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An International Model for Antibiotics Regulation

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ABSTRACT

We face a global antibiotics resistance crisis. Antibiotic drugs are rapidly losing their effectiveness, potentially propelling us toward a post-antibiotic world. The largest use of antibiotics in the world is in food-producing animals. Food producers administer these drugs in routine, low doses—the types of doses that are incidentally the most conducive to breeding antibiotic resistance. In general, individual countries have been too slow to act in regulating misuse and overuse of antibiotics in food-producing animals. This problem will only worsen with the significant projected growth in meat consumption and production expected in emerging economies in the near future. Although individual countries regulating antibiotics can have important effects, one country alone cannot insulate itself entirely from the effects of antibiotic resistance, nor can one country solve the crisis for itself or for the world. The global nature of the food system and the urgency of the problem require immediate global solutions. Adapting a democratic experimentalist approach at the international level can help achieve this goal. Using an international democratic experimentalist framework in conjunction with the World Organization for Animal Health (OIE) would provide for increased systematized data collection and lead to heightened, scientifically informed OIE standards, enforceable by the World Trade Organization (WTO), which could have a significant impact on the reduction of subtherapeutic use of antibiotics internationally. International democratic experimentalism addresses the global intricacy, time sensitivity, context- and culture-specificity, and knowledge-intensiveness of this problem. By encouraging more countries to experiment to solve this problem, the democratic experimentalist model would help develop a larger database of solutions to enable more meaningful cross-country comparisons across a wider range of contexts. This approach maintains democratic governance and legitimacy while maximizing data collection, efficiency, translatability, transparency, and information-sharing. Adapting democratic experimentalism internationally can enable the kind of concerted international effort required to address the pressing problem of antibiotic resistance.

INTRODUCTION

Antibiotics are a critical component of modern medicine, commonly used to treat infectious diseases. Troublingly, these drugs, also known as antimicrobials, are rapidly losing their effectiveness. As a result, we are advancing toward a post-antibiotic world

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in which basic infections that were once easily treated are becoming increasingly dangerous. At this rate, common illnesses will become potentially deadly and more complex procedures that we now take for granted in modern medicine—such as chemotherapy, surgeries, and dialysis—will carry untenable risk.[1] Already antibiotic resistance has placed significant burdens on the healthcare system in the United States and globally.[2] This situation stands only to worsen: future projections are even more alarming for the United States and Europe and most especially for the developing world.[3]

The overuse and misuse of antibiotics speeds the growth of antibiotic resistance and has created the grave threat to public health we face today. One of the epicenters for the excessive and inappropriate use of antibiotics, which may contribute significantly to the spread of antibiotic resistance, lies in the modern industrial agriculture system. The vast majority of antibiotics sold in the United States each year—an estimated 70–80 percent—are for use in animal agriculture.[4] These antibiotics are primarily administered subtherapeutically 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 are incidentally the most conducive to breeding antibiotic-resistant bacteria. Although some level of antibiotic resistance is a naturally occurring phenomenon that is scientifically inevitable, this type of misuse accelerates the process. Resistant bacteria then get transmitted to humans through various mechanisms and reduce the efficacy of antibiotic drugs in humans.

The global community has recognized this serious threat for decades, and it has been met with varying levels of action from governments. However, even with the recognition of the severe threat posed, by 2030 global consumption of antibiotics in food-producing animals is projected to increase by about 67 percent.[5] Studies have shown that, by conservative estimates, 300 million people are expected to die from

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1 U.S. DEP'T OF HEALTH & HUMAN SRVS., CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 24 (2013), http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf [hereinafter ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES].

2 EUROPEAN COMM'N, *Antimicrobial Resistance* (2016), http://ec.europa.eu/dgs/health_food-safety/amr/index_en.htm [hereinafter EUROPEAN COMM'N, *Antimicrobial Resistance*]; 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 DISEASES 1175, 1175–84 (2009).

3 Thomas P. Van Boeckel et al., *Global Trends in Antimicrobial Use in Food Animals*, 112 PROC. NAT'L ACAD. OF SCI. U.S., 5649, 5649 (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); EUROPEAN COMM'N, AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE 1, http://ec.europa.eu/dgs/health_food-safety/docs/amr_factsheet_en.pdf [hereinafter AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE].

4 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 [https://perma.cc/ST97-JHH2] [hereinafter INDUSTRIAL FOOD ANIMAL PRODUCTION]; *See also* 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].

