].

14. For example, the federal government has exclusive authority in food labeling, though states may have some authority to legislate in this area as well, as indicated by the controversy generated by the Vermont Genetically Modified Organism (GMO) labeling law. *See* 21 U.S.C. § 343-1 (2012); 9 VT. STAT. ANN. § 3043 (2016); Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN. ST. L. REV. 789, 790–91 (2014).

15. *See* *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

16. *See* *Wyeth v. Levine*, 555 U.S. 555, 576 (2009); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 244 (3d Cir. 2008).

Democratic experimentalism should inform preemption doctrine when the policy area at hand is knowledge-intensive and involves scientific uncertainty, where experimentation is key to problem-solving, and especially where there is a threat to public health. Animated by the potential fruits of experimentalism, preemption doctrine in this context should evolve to favor the democratic experimentalist approach.

As the only state action in this critical area, ensuring the experimentalist implementation of the California law and securing its fate against preemption are crucial to addressing the threat that overuse of antibiotics poses to public health. A democratic experimentalist-infused preemption doctrine thus becomes critical to public health and safety. How the law is implemented, particularly from a data collection perspective, and whether it is preempted could significantly impact the advancement of scientific knowledge in this area and the state of human health in the decades to come. It could also have considerable effects on states' abilities to address the critical problem of antibiotic resistance in humans and other similar issues as they emerge. Finally, the successes or failures of the California law can help provide practical guidance to other states on best practices in legislating in this area.

Part I of this paper provides background on the history of antibiotics and elucidates the threat of antibiotic resistance. Part II introduces democratic experimentalism and presents it as a theoretical lens to inform the problem-solving process for reducing the overuse of antibiotics in food-producing animals. Part III gives the history of federal regulation in this area and outlines the new California antibiotics law. Part IV situates the federal and state regimes within the democratic experimentalist framework. Part V analyzes federal preemption as it applies to the California antibiotics law, concluding that the law should not be preempted. I conclude by arguing that democratic experimentalism should inform preemption doctrine in contexts that involve knowledge-intensive and scientifically uncertain policy areas. Finally, I suggest some lessons states can learn from the California law's implementation.

## I. THE RISE OF ANTIBIOTIC RESISTANCE

### A. Background on Antibiotics and Their Introduction Into Agriculture

The advent of antibiotic drugs was a miracle of modern medicine, enabling doctors to cure once deadly infections in a matter of days.<sup>17</sup> Lifesaving medical

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17. See, e.g., Stuart B. Levy, *The Challenge of Antibiotic Resistance*, SCI. AM. Mar. 1998, at 46, [http://www.micro.utexas.edu/courses/kalthoff/bio346/PDF/Readings/08Levy%20\(1998\).pdf](http://www.micro.utexas.edu/courses/kalthoff/bio346/PDF/Readings/08Levy%20(1998).pdf) [<https://perma.cc/GTD6-GYCZ>] ("Ever since antibiotics became widely available in the 1940s,



procedures that are now commonplace, including surgery, chemotherapy, transplants, and kidney dialysis, are successful because of the existence of effective antibiotic drugs that combat the risk of infection inherent to these procedures.<sup>18</sup> Antibiotic drugs cure illness, alleviate suffering, and allow humans to live longer and healthier lives.

The profound effects of antibiotic drugs extend beyond humans to animal agriculture as well.<sup>19</sup> Today, an estimated 70 to 80 percent of all antibiotic drugs in the United States each year are sold and distributed for use in animal agriculture.<sup>20</sup> In addition to treating specific instances of bacterial infection, antibiotic drugs are more commonly administered in low, subtherapeutic doses in animal feed and water for two purposes: production—that is, to promote growth and feed efficiency—and disease prevention.<sup>21</sup> In the late 1940s, pharmaceutical waste was used as a protein source in animal feeds, and farmers soon noticed that these additions appeared to enhance growth rates without a corresponding increase in feed consumption.<sup>22</sup> Investigation of this phenomenon revealed that the antibiotic drugs were responsible for the growth promotion and increased feed efficiency, leading to the widespread use of low doses of antibiotic drugs in animal feed.<sup>23</sup> In addition, as modern industrial agriculture developed, producers substantially increased the concentration of animals in their facilities to increase profit margins; correspondingly, the sanitary conditions of these farms declined.<sup>24</sup> The extreme crowding and lack of sanitation that characterize industrial farming created conditions that put animals at increased risk—indeed, unnatural risk—of infection.<sup>25</sup> To enable these production conditions, producers

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they have been hailed as miracle drugs—magic bullets able to eliminate bacteria without doing much harm to the cells of treated individuals.”)

18. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 24.
19. See, e.g., Jay P. Graham et al., *Growth Promoting Antibiotics in Food Animal Production: An Economic Analysis*, 122 PUB. HEALTH REP. 79, 80 (2007) (“The use of antibiotics to enhance growth and feed efficiency and reduce mortality in broiler [chicken] production was introduced without rigorous testing as to efficacy some 50 years ago.”).
20. Livestock: Use of Antimicrobial Drugs, Senate Floor Analyses, Senate Rules Committee (Sept. 11, 2015); Casey et al., *supra* note 3, at 1; Heinzerling, *supra* note 3, at 1010–12; INDUSTRIAL FOOD ANIMAL PRODUCTION, *supra* note 3, at 2.
21. ELLEN K. SILBERGELD ET AL., PEW COMM’N ON INDUS. FARM ANIMAL PROD., ANTIMICROBIAL RESISTANCE AND HUMAN HEALTH 9 (2008), [http://www.pewtrusts.org/-/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/industrial\\_agriculture/pcfapantbiorprtvpdf.pdf](http://www.pewtrusts.org/-/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/industrial_agriculture/pcfapantbiorprtvpdf.pdf) [<https://perma.cc/8JXD-S4VJ>] [hereinafter PEW COMMISSION].
22. *Id.* at 24.
23. *Id.*
24. *Id.*
25. *Id.*; KENNETH H. MATHEWS, JR., USDA ECON. RESEARCH SERV., ANTIMICROBIAL DRUG USE AND VETERINARY COSTS IN U.S. LIVESTOCK PRODUCTION 3 (2001), [<https://perma.cc/N3UW-XZ6S>] (“It is generally conceded that commercial livestock production

administer antibiotics prophylactically to prevent the herd- and flock-wide spread of disease.<sup>26</sup> Antibiotic drugs allow food producers to cut costs by substituting low doses of antibiotics for other seemingly more costly methods of disease prevention such as providing more land for animals and maintaining more sanitary living conditions.<sup>27</sup>

## B. The Rise and Threat of Antibiotic Resistance

The evolution of bacteria resistant to antibiotic drugs is an inevitable consequence of bacterial reproduction and mutation. When antibiotic drugs kill bacteria, some bacteria resistant to the drugs may survive and reproduce.<sup>28</sup> Using antibiotic drugs at low levels over a long period of time increases the likelihood of resistant bacteria reproducing.<sup>29</sup> In 1945, Sir Arthur Fleming warned about the dangers of low-dose use of antibiotics as he accepted the Nobel Prize in Medicine for his work developing the antibiotic drug penicillin: “It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them . . . [T]here is the danger that the ignorant man may easily underdose himself and by exposing his microbes to non-lethal quantities of the drug make them resistant.”<sup>30</sup> This warning is precisely the reason that when prescribing a round of antibiotics, doctors today strongly emphasize the need for patients to finish the entire prescribed course and not prematurely discontinue use when symptoms subside.

The past seventy-five years of antibiotic use and development have realized Fleming’s early fears: We have become Fleming’s “ignorant man.” Penicillin-resistant *Staphylococcus* was identified in 1940, when penicillin was only in limited use.<sup>31</sup> Antibiotic-resistant bacteria continued to appear as new antibiotic drugs were developed. Tetracycline was introduced in 1950, and tetracycline-resistant *Shigella* was identified in 1959.<sup>32</sup> As the use of antibiotics became more widespread, the time between the introduction of a new antibiotic and the

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in the United States, especially confinement production, would be virtually impossible without antimicrobial drugs.”).

26. PEW COMMISSION, *supra* note 21, at 24.

27. *Id.* (finding that U.S. hog producers saved approximately \$63 million in feed costs in 1999 due to their use of low levels of subtherapeutic drugs, and would have suffered an estimated loss of \$45.5 million if antibiotic use was banned).

28. *Id.* at 9.

29. *Id.*

30. Alexander Fleming, Nobel Lecture, *Penicillin*, in NOBEL LECTURES IN PHYSIOLOGY OR MEDICINE 1942–1962, at 83, 93 (1964).

31. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 28.

32. *Id.*

first identification of bacterial resistance has often shrunk considerably. For example, levofloxacin was introduced in 1996 and levofloxacin-resistant pneumococcus was identified the same year; Linezolid was introduced in 2000 and linezolid-resistant *Staphylococcus* was identified in 2001; ceftaroline was introduced in 2010 and ceftaroline-resistant *Staphylococcus* was identified in 2011.<sup>33</sup> These contracted time frames reflect the increasingly widespread problematic uses of these drugs.<sup>34</sup> Furthermore, and of grave concern, scientists have increasingly identified pan-drug resistant bacteria (bacteria showing resistance to all available antibiotics).<sup>35</sup> Most recently, in November 2015, bacteria resistant to colistin were first discovered in China.<sup>36</sup> As a drug of last resort, colistin is prescribed when all other antibiotics fail, making it an antibiotic of critical importance. Just weeks after its initial discovery in China, the resistant bacteria had spread to Europe, Asia, and Africa.<sup>37</sup> Although the current threat is low because other antibiotics can still treat colistin-resistant bacteria, the existence of colistin-resistant bacteria is significant because it raises the prospect of untreatable infections in the future.<sup>38</sup> These new bacteria have been found in both farms and in samples of human infections in Europe, suggesting an interplay between antibiotic use in agriculture and the spread of antibiotic-resistant bacteria in humans.<sup>39</sup> In a 2010 speech before a subcommittee of the U.S. House of Representatives, Centers for Disease Control (CDC) Director Thomas R. Frieden said: “Without continuing to improve on our response to the public health problem of antibiotic resistance, we are potentially headed for a post-antibiotic world in which we will have few or no clinical interventions for some infections.”<sup>40</sup>

Antibiotic resistance poses substantial health, safety, and economic concerns. The CDC reports that two million Americans acquire serious antibiotic-resistant infections each year, causing 23,000 deaths.<sup>41</sup> A study by Tufts University and Cook County Hospital in Chicago estimated that patients with antibiotic-resistant

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33. *Id.*

34. *Id.*

35. *Id.*; Thomas R. Frieden, M.D., M.P.H., Dir., CDC, Antibiotic Resistance and the Threat to Public Health, Statement before the Committee on Energy and Commerce Subcommittee on Health, U.S. House of Representatives (Apr. 28, 2010), [<https://perma.cc/P7F2-BJFF>] [hereinafter Frieden Statement].

36. James Gallagher, *Bacteria That Resist 'Last Antibiotic' Found in UK*, BBC (Dec. 21, 2015), <http://www.bbc.com/news/health-35153795> [<https://perma.cc/572Y-9Y54>].

37. *Id.*

38. *Id.*

39. *Id.*

40. Frieden Statement, *supra* note 35.

41. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 6.

infections had excess hospital stays of one to two weeks.<sup>42</sup> The methicillin-resistant strain of the bacteria *Staphylococcus aureus* (MRSA), which has made headlines in the past several years for its resistance to treatment and its ability to thrive in hospital environments, can cause life-threatening bloodstream infections, pneumonia, and surgical site infections.<sup>43</sup>

Antibiotic resistance also imposes significant economic burdens. The same Tufts and Cook County Hospital study estimated that the annual healthcare costs of drug-resistant bacterial infections in the United States is between \$16.6 and \$26 billion.<sup>44</sup> The national economy also suffers: The study estimated that in 2000, the total societal costs of antibiotic-resistant infections to U.S. households was approximately \$35 billion, including lost wages, extended hospital stays, and premature deaths.<sup>45</sup> In addition, these data were collected in 2000, when the rate of reported antibiotic-resistant infections was half of what it is now; these estimates are likely quite conservative today.<sup>46</sup>

These issues become even more urgent with the recognition that emerging economies, including Brazil, India, and China, are projected to increase antibiotic use in animal production by upwards of 100 percent by 2030.<sup>47</sup> None of these countries has prudent antibiotics regulation in place—and some have no regulations at all on the use of antibiotics in food-producing animals.<sup>48</sup> The

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42. Rebecca R. Roberts et al., *Hospital and Societal Costs of Antimicrobial-Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship*, 49 *CLINICAL INFECTIOUS DISEASE* 1175, 1175–84 (Oct. 15, 2009), <http://www.ncbi.nlm.nih.gov/pubmed/19739972> [<https://perma.cc/DQ38-RW5S>].
  43. *Methicillin-Resistant Staphylococcus aureus (MRSA)*, CDC, <http://www.cdc.gov/mrsa> [<https://perma.cc/8XVU-M2ZN>].
  44. Roberts et al., *supra* note 42; *Antibiotic-Resistant Infections Cost the U.S. Healthcare System in Excess of \$20 Billion Annually*, PR NEWSWIRE (Oct. 19, 2009, 9:00 AM ET), <http://www.prnewswire.com/news-releases/antibiotic-resistant-infections-cost-the-us-healthcare-system-in-excess-of-20-billion-annually-64727562.html> [<https://perma.cc/K7AT-PGTM>].
  45. Roberts et al., *supra* note 42; *Antibiotic-Resistant Infections Cost the U.S. Healthcare System in Excess of \$20 Billion Annually*, *supra* note 44.
  46. Roberts et al., *supra* note 42; *Antibiotic-Resistant Infections Cost the U.S. Healthcare System in Excess of \$20 Billion Annually*, *supra* note 44.
  47. Thomas P. Van Boeckel et al., *Global Trends in Antimicrobial Use in Food Animals*, 112 *PROC. NAT'L ACAD. SCI. U.S.* 5649, 5650 (2015); Lance B. Price, Professor, George Washington Univ. Milken Sch. of Pub. Health, Presentation at Drugs, Animals, and Food: Law & Policy of Antibiotics in the Food System, Harvard Law School-UCLA Food Law & Policy Conference (Oct. 23, 2015).
  48. See Price, *supra* note 47. For example, China has minimal regulations and inadequate monitoring and enforcement. See Hudson Lockett, *Antibiotics Abuse Makes China's Pork Industry a Hotbed for Drug-Resistant Bugs*, *CHINA ECON. REV.* (Apr. 13, 2015), <http://www.chinaeconomicreview.com/growth-addiction>. India has few laws governing antibiotic use in food-producing animals. CTR. FOR DISEASE DYNAMICS, ECON., & POLY., *ANTIBIOTIC USE AND RESISTANCE IN FOOD ANIMALS: CURRENT POLICY AND RECOMMENDATIONS 2* (2016), [http://www.cddep.org/sites/default/files/india\\_abx\\_report.pdf](http://www.cddep.org/sites/default/files/india_abx_report.pdf). Brazil has only a few regulations

United States imports agricultural products including meat and produce (which notoriously carry bacteria from meat products) from all over the world, primarily from countries that lack prudent antibiotics regulation including China, Brazil, other South American countries, and to a lesser extent India.<sup>49</sup> In order to protect its population, the United States must take the lead in quality control in antibiotic use with regard to this imported meat. But the quick and intercontinental spread of colistin-resistant bacteria suggests that the United States must go even further in promoting judicious use of antibiotics domestically and globally: Even if the United States does not produce antibiotic-treated meat, it will not be insulated from the effects of global routine uses of antibiotics. Given the global consequences of antibiotic resistance, it is imperative for the United States to be a leader in devising a comprehensive solution rather than to continue to be a primary culprit in worsening the problem. It can begin to do so by reducing and eventually eliminating routine use of antibiotics in this country and by requiring the same from its trading partners.