5 EUROPEAN COMMISSION, AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE 1, http://ec.europa.eu/dgs/health_food-safety/docs/amr_factsheet_en.pdf [hereinafter AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE].

antibiotic resistance between 2014 and 2050 at a cost of between $60–$100 trillion—the equivalent to a loss of about one year's total global output.[6] To address the escalating problem of antibiotic resistance in humans, it is imperative to reduce the subtherapeutic use of antibiotics in food-producing animals.

Various countries and entities have experimented with legislation and regulation around antibiotics—some with great success, and others falling short. The vast majority of countries, however, have taken little or no action on the matter. Indeed, at present only 25 percent of countries have implemented a national policy to address antibiotic resistance.[7] Some countries, such as Sweden and Denmark, acted decades ago to curtail dangerous antibiotics use in food-producing animals.[8] The European Union banned the use of antibiotics in food-producing animals for growth promotion purposes in 2006, but still allows their use for disease prevention.[9] In contrast, for 18 years the U.S. Congress has failed to pass a bill, reintroduced each year, that would prohibit the subtherapeutic use of antibiotics.[10] Forty years after threatening to withdraw approval for subtherapeutic use of antibiotics, the U.S. Food and Drug Administration (FDA) has failed to follow through, instead promulgating a set of voluntary guidelines for industry to follow.[11] California, however, has passed the first and only state law in the United States prohibiting the subtherapeutic use of antibiotics in food-producing animals, both for growth promotion and disease prevention purposes.[12] The law will take effect in 2018, and indicates the variation that can occur in regulating antibiotics even within the same country.[13]

The problem of antibiotics resistance is not confined to domestic borders. Once bred, resistant bacteria spread rapidly around the world: a resistant strain of bacteria found in a pig in China can surface just weeks later in Europe, Africa and other parts of Asia.[14] For this reason, domestic solutions alone will not suffice to solve the

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6 AMR REVIEW, TACKLING A CRISIS FOR THE HEALTH AND WEALTH OF NATIONS, 7 (2014), https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf.

7 AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, *supra* note 5.

8 Carol Cogliani et al., *Restricting Antimicrobial Use in Food Animals: Lessons from Europe*, 6 MICROBE 274, 274 (2011), http://emerald.tufts.edu/med/apua/research/pew_12_846139138.pdf.

9 Commission Regulation 1831/2003 of Sept. 22, 2003, On Additives for Use in Animal Nutrition, art. 11, 2003 O.J. (L 268) 29, 36 (EC).

10 Preservation of Antibiotics for Medical Treatment Act of 2015, H.R. 1552, 114th Cong. (2015), https://www.govtrack.us/congress/bills/114/hr1552/text; Press Release, Congresswoman Louise M. Slaughter, https://louise.house.gov/media-center/press-releases/rep-slaughter-only-microbiologist-congress-reintroduces-legislation-save.

11 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 also* Diana R. H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA*, 90 IND. L.J. 1047 (2015); 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].

12 *See* S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015).

13 *Id.*

14 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].

problem of antibiotic resistance. There must be concerted international action and information-sharing in order to address this grave threat, which does not know international boundaries. Particularly with the current and projected rise of meat consumption in emerging economies such as Brazil, China, and India,[15] ensuring judicious use of antibiotics in food-producing animals at a global level grows ever more critical.

It is unclear, however, which laws, regulations, and practices will best help reduce the use of antibiotics in food-producing animals. Because this problem is knowledge-intensive—that is, requires significant amounts of information to solve—and is characterized by scientific and social scientific uncertainty, it is not one for traditional command-and-control legislation to solve. When there is no clear solution to mandate legislatively, command-and-control legislation will fall short.

At the domestic level, democratic experimentalist theory offers a promising framework for addressing the 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 provide data on their performance to the central institution to pool and compare. The central institution assesses local performances and re-benchmarks accordingly.[16] This approach has clear benefits for problems that are knowledge-intensive and have scientifically uncertain solutions. It allows for experimentation, data gathering, and comparisons across contexts to efficiently and swiftly identify as yet unknown solutions.

Given its promise, and given the imperative to address antibiotics resistance in a concerted way globally, the democratic experimentalist framework should be adapted from the domestic context to the international level. Adding this additional international layer to the democratic experimentalist framework could significantly bolster the effort against antibiotics resistance.

Part II of this paper provides brief background on the history of antibiotics and the rise of antibiotics resistance, situating the issue as a critical threat to global public health. Part III provides an overview of global regulation of antibiotics. Part IV identifies democratic experimentalism as a key approach for addressing antibiotics resistance at the domestic level and argues for adapting this framework to the international context. It contends that a democratic experimentalist-informed international approach could be critical to ensuring public health and safety globally. Part V anticipates and addresses potential counter-arguments.

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15 Thomas P. Van Boeckel et al., *Global Trends in Antimicrobial Use in Food Animals*, 112 PROC. NAT'L ACAD. OF SCI. U.S., 5649, 5649 (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).

16 Emilie Aguirre, *Contagion Without Relief: Agency Action and the California Antibiotics Law*, 64 UCLA L. REV. 548, 553 (forthcoming 2017).

I. ANTIBIOTICS RESISTANCE: THE PROBLEM

A. History of Antibiotics and Their Introduction to Agriculture

The discovery of antibiotics was considered a miracle, enabling the curing of once deadly infectious diseases almost instantaneously.[17] Life-saving medical procedures, including surgery, chemotherapy, transplants, and kidney dialysis, are now commonly available because of antibiotic drugs that treat the risk of infection inherent to these procedures.[18]

It is not only humans who consume antibiotic drugs. In fact, in the United States, an estimated 70–80 percent of antibiotic drugs are used not on humans but in animal agriculture.[19] The vast majority of drugs used in food-producing animals are administered in animal feed in low, routine, subtherapeutic doses to promote growth and prevent disease.[20] They are not primarily used to treat specific instances of bacterial infection as they arise.[21]

Farmers discovered in the 1940s that using pharmaceutical waste as a protein source in animal feed sped animal growth without requiring additional feed.[22] Further investigation revealed that it was the antibiotic drugs in the pharmaceutical waste that were increasing feed efficiency. This discovery led to the widespread use of routine low doses of antibiotics in animal agriculture.[23] Simultaneously, as modern industrial agriculture expanded, demand for improved efficiency led to increasing concentrations of animals and attendant decreases in sanitary conditions.[24] This extreme crowding and lack of sanitation placed animals at greater risk of infection.[25] To prevent the spread of disease throughout highly concentrated flocks and herds, producers would rely on routine prophylactic use of antibiotics.[26] The appeal of antibiotics was therefore twofold, increasing animal growth using the same amount of feed, and enabling reduced sanitation and the high concentration of animals.[27]

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17 *See, e.g.*, Stuart B. Levy, *The Challenge of Antibiotic Resistance*, 278 SCI. AM. 32, 32 (Mar. 1998), http://emerald.tufts.edu/med/apua/about_issue/Scientific%20American.pdf ("Ever since antibiotics became widely available in the 1940s, 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 UNITED STATES, *supra* note 1.

19 Heinzerling, *supra* note 4, at 1010–12; *Livestock: Use of Antimicrobial Drugs*, Senate Floor Analyses, Senate Rules Committee (Sept. 11, 2015); INDUSTRIAL FOOD ANIMAL PRODUCTION, *supra* note 4, at 2; *See also* Casey et al., *supra* note 4.

20 Ellen K. Silbergeld et al., PEW COMM'N ON INDUS. FARM ANIMAL PROD., ANTIMICROBIAL RESISTANCE AND HUMAN HEALTH 21 (Pew 2008), http://www.pewtrusts.org/~/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/industrial_agriculture/pcifapantbiorprtvpdf.pdf [https://perma.cc/8JXD-S4VJ] [hereinafter PEW COMM'N].

21 *Id.*

22 *Id.* at 24.

23 *See*, *e.g.*, *id*.

24 *See*, *e.g.*, *id*.

25 *Id.*; KENNETH H. MATHEWS, JR., USDA ECON. RESEARCH SERV., ANTIMICROBIAL DRUG USE AND VETERINARY COSTS IN US LIVESTOCK PRODUCTION 3 (May 2001), ("It is generally conceded that commercial livestock production in the United States, especially confinement production, would be virtually impossible without antimicrobial drugs.").

26 PEW COMM'N, *supra* note 20, at 21.

27 *Id.* at 21.