### 1. The Link Between Agricultural Use and Resistance in Humans

There are two main classes of use of antibiotic drugs: clinical use in humans and agricultural use in food-producing animals. It is well accepted that the misuse of antibiotics in human healthcare is an important contributor to antibiotic

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restricting the use of specific antibiotics. *See, e.g.*, Instrução Normativa No. 14, de 17 de Maio de 2012, Diário Oficial da União [D.O.U.] de 18.5.2012 (Braz.) (banning the antibiotics spiramycin and erythromycin); Portaria No. 97, Art. 15 § 2, de 28 de Julho de 2008, Ministerio da Agricultura, Pecuária e Abastecimento de 29.7.2008 (Braz.) (establishing that animal feed can only contain one antibiotic and one anticoccidial).

49. Brazil is the eighth-largest supplier of agricultural imports to the United States, including \$307 million in red meats each year. It is also the second-largest supplier of prepared meats (\$221.8 million in 2014). *Brazil*, OFF. OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/countries-regions/americas/brazil> [<https://perma.cc/FRX6-4GWX>]; *U.S. Food Imports*, USDA ECON. RES. SERV., <https://www.ers.usda.gov/data-products/us-food-imports> [<https://perma.cc/73RL-WKWP>] (follow “Meats and Meat Products” hyperlink under “Value of U.S. food imports, detailed tables by food group”); USDA FOREIGN AGRIC. SERV., <https://apps.fas.usda.gov/gats/default.aspx> [<https://perma.cc/923Z-3A96>]. China is the third-largest supplier of agricultural imports to the United States and the third-largest supplier of poultry (\$24.8 million in 2014). *The People’s Republic of China*, OFF. OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china> [<https://perma.cc/7CB7-NLN8>]; *U.S. Food Imports, supra*; USDA FOREIGN AGRIC. SERV., *supra*. India is the fifth-largest supplier of agricultural imports to the United States. *India*, OFF. OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/countries-regions/south-central-asia/india> [<https://perma.cc/9Z9J-NTQY>].

resistance and a problem in all healthcare settings.<sup>50</sup> According to the CDC, prescribing antibiotics in outpatient settings could be reduced by more than 30 percent without worsening health outcomes for patients.<sup>51</sup> But to what extent does the overuse and misuse of antibiotics in agriculture affect the prevalence of antibiotic-resistant bacteria in humans? It is undisputed that antibiotic-resistant bacteria have breached the species barrier between food-producing animals and humans multiple times, making it plausible that resistant pathogens acquired from livestock have a direct effect on human health.<sup>52</sup> The scientific evidence has found that the “possibility for animal-to-human transmission . . . brings heightened concerns about livestock as potential reservoirs of zoonotic infections that may with further evolution become adapted to circulation within the human population.”<sup>53</sup> It is important to note that due to limited data and the complexity of studying the epidemiology of transmission, scientists do not yet know the precise mechanisms through which the transfer of resistant bacteria occurs, nor the extent to which these transfers are occurring, making it difficult to quantify the relationship between antibiotic use in animals and the occurrence of clinical resistance in humans.<sup>54</sup> However, in the most comprehensive assessment of the topic to date, an expert panel of the World Health Organization (WHO), Food and Agriculture Organization, and World Organization for Animal Health found “clear evidence of adverse human health consequences due to resistant organisms resulting from non-human usage of antimicrobials.”<sup>55</sup> In addition, numerous studies have traced human infection by drug-resistant pathogens back to animal sources.<sup>56</sup>

The transfer of antibiotic-resistant bacteria from food-producing animals to the human population occurs in various ways: through food-borne contact (such

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50. Alicia Demirjian et al., *CDC Grand Rounds: Getting Smart About Antibiotics*, 64 *MORBIDITY & MORTALITY WKLY. REP.* 871, 871 (2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a3.htm> [<https://perma.cc/8V48-WPDP>].
  51. *Battle of the Bugs: Fighting Antibiotic Resistance*, FDA, <http://www.fda.gov/Drugs/Resources/ForYou/Consumers/ucm143568.htm> [<https://perma.cc/VX26-PA29>].
  52. Chang, *supra* note 11.
  53. *Id.* at 242–43.
  54. *Id.*; Henrik C. Wegener, *Antibiotic Resistance—Linking Human and Animal Health*, in *IMPROVING FOOD SAFETY THROUGH A ONE HEALTH APPROACH: WORKSHOP SUMMARY 331* (Eileen R. Choffnes et al. eds., 2012).
  55. Wegener, *supra* note 54, at 334.
  56. See, e.g., Timothy F. Jones et al., *An Outbreak of Community-Acquired Foodborne Illness Caused by Methicillin-Resistant Staphylococcus Aureus*, 8 *EMERGING INFECTIOUS DISEASES* 82 (2002); M. Teuber, *Spread of Antibiotic Resistance With Food-Borne Pathogens*, 56 *CELLULAR & MOLECULAR LIFE SCI.* 755 (1999); David G. White et al., *The Isolation of Antibiotic-Resistant Salmonella From Retail Ground Meats*, 345 *NEW ENG. J. MED.* 1147 (2001); David G. White et al., *Antimicrobial Resistance of Foodborne Pathogens*, 4 *MICROBES & INFECTION* 405 (2002).

as meat consumption); direct animal contact; and environmental contact, particularly when manure is spread via air, water, dust, and soil.<sup>57</sup> Food-borne contact occurs when antibiotic-resistant bacteria remains on meat that is not processed or cooked properly and spreads to humans.<sup>58</sup> It can also occur when fertilizer or water containing animal feces and antibiotic-resistant bacteria is used on food crops that are then ingested by humans.<sup>59</sup> This route of exposure and the nonfood-borne routes of exposure mean that consumers may not even need to eat meat to be affected by antibiotic resistance. The nonfood routes of exposure also suggest that those who live nearer to production facilities may be at greater risk to environmental exposure.<sup>60</sup>

Despite the knowledge that misuse of antibiotic drugs hastens the evolution of drug-resistant bacteria and that antibiotic-resistant bacteria in food-producing animals can transfer to humans, misuse of antibiotics in agriculture has shown no signs of slowing down.<sup>61</sup> In fact, their misuse continues to increase despite significant outbreaks of drug-resistant bacteria and mounting evidence showing the increasing proliferation and consequences of antibiotic resistance, including from use in agriculture.<sup>62</sup> The most recent data show that sales and distribution of medically important antibiotic drugs for use in food-producing animals increased 23 percent from 2009 to 2014.<sup>63</sup> It is difficult to determine actual usage figures with certainty because data on antibiotic administration in food-producing animals are extremely limited and the FDA is only required to collect and report data on sales, and not on actual usage. Using sales data as a proxy, however, suggests that actual usage is also likely to be high.<sup>64</sup>

Another relevant question is whether the antibiotics administered to food-producing animals are the same as those administered to humans, such that the generation of bacteria resistant to the animal drugs would have any effect on

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57. See PEW COMMISSION, *supra* note 21, at 7–9; see also ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 36–37; Casey et al., *supra* note 3.

58. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 14.

59. *Id.*

60. See Casey et al., *supra* note 3, at 1989.

61. See FDA, 2014 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 6 (2015), <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf> [<https://perma.cc/MS9D-CEBA>].

62. See ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 11.

63. FDA, *supra* note 61, at 6.

64. See MARGARET MELLON ET AL., HOGGING IT: ESTIMATES OF ANTIMICROBIAL ABUSE IN LIVESTOCK (2001), [http://www.iatp.org/files/Hogging\\_It\\_Estimates\\_of\\_Antimicrobial\\_Abuse\\_in.pdf](http://www.iatp.org/files/Hogging_It_Estimates_of_Antimicrobial_Abuse_in.pdf) [<https://perma.cc/9KHR-RHH4>]; Ralph Loglisci, *New FDA Numbers Reveal Food Animals Consume Lion's Share of Antibiotics*, CTR. FOR A LIVABLE FUTURE (Dec. 23, 2010), <http://www.livablefutureblog.com/2010/12/new-fda-numbers-reveal-food-animals-consume-lion%E2%80%99s-share-of-antibiotics> [<https://perma.cc/2GPL-QYKK>].

humans. In short, the answer is yes. As of 2014, 62 percent of the antibiotics administered to food-producing animals were medically important to humans.<sup>65</sup> Because these antibiotics are the same or substantially similar to those used on humans, as antibiotic-resistant bacteria spread, the treatment of humans becomes less effective and the rates of antibiotic-resistant infections grow.<sup>66</sup>

In 2003, the National Academy of Science's Institute of Medicine stated: "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine is not enough. Substantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture as well."<sup>67</sup> The CDC<sup>68</sup> and WHO<sup>69</sup> agree, joining a chorus of scientific, public health, and environmental professionals<sup>70</sup> who recognize the threat current industrial farm practices pose and who have specifically targeted animal agriculture as an area of needed regulation and private sector behavior change.<sup>71</sup> However, antibiotics are attractive to food producers because they enable those producers to use less feed and to maintain less sanitary conditions and smaller, cramped living spaces.<sup>72</sup> The perception

65. FDA, *supra* note 61, at 30.

66. See INDUSTRIAL FOOD ANIMAL PRODUCTION, *supra* note 3, at 2. See generally PEW COMMISSION, *supra* note 21; Roberts et al., *supra* note 42.

67. MARK S. SMOLINKSI ET AL., MICROBIAL THREATS TO HEALTH: EMERGENCE, DETECTION AND RESPONSE 207 (2003).

68. ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 2, at 37 (recognizing that "[s]cientists around the world have provided strong evidence that antibiotic use in food-producing animals can harm public health" and concluding that "antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, not to promote growth").

69. WORLD HEALTH ORGANIZATION, WHO GLOBAL STRATEGY FOR CONTAINMENT OF ANTIMICROBIAL RESISTANCE 37 (2001), [http://www.who.int/drugresistance/WHO\\_Global\\_Strategy\\_English.pdf](http://www.who.int/drugresistance/WHO_Global_Strategy_English.pdf) [<https://perma.cc/KN8B-NNNG>] (recognizing that inappropriate antibiotic use poses an emerging public health threat and that antibiotics are commonly misused in animal production, and recommending that governments "terminate or rapidly phase out the use of antibiotics for growth promotion if they are also used for treatment of humans").

70. See generally Jerome A. Paulson & Theoklis E. Zaoutis, *Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics*, 136 PEDIATRICS 1670 (2015); REVIEW ON ANTIMICROBIAL RESISTANCE, ANTIMICROBIALS IN AGRICULTURE AND THE ENVIRONMENT: REDUCING UNNECESSARY USE AND WASTE (2015), <http://amr-review.org/Publications> (follow "8 December 2015-Antimicrobials in agriculture" hyperlink) [<https://perma.cc/XQ98-D4GK>]; Van Boeckel et al., *supra* note 47; FDA, *supra* note 61; *Putting Meat on the Table: Industrial Farm Animal Production in America*, PEW COMM'N ON INDUS. FARM ANIMAL PRODUCTION FANSITE, [http://www.ncifap.org/\\_images/PCIFAPFin.pdf](http://www.ncifap.org/_images/PCIFAPFin.pdf) [<https://perma.cc/7H2G-9JEM>].

71. See generally PEW COMMISSION, *supra* note 21.

72. See LISA Y. LEFFERTS ET AL., FEED FOR FOOD PRODUCING ANIMALS: A RESOURCE ON INGREDIENTS, THE INDUSTRY, AND REGULATION, JOHNS HOPKINS CTR. FOR A LIVABLE FUTURE 6 (2007), [http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/\\_pdf/research/cf\\_reports/animal\\_feed.pdf](http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/_pdf/research/cf_reports/animal_feed.pdf) [<https://perma.cc/63KT-BXTB>]; MATHEWS, *supra* note 25, at 3. But see Jay P. Graham et al., *Growth Promoting Antibiotics in Food*



traditionally has been that reducing prophylactic antibiotic use would significantly raise costs for many food producers, which has led some in the animal agriculture industry to oppose these efforts.<sup>73</sup> It is unclear, however, that these concerns are merited. In Denmark, the economic impacts of banning the subtherapeutic use of antibiotics have been minimal.<sup>74</sup> The ban has resulted in an increased production cost for hogs of just over 1 percent and no net increase in costs for poultry production.<sup>75</sup> Overall, the combination of production effects on hogs and poultry farmers has caused a loss of just 0.03 percent to Denmark's economy.<sup>76</sup>

In addition, even though some large food chains have committed to phasing out the use of antibiotics in the meat in their products over the next decade,<sup>77</sup> industry resistance and continually rising rates of antibiotic use draw into question whether voluntary measures can be effective and whether their timeframe is acceptable. These doubts are amplified when taking into account that many emerging economies that export meat to the United States are projected to more than double their use of antibiotics in the next fifteen years.<sup>78</sup> More likely, the realities of modern industrial farm animal production will require regulation to stem the growing rates of antibiotic resistance.

Finally, it is important to mention the realistic potential effect of regulating antibiotic use in food-producing animals. Evidence from Denmark, where the subtherapeutic use of antibiotics in food-producing animals is banned, has shown that since the ban, human resistance trends appear to be mirroring the decline in use of antibiotics in agriculture.<sup>79</sup> Some studies suggest that regulation may have

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*Animal Production: An Economic Analysis*, 122 PUB. HEALTH REP. 79, 80 (2007) (collecting large-scale empirical data collected by U.S. industry that demonstrates that the use of growth-promoting antibiotics in poultry production is associated with economic losses to producers).