B. *The Rise of Antibiotic Resistance*

Antibiotic resistance is a scientifically inevitable natural phenomenon.[28] When antibiotic drugs kill bacteria, some bacteria that are resistant to the drugs can survive and reproduce.[29] Administering routine subtherapeutic doses of antibiotics speeds this process considerably, breeding antibiotic-resistant bacteria at much faster rates.[30] Over the past 75 years of antibiotic use, the length of time that it takes between discovering a new antibiotic drug and discovering antibiotic-resistant bacteria to that drug has contracted considerably. For example, tetracycline was introduced in 1950 and tetracycline-resistant Shigella was not identified until 1959.[31] By comparison, the drug 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.[32] Most recently, in November 2015, scientists discovered bacteria resistant to colistin in China.[33] Doctors prescribe colistin as a drug of last resort—that is, 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, Africa, and throughout Asia.[34] In addition, scientists have increasingly identified pan-drug resistant bacteria, which are resistant to all available antibiotics.[35] Thomas R. Frieden, director of the Centers for Disease Control (CDC), remarked in a 2010 speech before Congress that "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."[36]

The rise of antibiotics resistance is a significant problem. It leads to increased healthcare costs, prolonged hospital stays of one to two extra weeks, treatment failures, and a number of deaths each year.[37] In the US alone, over two million Americans acquire serious antibiotic-resistant infections each year and at least 23,000 die as a

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28 *Id.* at 9.

29 *Id.*

30 *Id.*

31 ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, *supra* note 1, at 28.

32 *Id.*

33 James Gallagher, *Bacteria That Resist 'Last Antibiotic' Found in UK*, BBC (Dec. 21, 2015), https://perma.cc/572Y-9Y54.

34 *Id.* Although the current threat is low because other antibiotics can still treat the colistin-resistant bacteria, the existence of colistin-resistant bacteria is significant because it raises the prospect of untreatable infections in the future.

35 ANTIBIOTIC RESISTANCE THREATS IN THE US, *supra* note 18, at 28; *Antibiotic Resistance and the Threat to Public Health*, Committee on Energy and Commerce Subcommittee on Health, U.S. House of Representatives (April 28, 2010) (statement of Thomas R. Frieden M.D., M.P.H Director Centers for Disease Control and Prevention U.S. Department of Health and Human Services (HHS)), https://perma.cc/P7F2-BJJF. [hereinafter Frieden Statement].

36 Frieden Statement, *supra* note 31.

37 EUROPEAN COMMISSION, *Antimicrobial Resistance*, *supra* note 1; 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 DISEASES 1175, 1175–84 (2009).

result.[38] In the European Union, 25,000 people die each year from antibiotic-resistant infections.[39] Globally, as many as 700,000 people may die each year from antibiotic-resistant infections.[40] If current trends persist, 300 million people worldwide will die prematurely from antibiotic-resistant infections over the next 35 years.[41] Troublingly, Africa and Asia will bear the brunt of the burden of antibiotic resistance, with nearly 90 percent of the projected global deaths occurring on these two continents.[42]

There are also significant economic costs. One study estimated that annual healthcare costs of antibiotic-resistant infections in the United States are between $16.6 and $26 billion, and that the total loss was approximately $35 billion, including lost wages, extended hospital says, and premature deaths.[43] This analysis was performed in 2000, when the rate of reported antibiotic-resistant infections was half today's rate, suggesting these estimates are quite conservative today. In Europe, the healthcare costs and costs associated with lost productivity alone are estimated at over €1.5 billion each year.[44]

Most of the antibiotic drugs used in animal agriculture are the same or substantially similar to those used on humans.[45]Although the relationship between antibiotics use in animal agriculture and antibiotic resistance in humans is complex and difficult to quantify, in the most comprehensive assessment of this question to date, the World Health Organization, Food and Agriculture Organization, and World Organization for Animal Health (OIE) found clear evidence that antibiotic use in food-producing animals was having an adverse effect on human health.[46] Numerous other studies have corroborated this finding, tracing human infection by antibiotic-resistant pathogens back to animal agriculture.[47] To take a real world example, in Denmark, which has

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[38] ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, *supra* note 18, at 6.

[39] EUROPEAN COMMISSION, *Antimicrobial Resistance*, *supra* note 2.

[40] AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, *supra* note 5.

[41] EUROPEAN COMMISSION, *Antimicrobial Resistance*, *supra* note 2.

[42] AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, *supra* note 5.

[43] Roberts et al., *supra* note 33; *Antibiotic-Resistant Infections Cost the U.S. Healthcare System in Excess of $20 Billion Annually*, PR NEWSWIRE (Oct. 19, 2009), https://perma.cc/K7AT-PGTM.

[44] EUROPEAN COMMISSION, *Antimicrobial Resistance*, *supra* note 2.

[45] FOOD AND DRUG ADMIN.DEP'T OF HEALTH AND HUMAN SERVICES, 2014 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 30 (2015), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf [hereinafter FDA]; *see* INDUSTRIAL FOOD ANIMAL PRODUCTION, *supra* note 4, at 2; *see generally* PEW COMMISSION, *supra* note 20; Roberts et al., *supra* note 33.

[46] Henrik C. Wegener, *Antibiotic Resistance—Linking Human and Animal Health*, *in* IMPROVING FOOD SAFETY THROUGH A ONE HEALTH APPROACH: WORKSHOP SUMMARY 331, 334 (Eileen R. Choffnes et al. eds., 2012).

[47] *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).

banned subtherapeutic use of antibiotics in food-producing animals, the prevalence of antibiotic resistance in humans is on the decline since the ban.[48]

Despite these threats to human health, antibiotic use in food-producing animals continues to grow, increasing three percent from 2013 to 2014 and 23 percent from 2009 to 2014 in the United States alone.[49] The urgency of this state of affairs escalates when considering the rising demand for meat in emerging economies, including Brazil, India, and China, which are projected to increase antibiotic use in animal agriculture by 100 percent by 2030.[50] None of these emerging economies has meaningful restrictions on the subtherapeutic use of antibiotics.[51] Given the speed with which antibiotic-resistant bacteria spread worldwide, as illustrated by the colistin example, it will not be enough for a handful of countries to address this issue on their own, nor can countries entirely insulate themselves from this threat through individual action. Antibiotics resistance is a global threat to health; to solve it, a concerted global approach will be necessary.

II. CURRENT REGULATION OF ANTIBIOTICS GLOBALLY: AN OVERVIEW

A. Europe

Despite the necessity for a concerted global effort to address this problem, at present only 25 percent of countries have implemented a national policy to address antibiotic resistance.[52] Countries in Europe have taken the most action in this area. Sweden has the longest history of regulating the overuse of antibiotics. It has collected data on antibiotic use in agriculture since 1980 and it banned the use of antibiotics for growth promotion purposes in 1986.[53] Close to a decade later in 1995, major global pork producer Denmark began regulating agricultural antibiotics use. By 2000 it had banned the use of all antibiotics for growth promotion in animals.[54] Denmark also established a system for monitoring antibiotics resistance in food-producing animals in 1995,

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48 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.

49 FDA, *supra* note 42, at 6.

50 Thomas P. Van Boeckel et al., *Global Trends in Antimicrobial Use in Food Animals*, 112 PROC. NAT'L ACAD. OF SCI. U.S., 5649, 5649 (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).

51 *See* Price, *supra* note 47; 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; 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; *see, e.g.*, Instrução Normativa No. 14, de 17 de Maio de 2012, Diário Official 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).

52 AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, *supra* note 5.

53 Cogliani et al., *supra* note 8.

54 *Id.* at 276.

followed by similar monitoring in humans three years later.[55] As a result of these and other measures, Denmark saw a 51 percent reduction in antibiotics use in pigs and 90 percent reduction in poultry, while increasing pork production by 47 percent and slightly increasing poultry production.[56] Denmark remains one of the world's top exporters in pork and is now regarded worldwide as the gold standard in antibiotics regulation and the judicious use of antibiotics in animal agriculture.

In 2006, the European Union banned the use of antibiotics for growth promotion purposes.[57] There is no ban, however, on subtherapeutic use of antibiotics for disease prevention purposes. Countries within the European Union are free to regulate beyond this floor set and several have. As a result, there is significant variation in antibiotic use in food-producing animals among EU countries, ranging from Cyprus and Spain with the highest use of antibiotics to Sweden and Slovenia with the lowest (Denmark follows closely after).[58] Overall in Europe the results have been mixed, with sales of antibiotics for animal use decreasing in eleven countries but increasing in six.[59]

It may have been expected that such a straightforward piece of command-and-control legislation—an EU-wide ban—would have similar, effective results across countries, or at the very least would help reduce antibiotics use on the whole in the European Union. Such was not the case, as the Netherlands' experience illustrates.

The 2006 EU-wide ban had unexpected and troubling results in the Netherlands. After the ban, antibiotics use there stayed constant, as producers increased their so-called therapeutic uses of antibiotics to compensate for the decrease in subtherapeutic use.[60] Faced with these results, and armed with the knowledge that Denmark had successfully reduced its antibiotics use with no impact on production and profits, the Netherlands set a target of reducing antibiotics use by 50 percent in three years.[61] Drawing from the Danish experience, it implemented other interventions alongside the ban, including policies to improve relationships between producers and veterinarians, a registration process for veterinary antibiotics prescriptions, and more.[62] The Dutch met their target of 50 percent reduction one year early, without impacting profits or production, illustrating the feasibility of reducing agricultural antibiotic use in a short time without affecting profitability.[63] The Netherlands subsequently set a new target of 70 percent overall reduction in 2015.[64]

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55 *Id.*

56 *Id.*

57 Commission Regulation 1831/2003 of Sept. 22, 2003, On Additives for Use in Animal Nutrition, art. 11, 2003 O.J. (L 268) 29, 32 (EC).