73. See MATHEWS, *supra* note 25 (stating in its abstract that "discontinuing the use of antimicrobial drugs in hog production would initially decrease feed efficiency, raise food costs, reduce production and raise prices to consumers"); Scott M. Russell, *Ban Antibiotics in Poultry? Why the Policymakers Have It Wrong*, WATT POULTRY USA, Mar. 2003, at 16, 22.
74. PEW CHARITABLE TRUSTS, AVOIDING ANTIBIOTIC RESISTANCE: DENMARK'S BAN ON GROWTH PROMOTING ANTIBIOTICS IN FOOD ANIMALS, [http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content\\_level\\_pages/issue\\_briefs/denmarkexperiencepdf.pdf](http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content_level_pages/issue_briefs/denmarkexperiencepdf.pdf) [<https://perma.cc/73LX-GEC8>].
75. *Id.*
76. *Id.*
77. See, e.g., Jennifer Hackett, *Subway Joins Other Fast-Food Giants to Cut Back on Antibiotics*, SCI. AM. (Oct. 28, 2015), <http://www.scientificamerican.com/article/subway-joins-other-fast-food-giants-to-cut-back-on-antibiotics> [<https://perma.cc/AW2C-665T>]; Stephanie Strom, *McDonald's Moving to Limit Antibiotic Use in Chickens*, N.Y. TIMES (Mar. 4, 2015), [http://www.nytimes.com/2015/03/05/business/mcdonalds-moving-to-antibiotic-free-chicken.html?\\_r=0](http://www.nytimes.com/2015/03/05/business/mcdonalds-moving-to-antibiotic-free-chicken.html?_r=0) [<https://perma.cc/7SH6-DPP3>].
78. Van Boeckel et al., *supra* note 47, at 5649–54; Price, *supra* note 47.
79. PEW CHARITABLE TRUSTS, *supra* note 74.

little effect on reducing the prevalence of antibiotic-resistant bacteria *already present* in humans.<sup>80</sup> Instead, “the greatest value in restricting antibiotics use, as is the case in human medicine, may not be in reversing resistance, but in preventing further increases in prevalence.”<sup>81</sup> It is possible that the antibiotic resistance that has already occurred and spread to humans cannot be undone. In light of this potential irreversibility, it is imperative to minimize the development of new resistant strains of bacteria for current drugs that have not yet led to resistant bacteria, and for future antibiotics that have yet to be developed. In either case—whether to reverse antibiotic resistance in humans or prevent future increases—it is important to begin regulating the misuse of antibiotics in food-producing animals immediately to reduce threats to public health, particularly where there is a risk those threats will become irreversible in the future. To maximize efficiency, legislators should consider using a democratic experimentalist framework in enacting these laws.

## II. DEMOCRATIC EXPERIMENTALISM

### A. Introduction to Democratic Experimentalism

Democratic experimentalism is a process of developing laws and policies in which central institutions delegate authority to subnational jurisdictions to pursue generally declared goals.<sup>82</sup> The central institution plays a managerial role, using information gathered from local institutions to assess and compare local performances and then to reassess and revise initial benchmarks.<sup>83</sup> Under the democratic experimentalist model, the centralized government works with autonomous and decentralized local actors to develop efficient and adaptable rules that respond to local conditions and participating actors.<sup>84</sup> Democratic experimentalism thus combines respect for local variation with centrally coordinated structure and discipline.<sup>85</sup> Its central thrust is to induce continuous learning and revision of standards, emphasizing deliberative engagement among officials and stakeholders.<sup>86</sup>

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80. Chang, *supra* note 11, at 244.

81. *Id.*

82. Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 GEO. L.J. 53, 54–55 (2011).

83. *See id.* at 79.

84. Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267, 316–17 (1998).

85. Sabel & Simon, *supra* note 82, at 78.

86. *Id.* at 55.

Democratic experimentalist scholars contend that this form of lawmaking—developed in the private sphere and transplanted into the public sphere—has great potential to help solve seemingly intractable problems of our time, especially in the context of the modern administrative state.<sup>87</sup> Indeed, although democratic experimentalism has thus far maintained a somewhat low profile in legal scholarship, it has manifested in practice in several recent regulatory initiatives, including for example the Food Safety Modernization Act and the Race to the Top Education program.<sup>88</sup> In order to understand the salience of democratic experimentalism to modern problem-solving, it is important to understand the context in which the modern administrative state arose and the ways in which it has subsequently shifted.

The modern administrative state arose in a context in which the primary problem in legislating could be identified as “official ignorance”: Congress did not have adequate expertise to make law in certain areas. Recognizing the limits of its knowledge, it created expert administrative agencies and delegated to them the authority to regulate in the relevant areas.<sup>89</sup> Over the past eighty years, however, “the problem has shifted from ignorance to uncertainty”: The impediment to effective lawmaking is no longer congressional ignorance, but rather uncertainty on the part of all players about how to solve a new set of seemingly intractable problems.<sup>90</sup> Expertise is insufficient to solve problems whose solutions are uncertain, such as those associated with antibiotic resistance, and also for example, pollution, police abuse, prisons, welfare, housing, education, mental health, and so on.<sup>91</sup> Instead, pervasive uncertainty about how best to solve these problems requires joint collaboration, experimentation, and empirical testing of potential solutions.<sup>92</sup> Democratic experimentalist theory emerges as an attractive and pragmatic new approach to problem-solving—and perhaps unsurprisingly, one that regulatory initiatives are increasingly, albeit unknowingly, adopting. Precisely because it is premised on continuous learning, deliberative engagement, and revision of standards, democratic experimentalism deals directly with the problem of uncertainty, promising improved substantive outcomes. In giving rise to a newly conceived democratic community,<sup>93</sup> it also gives rise to an improved democratic

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87. See Charles Sabel, *Dewey, Democracy, and Democratic Experimentalism*, 9 CONTEMP. PRAGMATISM 35, 42 (2012); Sabel & Simon, *supra* note 82, at 55.

88. Sabel & Simon, *supra* note 82, at 55–56.

89. Sabel, *supra* note 87, at 42.

90. *Id.* at 43.

91. See generally Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1016 (2004).

92. See Sabel, *supra* note 87, at 43.

93. *Id.*

process for problem-solving and legislating. Both procedurally and substantively, democratic experimentalism offers significant potential.

### B. Democratic Experimentalism And Antibiotics

Democratic experimentalist theory contends that “policy experimentation is central to optimal policy choices.”<sup>94</sup> Certain problems—including the subtherapeutic use of antibiotics—are particularly well suited to applying democratic experimentalism as a regulatory framework and problem-solving mechanism. Scientifically related problems and policies especially lend themselves to experimentalism. Because the trial and error approach lies at the heart of scientific inquiry, experimentation is especially well suited to scientific policies and regulatory cultures, including, for example, the Environmental Protection Agency<sup>95</sup> and the Food Safety Modernization Act.<sup>96</sup> In the face of a scientific question and scientific uncertainty—such as how to reduce air pollution, improve food safety, or eliminate subtherapeutic antibiotic use—it is critical to combine experimentation with multi-stage, continuous feedback policymaking<sup>97</sup> to solve problems as efficiently and swiftly as possible. Efficient, swift problem-solving derived from experimentalism is even more critical where a problem presents a significant threat to public health and risks widespread or long-term harm if left unaddressed—as in the case of antibiotic resistance.

In addition, like air pollution, antibiotic-resistant bacteria are an uncontainable externality whose harm is not immediately attributable to any one source. There is little incentive for private actors to abate their subtherapeutic antibiotic use unless all other private actors also do so, and indeed, the positive effects of eliminating subtherapeutic antibiotic use are not maximized unless all actors participate.<sup>98</sup> Without unanimous collective action to eliminate subtherapeutic doses, resistant bacteria will continue to breed and spread at unacceptable rates. Pragmatic government action beyond voluntary guidelines is necessary to address this unpriced externality of breeding antibiotic-resistant pathogens.

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94. Bertrall L. Ross II, *Embracing Administrative Constitutionalism*, 95 B.U. L. REV. 519, 557 (2015).

95. Zachary J. Gubler, *Experimental Rules*, 55 B.C. L. REV. 129, 129–30, 153 (2014).

96. Sabel & Simon, *supra* note 82, at 55–56.

97. *See* Gubler, *supra* note 95, at 129–31.

98. WORLD HEALTH ORGANIZATION, GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE (2015), [http://www.wpro.who.int/entity/drug\\_resistance/resources/global\\_action\\_plan\\_eng.pdf](http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf) (“[S]ystematic misuse and overuse of these drugs in human medicine and food production have put every nation at risk. Few replacement products are in the pipeline. Without harmonized and immediate action on a global scale, the world is heading towards a post-antibiotic era in which common infections could once again kill.”).

At the same time that structured, disciplined government action is necessary, the regulatory scheme must also be adequately flexible to account for significant local variances associated with reducing subtherapeutic antibiotic use. The intricacies of eliminating subtherapeutic antibiotic use vary according both to locality and type of animal, whether pigs, cattle, or poultry, such that a top-down, command-and-control approach will not adequately account for local circumstances to be effective. Democratic experimentalism provides a key theoretical lens for regulating in the antibiotics context, because it accounts for the scientific nature of the problem and its critical threat to public health, and mandates structured, disciplined action while still flexibly accounting for local circumstances. This Article turns next to a history of federal and state action in antibiotics regulation before explaining how to adapt democratic experimentalist theory in the agricultural antibiotics context.

### III. FEDERAL AND STATE ACTION IN ANTIBIOTICS REGULATION

#### A. History of Federal Regulation in Antibiotics

The history of federal action in the subtherapeutic use of antibiotics in food-producing animals is long and complex, spanning nearly sixty-five years and across all three branches of the federal government. A comprehensive understanding of the intricate web of FDA action, executive action, and congressional action and inaction, punctuated by judicial action, is crucial to analyzing whether and how preemption arguments will apply to state laws regulating subtherapeutic antibiotic use and to understanding how democratic experimentalism can best be adapted to address this problem.

##### 1. FDA and Judicial Action

In the 1950s, the FDA, acting pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to approve new animal drugs, approved applications for the use of various antibiotics in food-producing animals at subtherapeutic levels for the purposes of growth promotion, feed efficiency, and disease prevention.<sup>99</sup> The FDA approved that the antibiotics could be administered on a herd- or flock-wide basis, rather than to specific diseased animals.<sup>100</sup> At the time, little was known about the effects that routine, low-level

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99. See *NRDC v. FDA*, 872 F. Supp. 2d 318, 322 (S.D.N.Y. 2012), *rev'd*, 760 F.3d 151 (2d Cir. 2014); see also 21 U.S.C. § 360b(a)(1) (2012).

100. *NRDC*, 872 F. Supp. 2d. at 322.

use of antibiotics on food-producing animals could have on increased antibiotic resistance in humans.<sup>101</sup> By the late 1960s, however, scientific evidence began to link the two.<sup>102</sup> In 1970, FDA responded by assembling a task force of scientists from the FDA, the National Institutes of Health, the U.S. Department of Agriculture, the CDC, academia, and industry, to study the risks associated with this routine use of subtherapeutic antibiotics in agriculture.<sup>103</sup> The task force report, published in 1972, found that the prevalence of antibiotic-resistant bacteria in humans had increased; the use of antibiotics in food-producing animals, especially at subtherapeutic levels, promotes the development of antibiotic-resistant bacteria; animals that consume antibiotics may serve as a reservoir of antibiotic pathogens, which can produce human infections; and the prevalence of bacteria carrying transferable resistant genes for multiple antibiotics had increased in animals—which it found was related to the subtherapeutic use of antibiotics.<sup>104</sup> Among other recommendations, the task force urged that antibiotics that are medically important to humans be prohibited from use in food-producing animals unless they met safety criteria established by the FDA.<sup>105</sup> It also recommended that several specific antibiotics only be used therapeutically unless they met specific safety criteria for non-therapeutic use.<sup>106</sup>

In response to the task force findings, the FDA in 1973 proposed to withdraw approval for all subtherapeutic uses of antibiotics in food-producing animals unless industry submitted data within two years that resolved conclusively the safety of such antibiotic use, pursuant to specific FDA criteria.<sup>107</sup> Among the most important of these criteria was the requirement that subtherapeutic use of an antibiotic drug be shown not to promote increased antibiotic resistance in humans.<sup>108</sup>

The withdrawal of approval did not take place in 1975 as threatened. Instead, after reviewing the evidence industry submitted, in 1977, the FDA proposed to withdraw approval of all subtherapeutic uses of penicillin in livestock and to restrict subtherapeutic use of two tetracyclines in livestock, finding that the use of the

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101. *Id.*

102. *Id.*

103. *See* FDA, REPORT TO THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION BY THE FDA TASK FORCE IN THE USE OF ANTIBIOTICS IN ANIMAL FEEDS, *supra* note 4, at 3.

104. *See id.*

105. *See id.* at 10.

106. *See id.*

107. *See* Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (Apr. 20, 1973) (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15 (2013)).

108. *See* Penicillin-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 43,772, 43,774 (Aug. 30, 1977).

drugs in this manner was no longer safe.<sup>109</sup> The agency issued notices of an opportunity for hearing over the proposed withdrawal and over twenty drug sponsors requested hearings, but the hearings were never held and the FDA never took any further action on the proposed withdrawals.<sup>110</sup> In the early 1980s, the FDA began approving new animal drug applications for the subtherapeutic use of penicillin and tetracycline in food-producing animals.<sup>111</sup> Counterintuitively, given its previous finding that the subtherapeutic use of these antibiotics was no longer safe, the FDA stated that new drug approvals should not be denied while it conducted its ongoing research into their safety.<sup>112</sup>

For twenty years, the FDA took no action. In 1999, five advocacy groups submitted a Citizen Petition to the FDA requesting that it follow through with revoking approval of the subtherapeutic use of antibiotics as it pledged to do in 1973 and 1977.<sup>113</sup> The FDA issued two tentative responses in 1999 and 2001 stating that it could not make a final decision at that time.<sup>114</sup> Several other advocacy groups filed another petition in 2005 with a similar request, again with no agency response.<sup>115</sup> In the face of another decade of FDA silence, in May 2011, the Natural Resources Defense Council (NRDC) and several other advocacy organizations filed a lawsuit against the FDA, seeking to compel the agency to initiate proceedings to withdraw approval of the subtherapeutic use of penicillin and tetracycline in livestock.<sup>116</sup> The lawsuit alleged that the FDA had unlawfully “withheld agency action” in violation of the FDCA and the Administrative Procedure Act and that the FDA was obligated by its 1977 findings to withdraw approvals of the relevant drugs.<sup>117</sup> During the lawsuit, the FDA finally responded to the 1999 and 2005 Citizen Petitions, denying them both.<sup>118</sup> The district

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109. *See* Penicillin-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. at 43,774; Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 56,264, 56,264 (Oct. 21, 1977).