58 AMR REVIEW, ANTIMICROBIALS IN AGRICULTURE AND THE ENVIRONMENT: REDUCING UNNECESSARY USE AND WASTE 16 (2015), https://amr-review.org/sites/default/files/Antimicrobials%20in%20agriculture%20and%20the%20environment%20-%20Reducing%20unnecessary%20use%20and%20waste.pdf.

59 AMR: A MAJOR EUROPEAN AND GLOBAL CHALLENGE, *supra* note 5.

60 Cogliani et al., *supra* note 8, at 276.

61 *Id.*; AMR REVIEW, *supra* note 5, at 17.

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

63 *Id.* at 180; AMR REVIEW, *supra* note 5, at 17.

64 D.C. Speksnijder et al., *Reduction of Veterinary Antimicrobial Use in the Netherlands: The Dutch Success Model*, 62 Zoonoses & Public Health 79, 82 (2015).

The Netherlands experience indicates the shortcomings of command-and-control legislation in this context—even legislation as straightforward as an outright ban—and highlights the importance of experimenting with different approaches, pooling data, and comparing experiences to achieve efficient and cost-effective reductions in antibiotics use in animals.

B. United States

In comparison to the European Union, the United States has taken little to no substantive action in this area. It is perhaps unsurprising that antibiotic use in food-producing animals has increased from 2009 to 2014. A bill called the Preservation of Antibiotics for Medical Treatment Act (PAMTA), which seeks to ban the subtherapeutic use of antibiotics in animals, has languished in Congress for 18 years.[65] It is reintroduced year after year to no avail.

FDA, the federal regulatory agency tasked with approving and regulating all antibiotic drugs, has promulgated a set of voluntary guidelines that recommend 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.[66] The guidelines invite industry to comply but do not require it.[67] They urge against the use of antibiotics for growth promotion purposes but are silent on their use for disease prevention purposes.[68]

The most promising action in the United States has occurred at the state level. In October 2015 California passed the first and only law in the United States banning the subtherapeutic use of antibiotics for both growth promotion and disease prevention purposes.[69] When the law comes into effect in January 2018, it will only be permissible to administer antibiotic drugs to food-producing animals when ordered by a licensed veterinarian through a prescription or through a similar process known as a veterinary feed directive, in the context of a valid veterinarian-client-patient relationship.[70] It will

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65 Preservation of Antibiotics for Medical Treatment Act of 2015, H.R. 1552, 114th Cong. (2015), https://www.govtrack.us/congress/bills/114/hr1552/text; Press Release, Congresswoman Louise M. Slaughter, https://louise.house.gov/media-center/press-releases/rep-slaughter-only-microbiologist-congress-reintroduces-legislation-save.

66 U.S. FOOD & DRUG ADMIN., *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 [hereinafter Guidance #209]; U.S. FOOD & DRUG ADMIN., *Guidance For Industry #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* (2013), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceCompliance Enforcement/GuidanceforIndustry/UCM299624.pdf [hereinafter Guidance #213].

67 Guidance #209, *supra* note 66; Guidance #213, *supra* note 66.

68 *See* Guidance #209, *supra* note 66; Guidance #213, *supra* note 66. FDA has also promulgated a final rule, the Veterinary Feed Directive (VFD), which attempts to legally bind drug sponsors who wish to voluntarily comply with Guidance #209 and #213. Even so, VFD still leaves open the loophole for using the antibiotics for disease prevention purposes. *See* Aguirre, *supra* note 16, at 572.

69 S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015).

70 *Id.* A veterinary feed directive drug is an animal drug intended for use in animal feed that can only be used under veterinary supervision. It can be thought of as an intermediary between a prescription drug

only be permissible to use antibiotic drugs to treat disease, to control the spread of disease, in connection to a surgery or medical procedure, or for prophylaxis in the event of an elevated risk of a particular disease.[71] The law is without a doubt the most progressive legislative action on antibiotics in the United States to date.