110. *See* Penicillin and Tetracycline in Animal Feeds, Notice of Hearing, 43 Fed. Reg. 53,827, 53,827 (Nov. 17, 1978); *see also* NRDC v. FDA, 872 F. Supp. 2d 318 (S.D.N.Y. 2012), *rev'd*, 760 F.3d 151 (2d Cir. 2014); Winters, *supra* note 6, at 1061.

111. Withdrawal of Approval, 48 Fed. Reg. 4554 (Feb. 1, 1983); *see* New Animal Drugs for Use in Animal Feeds; Penicillin-and Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 48 Fed. Reg. 4490, 4490 (proposed Feb. 1, 1983) (to be codified at 21 C.F.R. pt. 558).

112. New Animal Drugs for Use in Animal Feeds; Penicillin-and Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 48 Fed. Reg. at 4490–91; Winters, *supra* note 6, at 1061.

113. *See generally* NRDC v. FDA, 872 F. Supp. 2d 318, 322 (S.D.N.Y. 2012), *rev'd*, 760 F.3d 151 (2d Cir. 2014).

114. *See id.* at 325.

115. Winters, *supra* note 6, at 1062–63.

116. NRDC v. FDA, 884 F. Supp. 2d 127, 137 (S.D.N.Y. 2012).

117. *Id.*

118. *Id.* at 137 n.6.

court found for the plaintiffs and directed the FDA to begin the withdrawal proceedings.<sup>119</sup>

While the case was on appeal, in 2012, the FDA issued its finalized Guidance for Industry #209 on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.<sup>120</sup> Because of the time and expense of withdrawal proceedings, the FDA advocated against withdrawal of approval and in favor of a voluntary system of industry withdrawal as a more efficient strategy to reduce subtherapeutic antibiotic use in animals.<sup>121</sup> Guidance #209 established the voluntary framework for this reduction. It recommended that the “use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health” and to bring the use of antibiotics under the oversight of licensed veterinarians.<sup>122</sup> The FDA followed up one year later in December 2013 with Guidance for Industry #213, which provides recommendations on how to voluntarily comply with Guidance #209.<sup>123</sup> The next year, in 2014, the Second Circuit reversed the district court in the NRDC case, finding that the FDA had acted within its authority by not withdrawing approval of the subtherapeutic drugs.<sup>124</sup> Although the public interest organizations ultimately lost this case, it likely played a role in prompting the FDA to publish its voluntary guidance documents.<sup>125</sup>

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119. *Id.* at 151.

120. FDA, GUIDANCE FOR INDUSTRY #209: THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS (2012), <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf> [<https://perma.cc/V5VW-6L3P>].

121. *Id.* at 20.

122. *Id.* at 21.

123. FDA, 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 (2013), <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf> [<https://perma.cc/8Q4E-VVSH>]. Guidance #213 includes nonbinding recommendations intended to inform new animal drug producers how to comply voluntarily with the principles outlined in Guidance #209. Guidance #213 requests that drug companies voluntarily withdraw approvals to market antibiotics for use in animal feed and water for “production purposes” such as growth promotion and feed efficiency. It also requests that companies voluntarily amend approvals to market antibiotics over the counter so that a veterinary prescription or veterinary feed directive (VFD) is required to purchase and use these drugs in feed and water.

124. *See* NRDC v. FDA, 760 F.3d 151, 175–76 (2d Cir. 2014).

125. Press Release, NRDC, NRDC Petitions FDA: Agency’s Weak Attempt to Curb Antibiotic Abuse in the Livestock Industry Is Failing (Sept. 13 2016), <https://www.nrdc.org/media/2016/160913> [<https://perma.cc/8KHA-39G2>].



Finally, in October 2015, the FDA's Veterinary Feed Directive (VFD), a final rule, came into effect and created a legal loophole for the subtherapeutic use of antibiotics.<sup>126</sup> A VFD drug is defined as a new animal drug intended for use in animal feed that can only be used under veterinary supervision.<sup>127</sup> This category of drugs can be distinguished from over-the-counter drugs (which do not require a prescription or any veterinary oversight) and prescription drugs (which require a prescription from a veterinarian and a pharmacist to dispense).<sup>128</sup> At present, all products affected by FDA's plan—feed-use antibiotic drugs used for production purposes—are available over-the-counter.<sup>129</sup> However, if drug sponsors, who own the right to market the product, voluntarily modify the use conditions of their antibiotic feed drugs per Guidance #213 so that the drugs require veterinary supervision, the drugs will then become VFD drugs.<sup>130</sup> Twenty-five out of twenty-six of the current drug sponsors, representing over 99.95% of the total sales of products affected by Guidance #213,<sup>131</sup> have committed to change the use conditions of their feed-use drugs so that they are VFD.<sup>132</sup> By voluntarily changing their drugs' use conditions, drug sponsors bind the drugs to the conditions of this final rule, which prohibits using antibiotic drugs for growth promotion or feed efficiency. The drugs can then only be used for therapeutic purposes, including subtherapeutic disease prevention.<sup>133</sup> To comply with the guidance, pharmaceutical companies will simply have to remove "growth promotion" as an indication from the affected drugs' labels. Producers can continue to use the drugs in the same way as before but must say they are now using them for disease prevention purposes rather than growth promotion purposes.<sup>134</sup>

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126. Veterinary Feed Directive, 80 Fed. Reg. 31,708, 31,708 (June 3, 2015) (to be codified at 21 C.F.R. pts. 514, 558).

127. *Id.* at 31,708.

128. *Id.*

129. *FDA's Strategy on Antimicrobial Resistance—Questions and Answers*, FDA, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm> [<http://perma.cc/CB56-Z73P>].

130. Veterinary Feed Directive, 80 Fed. Reg. at 31,710.

131. These twenty-five drug sponsors hold 99.6 percent of the applications affected by Guidance #213 and represent 99.95 percent of the total sales of products affected by Guidance #213. *FDA Update on Animal Pharmaceutical Industry Response to Guidance #213*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390738.htm> [<https://perma.cc/5WBC-Q6XG>]. The one company that has not agreed to participate in the FDA's voluntary plan, Pharmaq AS, makes a drug used only in fish. Lisa Heinzerling, *The FDA's Continuing Incapacity on Livestock Antibiotics*, 33 STAN. ENVTL. L.J. 325, 334–35 (2014).

132. *FDA Update on Animal Pharmaceutical Industry Response to Guidance #213*, *supra* note 131.

133. Veterinary Feed Directive, 80 Fed. Reg. at 31,710.

134. Heinzerling, *supra* note 131, at 337–43.

This loophole perhaps suggests why drug sponsors have been so easily convinced to comply with the VFD. Indeed, one drug sponsor has stated it does not anticipate any drop in revenues as a result of complying with the FDA plan,<sup>135</sup> and another is planning to have its drug reclassified as prevention-related rather than production-related to bypass this hurdle.<sup>136</sup> Bacteria, however, do not distinguish between low doses of antibiotics administered for production purposes and low doses administered for disease prevention. By leaving this loophole open and giving veterinarians wide discretion to approve antibiotic drug use, the FDA's voluntary plan is poised to have little to no actual effect on reducing antibiotic use in food-producing animals.<sup>137</sup>

It is of particular note that Guidance #209 and the VFD are the first time the FDA has ever drawn a distinction between production and disease prevention in evaluating antibiotic risk.<sup>138</sup> Since the early 1970s and as recently as 2003 and 2012, the FDA has not distinguished between the two when referring to subtherapeutic uses of antibiotics that need to be eliminated.<sup>139</sup> The FDA provides no reasoning for its departure from its own previous practice or for its decision to start promoting the limitation on the use of one (production purposes) but not the other (disease prevention).<sup>140</sup>

The stated purpose of the VFD is to simplify the process of becoming a VFD drug, to facilitate the transition of feed-use antibiotic drugs from over-the-counter to VFD status, and to make the VFD process less burdensome to navigate.<sup>141</sup> In reality, however, if the FDA can convince all drug sponsors to comply, the VFD is in fact a back-door means for the agency to ban the use of antibiotics for growth promotion purposes without having to go through the process of promulgating a final rule to that effect.

In addition, the implementation of the VFD may not prove to be as simple a process to reduce antibiotic use as it purports to be, because the FDA's approach has several limitations. First, it requires numerous layers of complex and sustained voluntary action from drug sponsors beyond just the initial written agreement

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135. Beth Hoffman, *New FDA 'Rules' Not Likely to Reduce Antibiotic Use on Farm*, FORBES (Dec. 13, 2013, 10:08 AM), <http://www.forbes.com/sites/bethhoffman/2013/12/13/new-fda-rules-will-not-reduce-antibiotic-use-on-farm> [https://perma.cc/NR4M-JPWD].

136. Richard Coulter & Larry L. Miller, *The Future of Stafac® (Virginiamycin) for Veterinary Use—Company Statement*, PHIBRO ANIMAL HEALTH CORP. (Apr. 12, 2013), <http://phibropro.com/downloads/GN13002USA0413-%20GFI%20209%20and%20213%20PAH%20Public%20Statement.pdf> [https://perma.cc/2QGY-3B4B].

137. Heinzerling, *supra* note 131, at 337–43.

138. *Id.* at 338–39.

139. *Id.*

140. *Id.*

141. Veterinary Feed Directive, 80 Fed. Reg. at 31,710.

they have already given.<sup>142</sup> It also requires all drug sponsors to remain in compliance throughout the entire process in order to be effective. In other words, the plan relies on all of the (profit-maximizing, self-interested) entities not to change their minds partway through the process and decide to capitalize on the new market opportunity left open by all of the other drug sponsors exiting the market for antibiotics used for production purposes.<sup>143</sup> The FDA has no consequence or strategy in place if drug sponsors drop out along the way and render the plan impotent.<sup>144</sup> Between the disease prevention loophole and the faulty reliance on voluntary industry action, the end result of the FDA plan is that what may at first seem to be the FDA attempting to find a clever alternative to limit antibiotic use—one that bypasses time- and resource-consuming formal processes—could, upon closer inspection, make no appreciable difference. In addition, because the FDA does not require data collection on the use of antibiotics in food-producing animals, it will not even be possible to track the effect of the agency's plan on the use of these types of antibiotics or on the prevalence of antibiotic resistance in humans.

## 2. Executive and Congressional (In)Action

In September 2014, the White House released an Executive Order and a National Strategy for combating antibiotic-resistant bacteria.<sup>145</sup> The Executive Order mandates that the FDA “continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.”<sup>146</sup> Similarly, the accompanying National Strategy aims to end the use of medically important antibiotics for growth promotion in food-producing animals and to bring antibiotic use for disease prevention under veterinary oversight.<sup>147</sup> In other words, it is essentially a recapitulation of the FDA voluntary guidance and VFD; not surprisingly, it promotes implementation of the FDA voluntary guidance to achieve these aims, and advocates for enhanced

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142. Heinzerling, *supra* note 131, at 333–37.

143. *Id.*

144. *Id.*

145. Exec. Order No. 13,676: Combating Antibiotic-Resistant Bacteria, 184 Fed. Reg. 56,931, 56,933 (Sept. 18, 2014); WHITE HOUSE, NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA (2014), [https://www.whitehouse.gov/sites/default/files/docs/carb\\_national\\_strategy.pdf](https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf) [<https://perma.cc/NSD8-U3CQ>].

146. Exec. Order No. 13,676: Combating Antibiotic-Resistant Bacteria, 79 Fed. Reg. 56,931, 56,933 (Sept. 18, 2004).

147. WHITE HOUSE, *supra* note 145.

data collection to track the problem, educational outreach, and raising public awareness.<sup>148</sup>

Congressional action in the area of antibiotics has been even less impactful than executive action. The Preservation of Antibiotics for Medical Treatment Act (PAMTA) and its Senate companion bill, the Preventing Antibiotics Resistance Act (PARA), could have a significant effect on reducing problematic antibiotic use if passed. These bills would require the FDA to withdraw approvals of non-therapeutic uses of medically important antibiotics in food animals, except where a company holding an approval demonstrates with reasonable certainty that the nontherapeutic use of the drug will not harm human health by promoting the development of antibiotic resistance.<sup>149</sup> The bills specifically list routine disease prevention as a nontherapeutic use.<sup>150</sup> PAMTA, however, has languished in Congress for sixteen years since its initial introduction in 1999.<sup>151</sup> PARA has similarly made no progress since it was first introduced in 2013.<sup>152</sup>

The federal government, including the FDA, would unquestionably be the strongest actor to promulgate antibiotic regulation. Despite increasing pressure from elected officials, experts, and advocates to take stronger action in this area,<sup>153</sup> federal reform on the issue has proven elusive. There is a patchwork of federal activity on the matter across all three branches of government, but no comprehensive federal scheme. Although the FDA has attempted to set up a mechanism binding industry to its voluntary commitments, the agency ultimately relies on the charity of corporate drug sponsors for the success of its plan, and even so, leaves a big disease prevention loophole—a loophole large enough to render the entire effort meaningless.

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148. *Id.* at 8–9.

149. H.R. 1552, 114th Cong. (1st Sess. 2015), <https://www.govtrack.us/congress/bills/114/hr1552/text> [<https://perma.cc/3HFT-D53V>]; S. 621, 114th Cong. (1st Sess. 2015), <https://www.govtrack.us/congress/bills/114/s621/text> [<https://perma.cc/KKN3-6VQE>].

150. H.R. 1552; S. 621.

151. *See* H.R. 1552; Lydia Zuraw, *Rep. Slaughter Reintroduces Preservation of Antibiotics Legislation*, FOOD SAFETY NEWS (Mar. 25, 2015), <http://www.foodsafetynews.com/2015/03/rep-slaughter-reintroduces-preservation-of-antibiotics-legislation> [<https://perma.cc/GMY9-8EJE>].

152. *See* S. 621.

153. JAY A. GREGORY, AM. MED. ASS'N HOUSE OF DELEGATES (A-14), REPORT OF REFERENCE COMMITTEE E, <http://www.mag.org/sites/default/files/downloads/ama14-refcommE-report.pdf> [<https://perma.cc/4TW5-BRFJ>]; *Tell FDA to Protect Public Health, Not Animal Factories*, CTR. FOR FOOD SAFETY (2014), [http://salsa3.salsalabs.com/o/1881/p/dia/action3/common/public/?action\\_KEY=13354](http://salsa3.salsalabs.com/o/1881/p/dia/action3/common/public/?action_KEY=13354) [<https://perma.cc/5DNS-YYER>]; Press Release, Senators Warren, Feinstein & Gillibrand Question FDA About Efforts to Curb Antibiotic Overuse in Food Animals (July 28, 2014), [http://www.warren.senate.gov/?p=press\\_release&cid=582](http://www.warren.senate.gov/?p=press_release&cid=582) [<https://perma.cc/CZ3N-WV9X>].

Despite having articulated over forty years ago the need to eliminate low-dose antibiotic use in food-producing animals, the federal government still has not implemented a coherent, robust legal scheme to achieve it. Understanding this history helps explain why routine subtherapeutic antibiotic use in food-producing animals continues to grow. Although the federal government has the power to effect meaningful and sweeping change, thus far the executive, legislative, and judicial branches have declined to do so.

## B. State Action and the California Antibiotics Law

In the absence of effective federal action, some states have attempted to enact their own laws and policies curbing antibiotic use in food-producing animals.<sup>154</sup> To date, all of the proposed state bills except one have been voted down or have languished in state legislatures.<sup>155</sup> In October 2015, California became the first and only state to enact a law that will prohibit the routine use of antibiotics in food-producing animals.<sup>156</sup> When SB-27 goes into effect in January 2018, the law will prohibit the use of antibiotics both for production purposes as well as for routine disease prevention, closing the significant loophole left open by the FDA voluntary scheme.<sup>157</sup> Administering antibiotic drugs to food-producing animals will only be permissible when ordered by a licensed veterinarian through a prescription or VFD, in the context of a valid veterinarian-client-patient relationship.<sup>158</sup> The use of antibiotic drugs will only be permissible to treat disease, to control the spread of disease, in connection with a surgery or medical procedure, or for prophylaxis in the event of an elevated risk of a particular disease.<sup>159</sup> Antibiotics

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154. These states include, for example, California, New York, Pennsylvania, Maryland, Minnesota, and West Virginia, which have each proposed legislation multiple times to regulate or prohibit routine subtherapeutic use of antibiotics in food-producing animals. *See* A.B. 1437, 2013–14 Gen. Assemb., Reg. Sess. (Cal. 2014); S.B. 835, 2014 Gen. Assemb. (Cal. 2014); Agriculture-Commercial Feed and Drinking Water-Antimicrobial Drug Prohibition, S.B. 520 (Md. 2013); An Act Prohibiting the Nontherapeutic Use of Antimicrobial Drugs for Food Animals and the Sale of Food Produced from Animals Administered Antimicrobial Drugs for Nontherapeutic Uses, H.F. 1290 (Minn. 2013–14); S.F. 1285, 88th Leg. (Minn. 2013); S.F. 1638, 88th Leg. (Minn. 2013); An Act in Relation to Nontherapeutic Use of Antimicrobial Agents in Animals, S. 201, Reg. Sess. (N.Y. 2015–2016); A.B. 769, 236th Leg. Sess. (N.Y. 2013); S.B. 233, 2013–14 Gen. Sess. (N.Y. 2013); Safe Foods and Families Act, S.B. 740 (Pa. 2015); H.B. 1195, 2013 Gen. Assemb. (Pa. 2013); S.B. 531, 2013 Gen. Assemb. (Pa. 2013); H.B. 2112, 2013 Leg. (W. Va. 2013).

155. N.Y. S. 201; Pa. S.B. 740; Minn. H.F. 1290; Md. S.B. 520.

156. S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015–2016).

157. *Id.*

158. *Id.*

159. *Id.*

will not be permitted for growth promotion or feed efficiency, nor may they be administered routinely for any purpose.<sup>160</sup>

Although the law allows for limited antibiotic use for disease prevention, the legislative history of SB-27 suggests it will be enforced so as not to allow routine disease prevention. The previous year, California Governor Jerry Brown vetoed another bill that would have codified FDA voluntary guidelines, stating in his veto message that he did so because the bill merely duplicated FDA guidance, leaving open the disease prevention loophole and not going far enough to reduce antibiotic use.<sup>161</sup> The fact that Governor Brown signed the 2015 bill into law indicates that it is crafted deliberately to go beyond FDA voluntary guidelines and regulates antibiotic use more strictly than does the federal scheme.

#### IV. DEMOCRATIC EXPERIMENTALISM AND CURRENT ANTIBIOTICS REGIMES

As discussed in Part II, democratic experimentalism offers a key theoretical lens for regulating in the antibiotics context for several reasons. This approach accounts for the scientific nature of antibiotic resistance and the problem's critical threat to public health. At the same time, it mandates structured, disciplined action while still flexibly accounting for local circumstances. This Part situates the current antibiotics regime, consisting of a state law and somewhat nebulous federal administrative agency action, within the democratic experimentalist framework, delineating how democratic experimentalist theory applies (and does not apply) to current antibiotics regulation and offering prescriptive suggestions for how the theoretical framework should apply in this context going forward. It argues that a new iteration of democratic experimentalism emerges, called layered democratic experimentalism, which offers great promise as a hybrid public-private mechanism for problem-solving. This Part concludes by describing challenges in applying democratic experimentalism to this problem, related primarily to concerns about equity and the lack of national uniformity.

##### A. The Emergence of Layered Democratic Experimentalism

In its simplest terms, democratic experimentalism consists of (1) centralized goal-setting; (2) delegation of experimentation to achieve that goal to subnational

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160. *Id.*

161. Letter from Edmund G. Brown, Jr., Governor of Cal., to the Members of the Cal. State Senate (Sept. 29, 2014), [http://gov.ca.gov/docs/SB\\_835\\_Veto\\_Message.pdf](http://gov.ca.gov/docs/SB_835_Veto_Message.pdf) [<https://perma.cc/54UR-VZH5>].

jurisdictions; (3) centralized data collection on local performance; and (4) centralized assessment of local performance and revising of initial benchmarks as necessary.<sup>162</sup>

The first step in democratic experimentalist inquiry is a central institution identifying and expressly stating a common goal. In this case, centralized goal-setting has surely occurred. At the federal level, the FDA has identified a common goal in its voluntary Guidance for Industry documents: reducing antibiotic resistance in humans by reducing or eliminating subtherapeutic antibiotic use in livestock.<sup>163</sup> In addition to the FDA, the White House has issued the National Action Plan for Combating Antibiotic-Resistant Bacteria.<sup>164</sup> One of the purposes of this plan is to “guide action by public health, healthcare, and veterinary partners in a common effort to address urgent and serious drug-resistant threats that affect people in the U.S. and around the world.”<sup>165</sup> In addition, the Action Plan announced that “[p]rogress towards achieving these outcomes will be monitored by the U.S. Government Task Force that developed [the plan].”<sup>166</sup> At the federal level, then, both the FDA and the White House have articulated the common goal of reducing antibiotic resistance in humans by reducing the subtherapeutic use of antibiotics in food-producing animals.

The state of California has announced its desire to achieve this federal goal in enacting SB-27.<sup>167</sup> The law was passed for the express purpose of “address[ing] an urgent public health problem” posed by overuse of antibiotics, and to reduce antibiotic resistance in humans by reducing the use of antibiotics in livestock.<sup>168</sup> Indeed, during the first Senate hearing on SB-27, Senator Hill, the bill’s author, articulated the bill’s goal by alluding to the growing public health threat posed by the overuse and misuse of agricultural antibiotics.<sup>169</sup> In enacting this law, California has taken steps in pursuit of the federal government’s articulated goal,

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162. Sabel & Simon, *supra* note 82, at 54–55, 78–79; Dorf & Sabel, *supra* note 84, at 316–17.

163. FDA, *supra* note 123; FDA, *supra* note 120.

164. WHITE HOUSE, NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA (2015), [https://www.whitehouse.gov/sites/default/files/docs/national\\_action\\_plan\\_for\\_combating\\_antibiotic-resistant\\_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf) [<https://perma.cc/Y37G-RUM9>].

165. *Id.* at 2.

166. *Id.* at 3.

167. S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015–2016) (codified as 4.5 CAL. FOOD & AGRIC. CODE § 14400).

168. Letter from Edmund G. Brown, Jr., Governor of Cal., to the Members of the Cal. State Senate (Oct. 10, 2015), [https://www.gov.ca.gov/docs/SB\\_27\\_Signing\\_Message.pdf](https://www.gov.ca.gov/docs/SB_27_Signing_Message.pdf) [<https://perma.cc/D5L7-A7UQ>].

169. SENATOR HILL, HEARING REPORT OF SENATE COMMITTEE ON AGRICULTURE, LIVESTOCK: USE OF ANTIBIOTICS, 2015 Leg., Reg. Sess. (Cal. Apr. 21, 2015).

resembling the beginnings of a democratic experimentalist relationship between state and federal government.

The resemblance of SB-27 to traditionally conceived democratic experimentalism begins to break down at this point, in that there is not a federal delegation to states to experiment locally in pursuit of achieving this goal. The California law was not enacted in response to a federal delegation of authority; in fact, it may even fly in the face of federal authority if it is found to be preempted. Despite the fact that this regime is not a neat example of democratic experimentalism, however, the theoretical framework does or can still apply, albeit in a more layered manner.

At first glance the California law may seem to resemble a traditional command-and-control piece of legislation. It operates as a ban on a certain set of practices. But it also has elements of democratic experimentalism and the potential for a democratic experimentalist implementation. The law calls for improved data collection in order to better understand the scientific problem at hand and to monitor livestock management in implementation of this law, and it plans to do both in continuous coordination with the relevant federal agencies and departments.<sup>170</sup> But the law leaves significant leeway in implementing its data collection requirements.<sup>171</sup> It is thus at a pivotal point: Its implementation is both critical and up for determination. If the law is implemented in a traditional command-and-control manner with little meaningful data collection, the democratic experimentalist framework would have little application and thus little effect as a theoretical framework. Alternatively, if the law is implemented with strategic and robust data collection requirements, California will emerge as a central coordinator, collecting and comparing data and possibly even serving as a curator of best practices among California firms. This implementation would underscore the law's engagement in an implicit delegation of authority to experiment to local firms. Perhaps even more compelling, if other states follow suit with their own laws regulating antibiotics and mandating data collection, the various states' experiences and the effects of their different legislations could be compared and best legislative practices discerned. This process would resemble a true democratic experimentalist approach among participating states.

What would then emerge is a layered public-private democratic experimentalism in which the federal government identifies a goal, state governments enact an initial benchmark and serve as data collectors and poolers, and local firms receive delegated authority to experiment to achieve the overarching goal. This approach does not represent traditional democratic experimentalism, but it

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170. S.B. 27.

171. *Id.*



is a powerful iteration. Experimentation in best practices at both the firm level (how to efficiently raise livestock without the subtherapeutic use of antibiotics) and the state level (which legislative practices result in the greatest reduction of agricultural use of antibiotics) is where real change and meaningful breakthroughs can occur.<sup>172</sup>

It may seem at first glance as though a ban is the only legislative option to eliminate problematic antibiotic use and that therefore this policy issue is not ripe for democratic experimentalism. It may also seem that a ban is a straightforward piece of command-and-control legislation with no democratic experimentalist characteristics. A brief example from the European Union illustrates why both of these suppositions are incorrect. The European Union banned antibiotics as growth promoters in 2006.<sup>173</sup> Because all member states must comply with the same blanket ban, the expectation is that the same or similar results would accrue in each country. This was not the case. Some countries' use of antibiotics has increased since the ban, others have remained constant, and still others have decreased. Since 2011, eleven European countries have decreased antibiotic use in livestock while six have increased.<sup>174</sup> In the Netherlands, for example, antibiotic use remained constant even as subtherapeutic use dropped, with producers simply increasing their therapeutic use of antibiotics to compensate for the ban on subtherapeutic use.<sup>175</sup> In response to these unsatisfactory results from EU-level regulation, in 2007 the Netherlands implemented its own supplementary measures alongside the ban, including increased on-farm transparency; requiring veterinary registration of prescribed antibiotics; creating an independent institute to monitor antibiotic use, report it publicly, and set benchmarks; and requiring custom treatment plans for each farm, among other measures.<sup>176</sup> The Netherlands implemented these measures in large part based on the successful Danish

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172. Tom Philpott, *How Factory Farms Play Chicken With Antibiotics*, MOTHER JONES (May/June 2016) <http://www.motherjones.com/environment/2016/05/perdue-antibiotic-free-chicken-meat-resistance> [https://perma.cc/ALM8-RM4M].

173. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on Additives for Use in Animal Nutrition, 2003 O.J. (L 268) 29.

174. EUROPEAN COMMISSION, AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, [http://ec.europa.eu/dgs/health\\_food-safety/docs/amr\\_factsheet\\_en.pdf](http://ec.europa.eu/dgs/health_food-safety/docs/amr_factsheet_en.pdf) [https://perma.cc/XA3J-E4WL].

175. Carol Coglian et al., *Restricting Antimicrobial Use in Food Animals: Lessons From Europe*, 6 MICROBE 274, 277 (2011), [http://emerald.tufts.edu/med/apua/research/pew\\_12\\_846139138.pdf](http://emerald.tufts.edu/med/apua/research/pew_12_846139138.pdf).

176. Dik Mevius & Dick Heederik, *Reduction of Antibiotic Use in Animals "Let's Go Dutch"*, 9 J. VERBRAUCHERSCHUTZ & LEBENSMITTELSICHERHEIT 177, 179 (2014), <http://link.springer.com/article/10.1007%2Fs00003-014-0874-z>.

approach.<sup>177</sup> As a result of these measures, the Netherlands reduced antibiotic use by 56 percent over five years, meeting its target reduction one year early.<sup>178</sup> This example illustrates how the other practices that a state legislates alongside a blanket ban can be critical and the importance of comparing to another entity's experience. Simply banning certain uses may not have the intended results and can still leave room for critical experimentation and comparison, illustrating how democratic experimentalism can provide a solution in this policy area.

Delegating this authority to states and even to firms, even implicitly as the California law has done, represents a critical approach to problem-solving in this area. If there is robust data collection in place to track experiences at the firm- and state-levels, best practices can be identified and then enshrined legislatively, and benchmarks set and re-set once met. This iterative process can continue until the problem is solved. Data collection is therefore a crucial step for the success of democratic experimentalism. Without robust data collection, experiences cannot be assessed and compared and benchmarks cannot be met.

California's success in this area could inspire other states to begin legislating around antibiotics as well, or at least mandating data collection.<sup>179</sup> This trend would come to resemble a bottom-up democratic experimentalist movement amongst states. What started as a non-traditional layered democratic experimentalist approach would in fact come to represent a participant-involved democratic movement, supporting and reinforcing the basic ethos behind democratic experimentalism. Layered democratic experimentalism thus offers great promise as a hybrid public-private mechanism for effective problem-solving.