C. Emerging Economies

Moving further down the spectrum of antibiotics regulation, China, India, and Brazil all have virtually no restrictions in place on the overuse or misuse of antibiotics in food-producing animals. China and India both have minimal regulations and inadequate monitoring and enforcement on antibiotic use in food-producing animals,[72] and Brazil only has a handful of regulations restricting the use of a few specific antibiotics.[73] With their rising populations, emerging economies, and rapidly increasing demand for meat, these three countries are critical to the future of antibiotics use globally. Achieving the judicious use of antibiotics there will be paramount to successfully addressing the problem of antibiotics resistance in humans worldwide.

III. ANTIBIOTICS AND DEMOCRATIC EXPERIMENTALISM: THE OPPORTUNITY

A. The Domestic Promise of Democratic Experimentalism

Democratic experimentalism offers a framework with important potential for helping solve this difficult problem. Before examining international approaches, it is important to situate democratic experimentalism at the domestic level, where this framework is traditionally understood.

Democratic experimentalism is a process of developing laws and policies by which a central institution sets a common goal and then delegates authority to local institutions to experiment to achieve that goal.[74] Local institutions provide data on their performances to the central institution to pool and compare. The central institution then assesses and compares local performances and uses that information to revise initial benchmarks.[75] Autonomous and decentralized local actors developing efficient and adaptable rules that respond to local conditions is central to the

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and an over-the-counter drug. Veterinary Feed Directive, 80 Fed. Reg. 31,708, 31,708 (June 3, 2015) (to be codified at 21C.F.R. pts. 514, 558), at 31,708.

71 *See* S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015).

72 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; CTR. FOR DISEASE DYNAMICS, ECON., & POL'Y., ANTIBIOTIC USE AND RESISTANCE IN FOOD ANIMALS: CURRENT POLICY AND RECOMMENDATIONS 2 (2016), http://www.cddep.org/sites/default/files/india_abx_report.pdf.

73 Instrução Normativa No. 14, de 17 de Maio de 2012, Diário Official 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).

74 Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 GEO. L.J. 53, 54–55 (2012).

75 *See id.* at 79.

democratic experimentalist model.[76] Democratic experimentalism thus combines respect for local variation with centrally coordinated structure and discipline.[77] In doing so, it enables continuous learning and revision of standards while emphasizing deliberative engagement among stakeholders.[78]

This form of lawmaking has great potential to help solve certain kinds of seemingly intractable problems.[79] To illustrate the point, although the theory has maintained a somewhat low profile in legal scholarship, it has surfaced in practice if not in name in several recent regulatory approaches, including for example the Food Safety Modernization Act and the Race to the Top Education program.[80]

To understand why democratic experimentalism is so important to modern problem-solving, it is important to understand the history and evolution of the administrative state.[81] The modern administrative state was born in a context in which official ignorance was the primary barrier to effective legislation—in the 1930s, Congress did not have adequate expertise to make law in certain areas.[82] To compensate, it created expert administrative agencies and delegated to them the authority to regulate in the relevant areas.[83] Since then, "the problem has shifted from ignorance to uncertainty," such that at present the barrier to effective legislation is not Congressional ignorance or a lack of expertise but rather widespread uncertainty of all on how to solve a new set of difficult modern problems, including for example antibiotics resistance, pollution, police abuse, welfare, education, and more.[84] Solving these problems therefore requires collaboration, experimentation, empirical testing, and information-sharing on potential solutions, highlighting the attractiveness of democratic experimentalist theory and helping explain why it has emerged increasingly, though not explicitly named as such, in recent regulatory initiatives.[85] Democratic experimentalism not only promises improved substantive outcomes, it also gives rise to an improved democratic process for problem-solving and legislating.[86]

The antibiotic resistance problem involves scientific and social scientific uncertainty, is knowledge-intensive, poses a significant threat to public health, is time sensitive, and requires flexibility for local variation, with each type of animal and each locality potentially requiring slightly or markedly different approaches to reduce antibiotic use. For these types of problems policy experimentation is central to optimal

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

77 *See* Sabel & Simon, *supra* note 74, at 78.

78 *See id.* at 55.

79 *See* Charles Sabel, *Dewey, Democracy, and Democratic Experimentalism*, 9 CONTEMP. PRAGMATISM 35, 42 (2012); Sabel & Simon, *supra* note 76, at 55.

80 *See* Sabel & Simon, *supra* note 74, at 55–56.

81 Aguirre, *supra* note 16, at 566–68.

82 *See* Sabel, *supra* note 79, at 42.

83 *Id.*

84 Sabel, *supra* note 76, at 43. *See generally* Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. R. 1016, 1043–47 (2004).