## B. Challenges in Applying Democratic Experimentalism

A lack of national uniformity is inherent in the democratic experimentalist model: In order to experiment, there must be variation among subnational jurisdictions. When considering whether to apply the democratic experimentalist framework to a policy problem, the value of democratic experimentation must always be weighed against the value of a single national regime. For companies whose operations span across California and another state, the current antibiotics regime will require compliance with two sets of laws. Operators in California also

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177. Dik Mevius & Dick Heederi, Reduction of Antibiotic Use in Animals: "Let's Go Dutch", 9 J. für Verbraucherschutz und Lebensmittelsicherheit, 177 (2014), <http://link.springer.com/article/10.1007%2Fs00003-014-0874-z>.

178. *Id.* at 180.

179. Over the last several years, concurrent with California's legislative process, a handful of other states have proposed legislation to address overuse of antibiotics in food-producing animals. Thus far none of the proposals has passed. *See, e.g.*, sources cited *supra* note 154.

face the cost disadvantage of having to produce their products without the use of subtherapeutic antibiotics while competing with producers in other states who will still be able to administer antibiotics in this way. If other states follow suit with their own antibiotics laws or use restrictions that vary from the federal government and from California, a more complicated patchwork of compliance may develop. In this case, then, the uniformity concern requires weighing the effects of experimentation to solve a pressing and little understood threat to public health and safety, against the cost to businesses and consumers of a non-uniform regime.

In order to conduct that balance, it is important to estimate as best as possible the actual financial costs of eliminating the subtherapeutic use of antibiotics in livestock. Doing so also sheds light on another concern associated with eliminating the subtherapeutic use of antibiotics: the inequitable effects on the poor of raising the price of meat. Evidence from Denmark, where the practice has been banned for over a decade, suggests that the effect on the cost of raising pork has been minimal.<sup>180</sup> In addition, Perdue, a leading chicken producer in the United States that has voluntarily begun phasing out the subtherapeutic use of antibiotics in two-thirds of its chickens, has indicated that the cost of doing so has not been significant, though it recoups the costs by passing them on to consumers in the form of a 20 percent price premium.<sup>181</sup> This passing on to consumers raises precisely the fears about inequity that may be associated with the ban on subtherapeutic antibiotics.

It is, however, important to remember the alternative. At present, an increasing number of companies and retailers are committing to eliminating the use of antibiotics in their products.<sup>182</sup> This trend leaves the poor with the unattractive option of consuming antibiotics-treated meat and increased exposure to antibiotic-resistant pathogens in their meat, while wealthier consumers can afford antibiotics-free meat and avoid exposure to these pathogens. In contrast, if firms were required to experiment in the elimination of subtherapeutic antibiotics and centralized institutions pooled data on their performance, the best practices for efficiently and cost-effectively doing so would begin to emerge, ultimately resulting in the least cost increases possible. In addition, the market price of meat currently does not reflect the actual cost of meat because, among other reasons, the current price does not account for the externality of breeding antibiotic-resistant pathogens in meat production. The current price of meat is the product of a shortcut that the industry has been taking for decades—a shortcut that is no

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180. PEW CHARITABLE TRUSTS, *supra* note 74, at 3.

181. Philpott, *supra* note 172.

182. See e.g., Hackett, *supra* note 77; Strom, *supra* note 77.

longer acceptable for public health. Legally eliminating subtherapeutic antibiotic use will require companies to innovate swiftly to produce meat cost-effectively in a way that does not seriously threaten public health. If companies choose to pass on any cost increases to consumers, rather than internalize the costs themselves, it will result in consumers paying the actual cost of meat and not an artificially deflated cost. It will also result in healthier meat and healthier production systems for all—not just for the wealthy.

Finally, because many major retailers are requiring suppliers to phase out the use of antibiotics in their production over the next decade, the writing is on the wall for firms. Enacting a legal framework that calls for democratic experimentalism will best support these firms in achieving these goals by establishing a collaborative, trial-and-error regime that rewards the most efficient problem-solvers. Doing so likely represents the most cost-effective mechanism for solving this problem. Similarly, although it is unclear how costly it is to comply with multiple sets of laws, it is likely that the streamlined and systematized schematic that democratic experimentalism offers would optimize these costs of compliance. Firms would certainly experience increased initial costs of compliance, but they could also benefit from the experience of other firms, helping them to recoup their initial costs. In addition, states would benefit from the legislative experiences of other states, and best practices would emerge on how to legislate most effectively to reduce antibiotic use.

## V. FEDERAL PREEMPTION AND DEMOCRATIC EXPERIMENTALISM

State legislation prohibiting the subtherapeutic use of antibiotics in farm animal production is a strong potential strategy for reducing the spread of antibiotic resistance. States are not free to regulate in every area, however, and state action in certain areas may be subject to constitutional challenge on preemption grounds. Federal preemption occurs when a federal law conflicts with a state law, whether directly or indirectly, rendering the state law void.<sup>183</sup> Federal preemption doctrine has its basis in the Supremacy Clause of the U.S. Constitution, which grants Congress the power to preempt state law when it legislates within the powers afforded to it under the Constitution.<sup>184</sup> As a result, where a state law comes into conflict with a valid federal law, federal law prevails.<sup>185</sup>

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183. See *e.g.*, *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

184. U.S. CONST. art. VI, § 2.

185. See, *e.g.*, *Fid. Fed. Sav. & Loan Ass'n*, 458 U.S. at 153.

Because states are independent sovereigns in our federal system, courts presume that “Congress does not cavalierly pre-empt state-law.”<sup>186</sup> A finding of preemption is “not favored ‘in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion or that the Congress has unmistakably so ordained.’”<sup>187</sup> Fields traditionally occupied by the states are especially shielded from preemption, as courts “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”<sup>188</sup> In particular, the U.S. Supreme Court has presumed that federal law does not invalidate state laws pertaining to health and safety.<sup>189</sup> This presumption is particularly important in the context of a state law regulating the use of antibiotic drugs in food-producing animals for the purpose of protecting the health and safety of its citizens.<sup>190</sup> This Part begins with a brief analysis of preemption doctrine as applied to SB-27, concluding that although a court should not find the California law to be preempted, one could ultimately find either way on this unsettled question of law. It then proceeds with an argument for democratic experimentalist-informed preemption doctrine to apply in specific contexts such as this one where the policy area at issue is knowledge-intensive and marked by scientific uncertainty.

## A. Brief Overview of Preemption

### 1. Express Preemption

There are two broad types of preemption: express and implied.<sup>191</sup> Express preemption occurs when Congress declares in the text of a statute its intent to preempt state law.<sup>192</sup> If the state law at issue is found to fall within the scope of the statute’s preemption clause, the state law is preempted.<sup>193</sup> In this case, the relevant federal statute is the FDCA. Congress passed this Act in 1938, expanding

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186. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

187. *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 634 (1981) (quoting *Chicago & Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981)).

188. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Lohr*, 518 U.S. at 485).

189. *Hillsborough Cty. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 715 (1985).

190. See A.B. 49, 2014–2015 Gen. Assemb., Reg. Sess. (Cal. 2014) (“The spread of antibiotic-resistant bacteria poses a risk to the health of Californians and reduced use of antibiotics for livestock production is likely to reduce the risks of the rise and spread of antibiotic-resistant bacteria through food and other pathways, thus reducing the risk to Californians.”).

191. See, e.g., *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

192. See, e.g., *id.*

193. See, e.g., *id.*

the federal government's role in ensuring the safety of food, drugs, and cosmetics, and creating the FDA.<sup>194</sup> The FDCA delegates to the FDA the statutory authority to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective."<sup>195</sup> Of particular relevance, Congress gave the FDA the authority to approve the use and labeling of any "new animal drug."<sup>196</sup> However, the statute does not contain express preemption language regarding the regulation of antibiotic drugs in food-producing animals, so express preemption does not apply.<sup>197</sup> In a recent case involving a question of federal preemption, *Association des Éleveurs de Canards et D'Oies du Québec v. Harris*, the U.S. District Court for the Central District of California considered whether a California statute banning force feeding to produce foie gras was expressly preempted by Poultry Products Inspection Act (PPIA), the federal statute that regulates the distribution and sale of poultry products.<sup>198</sup> PPIA contains a broadly sweeping preemption clause that expressly prohibits states from imposing "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than" those required by PPIA.<sup>199</sup> The court found that the statute was preempted because it imposed ingredient requirements—namely, force feeding requirements—for the sale of foie gras in California that were not required by the federal statute.<sup>200</sup> Although the court interpreted the meaning of "ingredient requirement" broadly in that case to include force feeding birds to produce foie gras, the same cannot be said for administering subtherapeutic antibiotics to animals. Unlike force feeding birds, which creates the type of fatty liver requisite for producing foie gras, administering subtherapeutic antibiotics to animals is not a necessary ingredient for creating any specific type of food. Therefore SB-27 does not trigger the PPIA preemption provision and is distinguishable from *Association des Éleveurs*.

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194. 21 U.S.C. § 393 (2012).

195. 21 U.S.C. §§ 393(b)(2) (2012).

196. 21 U.S.C. § 360b(a)(1) (2012).

197. *Jones v. Rath Packing Co.*, 430 U.S. 519, 538 (1977) (stating that the FDCA "contains no preemptive language").

198. *Ass'n des Éleveurs de Canards et d'Oies du Québec v. Harris*, 79 F. Supp. 3d 1136, 1139 (C.D. Cal. 2015).

199. 21 U.S.C. § 467e (2012). The Federal Meat Inspection Act (FMIA) regulates the distribution and sale of meat products. It contains a nearly identical preemption clause to PPIA. 21 U.S.C. § 678 (2012).

200. *Ass'n des Éleveurs de Canards et d'Oies du Québec*, 79 F. Supp. 3d at 1139.

## 2. Implied Preemption

In the absence of an express preemption clause, a court may still invalidate a state law under implied preemption. Within implied preemption are two categories: field preemption and conflict preemption.

Field preemption only occurs where Congress has not expressly preempted state law, but has legislated to create a federal regulatory scheme that is so pervasive as to “occupy the field” in that area of the law and warrant the inference that Congress did not intend the states to supplement it.<sup>201</sup> The Supreme Court has reserved findings of field preemption for cases involving comprehensive federal legal regimes, such as national labor law, where the intent of Congress was unmistakably to create a uniform national system.<sup>202</sup> The relevant question is whether the FDCA, in combination with the FDA antibiotics scheme, can be considered a pervasive federal regulatory regime akin to national labor legislation. After forty years of silent indecision vis-à-vis antibiotics in food-producing animals, the FDA chose to pursue an informal voluntary route consisting of two voluntary guidance documents and a final rule, in large part to avoid the complexity and cost of the formal process. The FDA’s choice to avoid formal processes weighs strongly against finding the existence of a comprehensive federal regulatory scheme occupying the entire field. In light of the current patchwork of voluntary and piecemeal federal action, it seems implausible that a court could conclude that a comprehensive federal regime exists to overcome the presumption for states to legislate to protect public health and safety, such that the unequivocal congressional intent was to prohibit supplementary state law regulating the dangerous overuse of antibiotics.<sup>203</sup>

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201. *Fidelity Federal Sav. and Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 152 (1982).

202. *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 241 (1959).

203. It is important to note that one district court case from 1986 has touched on the issue of field preemption and antibiotics. In *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corporation*, a nonprofit organization brought an action to compel a veal company to disclose information on its label regarding its production practices in raising veal. *Animal Legal Def. Fund Bos., Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 278 (D. Mass. 1986), *aff’d*, 802 F.2d 440 (1st Cir. 1986). The court held that the claims were preempted by the “comprehensive federal scheme” in the labeling, packaging, and marketing of meat and use of medicated animal feeds. *Id.* There are several critical distinctions between *Provimi* and SB-27. *Provimi* was a deceptive practices action primarily concerned with animal welfare and meat labeling. It attempted to compel corporate speech and require a certain label be affixed to certain meat. In contrast, SB-27 is a state law primarily concerned with protecting the health and safety of consumers from the dangerous overuse of antibiotics, a danger bolstered by mounting scientific evidence. SB-27 does not compel speech or concern labeling, packaging, or marketing meat. While *Provimi* implicated FDCA, FMIA, and PPIA, prompting the court to find a comprehensive regulatory regime was in place, SB-27 only implicates the FDCA and the FDA voluntary scheme regarding antibiotics. These cannot reasonably be considered a comprehensive federal regulatory regime. The holding in

Conflict preemption further breaks down into two types. The first type, known as “physical impossibility,” occurs when it is impossible to comply with both the federal and state statutes at once.<sup>204</sup> Physical impossibility cases are relatively clear-cut. The Supreme Court interprets physical impossibility preemption narrowly, reserving its application of the doctrine for cases where federal law and state law are entirely irreconcilable—for instance, where “state law penalizes what federal law requires.”<sup>205</sup> Here, compliance with the state law prohibiting the sub-therapeutic use of antibiotic drugs in food-producing animals would not make it operationally impossible to comply with federal law. The FDCA provides a process for approving animal drugs and medicated feed, but it does not require the use of any such drugs. In fact, complying with the California law will actually ensure that producers are in compliance with FDA’s voluntary guidance and are furthering the FDA objective of judicious use of antibiotics.<sup>206</sup> Physical impossibility conflict preemption thus does not apply.

The second type of conflict preemption, known as “obstacle,” occurs when state law represents an obstacle to fully achieving the purposes or objectives of Congress.<sup>207</sup> Obstacle preemption is much less clear-cut than physical impossibility preemption; perhaps unsurprisingly, courts more easily invoke this type of preemption than any of the others.<sup>208</sup> With respect to obstacle preemption, “the presumption against preemption of state laws dictates that a law must do ‘major damage’ to clear and substantial federal interests before the Supremacy Clause will demand that state law surrenders to federal regulation.”<sup>209</sup> There is no doubt that the California law is stricter than the FDA’s scheme. Indeed, Governor Brown’s veto message suggests that it was the California law’s explicit intent to go beyond the FDA’s guidelines. From an implied preemption perspective, the relevant question is whether the California law impermissibly conflicts with—indeed, does major damage to—the purposes and objectives of the FDCA such

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*Provimi* preempted a state law deceptive practices claim, whereas a similar finding in this case would invalidate a state law, something courts do not do lightly. It is implausible that the reasoning in *Provimi* could credibly be used to justify invalidating the California law under field preemption.

204. See, e.g., *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

205. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000).

206. See FDA, *supra* note 120, at 3; Veterinary Feed Directive, 80 Fed. Reg. 31,708, 31,708 (June 3, 2015) (to be codified at 21 C.F.R. pts. 514, 558).

207. *Geier*, 529 U.S. at 899 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

208. Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, in *PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM’S CORE QUESTION* 132 (William W. Buzbee ed., 2009).

209. *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1050 (7th Cir. 2013) (quoting *Hillman v. Maretta*, 133 S. Ct. 1943, 1950 (2013)).



that the state law is preempted when it regulates antibiotics that have been approved by the FDA and exceeds the FDA voluntary guidelines and VFD.

This analysis first requires assessing Congress's purposes and objectives under the FDCA. The creation of the FDCA expanded the federal role in drug regulation, particularly by creating the FDA and delegating to the agency the premarket drug approval process.<sup>210</sup> Even as Congress amended the FDCA over the years to enlarge the FDA's powers, it "took care to preserve state law," including adding a clause in 1962 "that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA."<sup>211</sup> Congress has added several express preemption clauses to the FDCA, including regarding medical device regulation,<sup>212</sup> cosmetic labeling and packaging,<sup>213</sup> and nutrition labeling (via the Nutrition Labeling and Education Act).<sup>214</sup> These express preemption clauses suggest that when Congress has desired to preclude supplementary state law on a subject governed by the FDCA, it has done so explicitly and via a detailed, narrowly tailored express preemption provision.<sup>215</sup> Though Congress delegated authority to regulate antibiotics to the FDA, it has consistently and explicitly disclaimed intent to impliedly preempt state law in this area.<sup>216</sup> Case law supports this proposition: When Congress has not spoken directly on the preemption issue and a state has imposed a stricter standard that does not make compliance with federal law impossible, courts generally assume that federal regulations have set a floor over which states may impose further requirements.<sup>217</sup>

Indeed, the Supreme Court has held that the FDA's premarket drug approval process is insufficient to show that Congress viewed state laws imposing stricter

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210. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009).

211. *Id.*; see also Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 793, 241 (1962).

212. See, e.g., 21 U.S.C. § 360k (2012).

213. See, e.g., 21 U.S.C. § 379s (2012).

214. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended at 21 U.S.C. § 343-1 (2012)).

215. See *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (citing the FDCA's express preemption provision for medical devices as evidence that Congress did not intend to impliedly preempt state tort claims involving prescription drugs); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 547 (1992) (Scalia, J., concurring in part and dissenting in part) ("The existence of an express pre-emption provision tends to contradict any inference that Congress intended to occupy a field broader than the statute's express language defines."); *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 612-14 (1991) (holding that plaintiff's state law claim was not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act because the Act's express preemption provision "would be pure surplusage if Congress had intended to occupy the entire field of pesticide regulation").

216. See *Wyeth*, 555 U.S. at 567; *Wis. Pub. Intervenor*, 501 U.S. at 612-14; *Cipollone*, 505 U.S. at 547.

217. See *Steel Inst. of N.Y. v. City of New York*, 832 F. Supp. 2d 310, 331 (S.D.N.Y. 2011), *aff'd*, 716 F.3d 31 (2d Cir. 2013); see also *Chinatown Neighborhood Ass'n v. Harris*, 33 F. Supp. 3d 1085, 1106 (N.D. Cal. 2014) ("Federal law is not a floor or a ceiling such [that] any state law varying from what federal law permits is preempted.").

standards on FDA-approved drugs as an obstacle to its purposes and objectives under the FDCA, especially in light of all the evidence that Congress did not desire for the FDCA to impliedly preempt state law.<sup>218</sup> The FDA's approval of the general use of a certain drug does not limit states' abilities to restrict the drug's use in dangerous contexts, according to the Supreme Court in *Wyeth v. Levine*. The approval of an antibiotic drug for use in food-producing animals does not equate to a requirement or even a desire that the antibiotic drug be allowed for use in every context.<sup>219</sup>

The statute itself declares that its purpose is to ensure the safety and effectiveness of veterinary drugs.<sup>220</sup> State law that intentionally exceeds the FDA scheme could arguably be seen as an impermissible obstacle to these congressional purposes. However, the FDA states in its response to commentary to the final rule that VFD drugs should only be used for disease prevention purposes where "appropriate for the treatment, control, or prevention of a specific disease,"<sup>221</sup> which counsels against the use of routinized, low doses administered herd- or flock-wide. The state regulation in this case seeks to achieve the same objective as the federal government: the judicious use of antibiotics in food-producing animals, particularly vis-à-vis routine use for disease prevention. The state is stepping in here to fill a gap in the absence of binding federal action and in the face of federal acknowledgment of the problem but political gridlock on how to act. Far from thwarting congressional federal objectives, the California law arguably furthers them by limiting antibiotic use in a way that reflects over forty years of FDA understanding and that is in line with the principle set forth in the VFD.

It is also unlikely that the FDA antibiotics scheme qualifies as an agency action that can sufficiently preempt state law. "[A]n agency regulation with the force of law can pre-empt conflicting state requirements,"<sup>222</sup> but "[c]ourts with good reason are wary of affording preemptive force to actions taken under more informal circumstances."<sup>223</sup> There is some authority for the proposition that only exercises of an agency's formal rulemaking authority are sufficient to preempt

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218. See *Wyeth*, 555 U.S. at 575. It should also be noted that it is unlikely this type of state law runs the risk of creating a patchwork of state laws. There simply are not many options for variation in the laws around subtherapeutic antibiotic use. The California law uncontroversially reflects forty years of FDA practice and understanding about subtherapeutic antibiotic use. It is likely any other state legislating in this area would adopt a similar or identical approach. If not, that state would run the risk of thwarting federal objectives.

219. See *Chinatown Neighborhood Ass'n*, 33 F. Supp. at 1106 ("Not banning some activity is not the same as affirmatively requiring that it be allowed.")

220. See 21 U.S.C. § 393(b)(1)-(2) (2012).

221. *Id.*

222. *Wyeth*, 555 U.S. at 576.

223. *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 245 (3d Cir. 2008).

state law.<sup>224</sup> Although there are exceptions to requiring formal notice and comment rulemaking,<sup>225</sup> nonbinding guidance is insufficient to preempt state law.<sup>226</sup> Even if formal rulemaking is not a strict threshold to preemptive power, it is unlikely that the FDA antibiotics scheme—two voluntary guidance documents coupled with one final rule—would be given preemptive weight. Although the FDA scheme should not be dismissed outright because it is not purely informal and does implicate a final rule, the scheme is a sort of hybrid with murky contours. Given the case law on point and the relatively high standard it sets for assigning preemptive effect to agency action, it seems unlikely this scheme would be considered sufficient to preempt state law.

On the other hand, the California law explicitly and deliberately exceeds the federal scheme established by the FDA. Normative reasoning aside, in drafting SB-27, the California legislature set out to exceed the federal scheme, as indicated by Governor Jerry Brown in his veto of the previous bill that replicated the FDA voluntary guidance. Intentionally exceeding the federal scheme could be viewed by a court as presenting an obstacle to the federal purposes and objectives of Congress. The FDA has considered this issue for over forty years, it has approved the use of these antibiotic drugs in livestock, and it has decided to pursue a voluntary scheme that does not prohibit the use of antibiotics for disease prevention purposes. Read this way, the California law stands in conflict with a federal scheme, which, although unsatisfactory, is relatively clear in its allowance of antibiotic drugs in livestock for these purposes.

In short, although the above preemption analysis suggests that the California law should prevail if challenged, a court could plausibly decide either way on the issue. A court could reasonably find that the law survives such a challenge because

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224. See *Good v. Altria Grp., Inc.*, 501 F.3d 29, 51 (1st Cir. 2007), *aff'd and remanded*, 555 U.S. 70 (2008) (“Unlike many other exercises of agency authority, formal rulemaking comes with a host of procedural protections under the Administrative Procedure Act (‘APA’), such as notice of the proposed rule, an opportunity for interested parties to participate, a statement of the basis and purpose of any rule adopted, and its publication in the Federal Register. 5 U.S.C. § 533 (2007). Limiting the preemptive power of federal agencies to exercises of formal rulemaking authority, then, ensures that the states will have enjoyed these protections before suffering the displacement of their laws.”).

225. See *Fellner*, 539 F.3d at 244 (noting that “in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law” (citing *Colacicco v. Apotex Inc.*, 521 F.3d 253, 271 (3d Cir. 2008))).

226. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340–41 (3rd Cir. 2009) (FDA’s informal policy statements on the use of the word “natural,” as well as several warning letters in which the FDA told a manufacturer to remove the term “natural” from a product’s label, did not give FDA’s policy the weight of law necessary to preempt state law); *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1074–76 (E.D. Cal. 2010) (following *Holk*, 575 F.3d 329).

it furthers federal objectives in a number of ways and is supported by California's compelling interest in protecting the health and safety of its citizens. Equally, a court could find that the law does not survive a preemption challenge because it deliberately exceeds the federal scheme established by the FDA after forty years of consideration. This analysis highlights how the law in this area is unsettled; states such as California that legislate beyond federal standards run the risk of courts invalidating their legislation on preemption grounds. This risk of invalidation underscores the threat preemption poses to the valuable problem-solving processes of experimentation and the fruits of data collection and pooling. The only legislation in the country that currently meaningfully addresses this critical issue is at risk of being invalidated: Preemption in this context could have deleterious effects on solving the antibiotic resistance crisis.

### B. Democratic Experimentalist-Informed Preemption Doctrine

Rather than limiting or threatening democratic experimentalism, in certain contexts such as this one preemption doctrine should encourage its valuable problem-solving processes. As Justices Brandeis and O'Connor have both noted, "[o]ne of federalism's chief virtues, of course, is that it promotes innovation by allowing for the possibility that 'a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.'"<sup>227</sup> Democratic experimentalist theory contends that policy experimentation is central to optimal policy choices in certain areas.<sup>228</sup> This theoretical framework can therefore help promote the virtues of federalism, as conceived by Justices Brandeis and O'Connor, by informing preemption doctrine and bolstering the argument against federal preemption in these certain areas.

What, then, are these certain areas? They can be categorized as "knowledge-intensive" and scientifically uncertain—where the impediment to effective lawmaking is not ignorance of some but uncertainty of all, and significant empirical data are needed to identify solutions. Expertise is insufficient to solve problems whose solutions are uncertain and involve unsettled scientific or social scientific questions. In these areas, amassing knowledge via experimentation, data pooling, and multi-stage, continuous feedback policymaking is critical to problem-solving.<sup>229</sup> As a result, these policy areas are unlikely to be resolved by

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227. *Gonzales v. Raich*, 545 U.S. 1, 42 (2005) (O'Connor, J., dissenting) (quoting *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)).

228. Bertrall L. Ross II, *Embracing Administrative Constitutionalism*, 95 B.U.L. REV. 519, 557 (2015).

229. See Gubler, *supra* note 95, at 129–31.

command-and-control legislation but are perfect candidates for democratic experimentalist legislation. Knowledge-intensive and scientifically uncertain issues may include, for example, antibiotic resistance, pollution, police abuse, education, housing, and welfare.<sup>230</sup> Where the issue at stake is a public good or significantly threatens public health, as in the case of antibiotic resistance, the argument is even stronger in favor of the democratic experimentalist approach because of the acute need for efficient and swift solutions and the unlikelihood that other forms of legislation or private actors will provide them rapidly enough of their own accord.

Other areas that could raise preemption questions can be differentiated from knowledge-intensive issues. For example, one policy area that might raise preemption questions can be thought of as “values-based”: Society must make a collective judgment about the types of values it wishes to promote and enshrine in law. These policy areas might include gay marriage, civil rights, and abortion. In these cases, allowing for experimentation at the local level would not yield any relevant information in terms of how best to legislate to achieve a certain goal and so democratic experimentalist-informed preemption doctrine would not apply. No amount of data pooling or empirical testing will inform how best to legislate in these areas; the legislation ultimately must reflect a collective societal value judgment. If there are benefits to be gained from allowing differing local laws, they are not experimental in nature. In knowledge-intensive policy areas, there is an articulated goal to be reached—for example, reducing antibiotic resistance in humans, alleviating police abuse, improving education—and the pathway to achieving that goal is an unclear scientific or social scientific question. In values-based policy areas, there is a collective value judgment to be made and reflected in law—for example, whether the state should recognize same-sex marriage, what should be considered a protected class under the law, and whether abortion should be permissible. Command-and-control legislation does not have the same trouble in these contexts that it does in knowledge-intensive contexts. The democratic experimentalist-informed preemption doctrine is thus narrow in scope: It should afford deference to experimental approaches only in knowledge-intensive policy areas, as defined above, and not sweepingly. In these knowledge-intensive areas, the democratic experimentalist theoretical framework bolsters the argument against preemption. Preemption doctrine should evolve to favor democratic experimentalism in these contexts.

Historical precedent exists for the potential of experimentalist state action to effect largescale change to improve the food system and public health. Legislative

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230. See generally Sabel & Simon, *supra* note 91.

action in food law and policy at the state level has helped spur significant change not only statewide, but also nationally as other states follow the first state or municipality's example. Examples of this phenomenon include the trans fat ban, menu labeling requirements, states adopting nutrition standards, farm to school laws, healthy food financing to incentivize locating grocery stores in certain areas, and cage-free egg laws.<sup>231</sup> To demonstrate the effect state and local action can have, take for example the trans fat ban experience. In 2006, New York City's Board of Health banned trans fat in restaurant food.<sup>232</sup> Philadelphia followed suit shortly after with its own ban,<sup>233</sup> followed by Boston in 2008.<sup>234</sup> Also in 2008, California became the first state to ban trans fat in restaurants, effective January 2010.<sup>235</sup> Just five years later, in 2015, the FDA issued a final determination revoking "generally recognized as safe" (otherwise known as GRAS) status for trans fat, finding that there is no safe amounts of trans fat that should be consumed.<sup>236</sup> By June 2018, all trans fat will be removed from prepared foods in the United States.<sup>237</sup> In less than ten years, the local and state actions in this area led to a national ban, highlighting the impact this type of experimentalist state action can have. It is critical to rethink how democratic experimentalist theory should inform federal preemption doctrine in knowledge-intensive and scientifically uncertain contexts so that it encourages, rather than threatens, local experimentation structured by central coordination and monitoring, in order to solve pressing policy problems—particularly those that involve threats to public health. Bolstering state laws in this way will encourage more frequent engagement in layered democratic experimentalist endeavors, with promising potential.

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231. See, e.g., Act Relative to School Nutrition of 2010 (codified as amended in scattered sections of the Mass. Gen. Laws); Farm to School Procurement Act of 2012 (as codified in ALA. CODE § 16-1-46 (2012) and as amended in ALA. CODE § 16-13B-2 (2012)); Healthy Food Retail Act of 2009 (as codified in LA. STAT. ANN. § 3:296); California Healthy Food Financing Initiative of 2011 (as codified in CAL. HEALTH & SAFETY CODE §§ 104660–64 (West 2006)); Standards for Confining Farm Animals/Prevention of Animal Cruelty Act (as codified in CAL. HEALTH & SAFETY CODE §§ 25990–94 (West 2010)).
232. See DEPT. OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF AN AMENDMENT (§ 81.08) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE, <https://web.archive.org/web/20070115114212/http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf> [<https://perma.cc/WVC8-U99B>].
233. Phila., Pa., HEALTH CODE § 6-307 (2015).
234. See BOS. PUB. HEALTH COMM'N, A REGULATION TO RESTRICT FOODS CONTAINING ARTIFICIAL TRANS FAT IN THE CITY OF BOSTON, [http://www.bphc.org/boardofhealth/regulations/Documents/Trans\\_Fat\\_Regulation.pdf](http://www.bphc.org/boardofhealth/regulations/Documents/Trans_Fat_Regulation.pdf) [<https://perma.cc/S46A-M929>].
235. CAL. HEALTH & SAFETY CODE § 114377 (2009).
236. Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650 (June 17, 2015).
237. *Id.*

### C. Lessons for States

States are important agents of change in food and health law and policy, often advancing the field where the federal government is cumbersome, slow, or ineffective. The experience of the California antibiotics law provides lessons for states, as well as other players in state and local policy, that wish to legislate effectively to improve food systems and public health. As the deputy director of the Antibiotic Resistance Action Center at George Washington University has stated, “this is a very, very good bill.”<sup>238</sup> This Part explores best practices for states to consider when legislating to improve food systems, both in antibiotics and beyond. This Part addresses both *ex ante* factors that should be considered prior to embarking on drafting the law itself and engagement in a deliberative writing process that maximizes the chances of the law being upheld if challenged.

#### 1. The Ex Ante Process and the Role of Popular Opinion and Scientific Evidence

An important lesson from the California antibiotics law is the value of making a deliberative policy choice when considering in which areas to legislate. One way to avoid invalidation of a law is to avoid it being challenged at all. Selecting a topic that is politically or popularly ripe is a key strategy to help avoid challenge. In addition, to gain the bolstering effect that democratic experimentalism may or should offer, legislatures should be sure to select policy areas that are appropriate for this type of legislative approach. Selecting a policy area for which democratic experimentalism can offer a helpful framework can strengthen the law by providing a sound theoretical basis for its purpose. Not only, then, can the democratic experimentalist approach help provide improved substantive outcomes, it also offers procedural promise in helping justify and uphold laws in certain well-suited policy areas.

For example, in the policy issue at hand, the tide of public opinion is turning against the use of antibiotics in meat and several large food companies have now committed to phasing out the use of antibiotics in their products over the next decade.<sup>239</sup> This turn of events forces their suppliers to change their production practices to meet the anticipated large demand from McDonald’s, Subway, Panera, and numerous other companies. It may not be politically palatable for

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238. Alex Zielinski, *California Takes a Stand on Antibiotics in Livestock*, THINKPROGRESS (Nov. 4, 2015), <http://thinkprogress.org/health/2015/11/04/3719085/ca-antibiotics-ban-influence> [https://perma.cc/BS4U-THHU].

239. See, e.g., Hackett, *supra* note 77; Strom, *supra* note 77.

meat producers to challenge the California law given that demand from companies and from the public is turning against the use of antibiotics in animal agriculture. The poultry and the beef industry groups in California have both stated that this movement toward phasing out the use of antibiotics is inevitable and reflects the trajectory of industry practice.<sup>240</sup> As opposed to five years ago when the industry denied that antibiotics were a problem, the political climate today has changed significantly, and industry, including both livestock producers and restaurant chains, acknowledge that they now “care about antimicrobial resistance.”<sup>241</sup>

To take another example, California recently passed two laws that require that egg-laying hens “be confined only in ways that allow these animals to lie down, stand up, fully extend their limbs and turn around freely,” and that ban the sale of eggs from hens not confined to those standards.<sup>242</sup> The law was challenged for improperly burdening interstate commerce and under implied preemption grounds.<sup>243</sup> It was not industry that challenged the law, however; six other states sued California.<sup>244</sup> The case was dismissed for lack of standing.<sup>245</sup> It has been suggested that egg producers have not, and perhaps will not, challenge the laws because of the potential “public relations debacle” that would ensue from shedding light on industrial farming practices.<sup>246</sup> The egg producers’ support of a provision in the 2014 Farm Bill that would have phased out the use of close confinement cages if passed suggests that industry players may have strategically decided to concede this issue. The time for California’s legislation was therefore ripe—even if the law does improperly burden interstate commerce or is preempted, it is unlikely a court will ever rule on the merits of the case because the implicated industry decided it was not in its best interest to challenge the law. California’s timing for passing legislation on this issue was prescient and could contribute to the law’s permanence despite its potential legal shortcomings.

The California antibiotics law also showcases the value of taking into account the strength of the relevant federal regime and prior case law. The federal regime is murky in the area of antibiotics, consisting of a federal statute and voluntary agency guidelines. Furthermore, the minimal prior case law in this area involves

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240. Zielinski, *supra* note 238.

241. *Id.*

242. Proposition 2, Standards for Confining Farm Animals (Cal. 2008), <http://www.smartvoter.org/2008/11/04/ca/state/prop/2> [<https://perma.cc/69CW-7QAG>]; Bill No. AB 1437 (Cal. 2009), [http://leginfo.ca.gov/pub/09-10/bill/asm/ab\\_1401-1450/ab\\_1437\\_bill\\_20100706\\_chaptered.html](http://leginfo.ca.gov/pub/09-10/bill/asm/ab_1401-1450/ab_1437_bill_20100706_chaptered.html) [<https://perma.cc/S5PE-E6JD>].

243. *Missouri v. Harris*, 58 F. Supp. 3d 1059, 1065 (E.D. Cal. 2014).

244. *Id.* at 1062.

245. *Id.* at 1063.

246. Diana R.H. Winters, *The Benefits of Regulatory Friction in Shaping Policy*, 71 FOOD & DRUG L.J. 228, 233–34 n.32 (2016).



distinguishable fact patterns from two district court cases, including one case from outside of California that was decided thirty years ago.<sup>247</sup> The lack of clear preemptive effect and compelling prior case law bolsters the California antibiotics law. Lawmakers may be well served to attempt to replicate these circumstances to the extent possible when selecting areas in which to legislate in the future.

The lesson from these two California legislative experiences relates to the ex ante process of legislating, cautioning lawmakers to carefully vet and select issues for legislation after considering the salience of the issue in the public arena and the current state of public opinion, the potential democratic experimentalism can offer as a legislative approach, the federal regime in place, and the strength of the case law on point.

## 2. Substantive Law Writing

The California law also shows the benefits of deliberative, calculated law writing to maximize the chances of success if challenged. First, it is important to identify and explicitly articulate compelling legislative objectives. Protecting health and safety is among the most compelling state objectives; in these cases, courts begin with the presumption that “state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause.”<sup>248</sup> In contrast, laws that aim to protect animal welfare and even the environment are not afforded the same deference.<sup>249</sup> Lawmakers seeking to enact laws to protect health and safety should therefore explicitly articulate this purpose and point to their basis for concern, particularly where there is strong scientific evidence available, to help boost the law’s chance of success. In addition, when states are also legislating via democratic experimentalist processes, they should also link this legislative approach with the compelling state objective in health and safety. Doing so can serve to mutually reinforce both democratic experimentalism as a valuable state process, and protecting public health and safety as a legitimate state aim. Linking democratic experimentalism and the protection of health and safety can bolster

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247. See *Animal Legal Def. Fund Bos., Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 278 (D. Mass. 1986), *aff’d*, 802 F.2d 440 (1st Cir. 1986); *Ass’n des Éleveurs de Canards et d’Oies du Québec v. Harris*, 79 F. Supp. 3d 1136 (C.D. Cal. 2015).

248. *Hillsborough Cty. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 715 (1985).

249. See, e.g., *Animal Legal Def. Fund Bos., Inc.*, 626 F. Supp. at 280; *Ass’n des Éleveurs*, 79 F. Supp. 3d at 1147; *Metro. Taxicab Bd. of Trade v. City of New York*, 633 F. Supp. 2d 83 (S.D.N.Y. 2009), *aff’d*, 615 F.3d 152, 158 (2d Cir. 2010) (holding that city regulations relating to fuel economy standards were preempted by the Energy Policy and Conservation Act and the Clean Air Act). *But see Cavel Int’l, Inc. v. Madigan*, 500 F.3d 551, 557–59 (7th Cir. 2007) (finding that prolonging the lives of horses by banning horse slaughter is a legitimate state interest, and ultimately finding that FMIA does not preempt).

both as more and more states use these justifications to support their legislative efforts.

Other law writing strategies that can maximize the chance of surviving a challenge are to tailor legislation to prior case law and, relatedly, to avoid burdening interstate commerce. California legislators have done so in SB-27, for example, by banning subtherapeutic use of antibiotics in the state while not banning the sale of meat treated with subtherapeutic antibiotics. Making this distinction in the law avoids burdening interstate commerce and implicating the dormant commerce clause, helping maximize the law's chances of survival given the willingness of courts to invalidate laws that discriminate against out-of-state producers.<sup>250</sup> Making this distinction also indicates that California has taken seriously the lessons from the courts in *Association des Éleveurs de Canards et d'Oies du Québec v. Harris*.<sup>251</sup> By not banning the sale of meat—and thereby not conditioning the sale of meat on a certain process of production, broadly interpreted as an ingredient requirement—California increases the chances that the law will not run afoul of *Association des Éleveurs* and will not be found to trigger the express preemption clauses under FMIA and PPIA.<sup>252</sup> Because courts have found that there is a comprehensive, preemptive federal regime regulating the sale of meat in interstate commerce, California's purposeful approach in legislating to make its intent clear serves the state well in avoiding implicating that regime. By tailoring its legislation to prior case law, California has set an example for other states that wish to pursue a legislative solution to the problem of antibiotic resistance.

## CONCLUSION

The use of antibiotics in food-producing animals in the United States poses a serious threat to public health. For the past several decades, the livestock and poultry industries have relied on administering routine, low doses of antibiotics to food-producing animals as a cheap method of promoting faster growth and to sustain their cramped and unsanitary system of production. The result has been

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250. The Dormant Commerce Clause prohibits states from imposing unreasonable burdens on interstate commerce. See *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 392 (1994) (“Discrimination against interstate commerce in favor of local business or investment is *per se* invalid, save in a narrow class of cases in which the municipality can demonstrate, under rigorous scrutiny, that it has no other means to advance a legitimate local interest”); *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 529–30 (1959) (holding that an Illinois statute requiring the use of a specific type of mudguard on trucks and trailers rather than customary straight mudguards placed an unconstitutional burden on interstate commerce despite being a nondiscriminatory local safety measure).

251. See *Ass'n des Éleveurs*, 79 F. Supp. 3d at 1146; see also *supra* note 190.

252. See *Ass'n des Éleveurs*, 79 F. Supp. 3d at 1146.

the rapid spread of antibiotic-resistant bacteria among food-producing animals, which is then transferred to humans through various environmental and foodborne means. Because this system is thought to boost industrial agriculture's profit margin and because scientists lack data to bring transparency to the extent of the threat these practices pose, the practices have been allowed to continue. For years, the federal government has neglected to act while the negative impact of antibiotic-resistant bacteria has grown and now threatens to become an untenable public health crisis. After years of impasse, California has become the first entity to break through the political gridlock and enact meaningful legislation banning the use of antibiotics in food-producing animals for both production *and* disease prevention purposes. For the first time ever in the United States, a law will require data collection on antibiotic use that will help equip scientists, policymakers, and firms with the evidence they need to craft effective laws and practices to combat human antibiotic resistance. The scientific uncertainty in how best to reduce antibiotic use efficiently and effectively means this problem is not one for traditional command-and-control legislation to solve. Instead, layered democratic experimentalism offers a powerful framework for problem-solving in this context.

California's law, if implemented strategically and robustly and using a layered democratic experimentalist framework, has groundbreaking potential. Not only might it significantly reduce dangerous antibiotic use in California, it could also enable, for the first time in the United States, more accurate tracking of the problem and data pooling on best local practices to solve it. This approach could result in more effective and better-shared solutions. This new, layered iteration of democratic experimentalism would harness the power of private firm innovation within a system of centralized, coordinated data sharing facilitated by the state, all under the umbrella of an articulated federal objective. Because California is a large and influential state—and has the third largest livestock industry in the country—the effect of this law and this theoretical framework for implementing the law could extend beyond state borders, affecting meat production not only in California but also nationally. If other states follow suit with their own legislation and data collection, state experiences could be compared and best legislative practices would begin to emerge.

Despite a strong case against preemption, however, the California law is at risk of invalidation on preemption grounds. Both because there is an overwhelming state interest in protecting public health in this area and because the law does not impede federal objectives—and indeed, actually furthers them—it should not be invalidated on preemption grounds if challenged. Even so, a court could plausibly find either way on the matter. Democratic experimentalism, however, provides a basis for rethinking federal preemption doctrine in this

context, bolstering the argument against preemption. Preemption doctrine should evolve to favor the democratic experimentalist approach in these contexts where the problem at issue is knowledge-intensive and marked by scientific uncertainty, and particularly where there is a threat to public health.

The tide of public opinion in the United States is shifting against the routine use of antibiotics in livestock. Several major companies have committed to eliminating or reducing meat raised with antibiotics in their supply chains over the next decade, but we cannot afford to solely rely on voluntary private action from major food companies to address this serious threat to public health. Nor can we afford to do so on the leisurely timetable of a decade or more that these companies have set forth. If the federal government continues to refuse to act, the fate of state action in this area is of critical concern. California's law is an important first step in the right direction. It must be implemented effectively to ensure optimal effect, and it must be joined by other states if we are to successfully address this looming public health crisis. Legally requiring judicious use of antibiotics in livestock across the United States and for meat entering the United States is vital to protecting human health from the ongoing threat of antibiotic-resistant bacteria and to reducing antibiotic use worldwide. Applying a layered democratic experimentalist framework and using that framework to bolster the argument against preemption could have considerable effect on both the state of human health in the decades to come as well as on the manner in which we legislate to solve the pressing problems of our time.