85 *See* Aguirre, *supra* note 16, at 566–67; Sabel, *supra* note 79, at 43.

86 *See* Aguirre, *supra* note 16, at 566–67; Sabel, *supra* note 79, at 43.

policy choices.[87] These problems also require combining experimentation with multi-stage, continuous feedback policymaking to identify solutions, and structured centralized government action that is also flexible enough to account for local circumstances. Lastly, it is critical to solve this problem as quickly as possible, due to the serious threat to public health and the irreversible potential consequences of delay. Antibiotic drug resistance currently outpaces the development of new antibiotic drugs, meaning that current drugs will be rendered obsolete before we discover new ones to replace them. Given these parameters, the democratic experimentalist framework is particularly well-suited for regulating to reduce antibiotic use domestically.[88]

However, because the antibiotic resistance problem transcends international borders, it is critical to pursue a concerted international effort alongside efforts at the domestic level. It is important next to consider whether and how this theoretical framework can be adapted to the international context.

B. International Democratic Experimentalism and Antibiotics Regulation

1. The Importance of an International Democratic Experimentalist Approach

A global effort is important to encourage more countries to begin taking action and experimenting in this area. Denmark, Sweden, and the Netherlands are important models for successfully reducing antibiotics use in food-producing animals, but these northern European solutions may not suitable for some or most other countries or regions. To make meaningful progress more countries must experiment with best practices to reduce antibiotics use in various contexts. Doing so will develop a bigger database of solutions to suit a wider range of countries and localities, ultimately enabling a more diverse range of countries to benefit from each other's experiences. This effort will allow for efficient comparison of experiences in the face of a problem that requires context- and culture-specific solutions as quickly as possible due to the urgency of the public health crisis, especially given the threat that current drugs will be rendered obsolete before we can develop new ones to replace them.

Adapting democratic experimentalism to the international level has particular advantages because it allows for this cross-country comparison and feedback and addresses the time sensitivity and context- and culture-specificity of the problem. The Netherlands example helps illustrate why. When Denmark banned antibiotic growth promoters, it experienced major reductions in antibiotics use in animals and significant production increases.[89] Denmark is now lauded as the gold standard in judicious antibiotics use worldwide. In the Netherlands, a seemingly identical ban failed miserably: animal antibiotic use remained constant after the ban.[90] The Netherlands' comparison of other countries' experiences, especially those of Denmark, revealed the importance of incorporating other interventions.[91] With these new interventions employed alongside the command-and-control legislation, the Dutch met their 50

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

[88] Aguirre, *supra* note 16, at 567–68.

[89] Cogliani et al., *supra* note 8, at 276.

[90] *Id.*

[91] *Id.* at 277.

percent reduction target a year early.[92] The value of comparing its own failed experience with the success of another—of examining why one worked when the other failed, when both policies appeared identical, and when it seemed command-and-control legislation would suffice—was critical to this achievement. When countries share results from experimental approaches, better and speedier results accrue. A democratic experimentalist approach will help systematize the Netherlands-Denmark experience, enabling other countries to share their experiences efficiently, systematically, and democratically. Significant differences—cultural, agricultural, or otherwise—mean that the Danish approach cannot be expected to work everywhere, further highlighting the need for broad-scale international democratic experimentalism.

2. *Key Considerations for Translating the Domestic Framework Internationally*

There are two key considerations to keep in mind when adapting the domestic democratic experimentalist framework to the international context. First, international approaches to regulation must achieve democratic governance to maintain their legitimacy, both perceived and actual. Second, the international framework must strive to produce a system that allows for experiences to be translated as much as possible across contexts, while acknowledging the impossibility of achieving perfect translation due to the deep variations that exist internationally, including in culture, geography, legal systems, and animals raised. It is important to attempt to devise a system to: (i) maximize translatability, especially in light of a proneness to make false assumptions that what works in one context will work everywhere; (ii) maximize transparency and information so that experiences can be assessed for suitability to local circumstances and to maximize replicability; and (iii) understand and acknowledge that we will never achieve perfect translatability, but that the inability to achieve the perfect cannot be made the enemy of achieving the good. With these key considerations delineated, we turn now to adapting democratic experimentalism to the international context.

3. *The Framework*

As is the case domestically, applying a democratic experimentalist framework internationally is a four-step process. In its simplest terms, democratic experimentalism consists of: (i) centralized goal-setting; (ii) delegation of experimentation to achieve that goal to subnational jurisdictions; (iii) centralized data collection on local performance; and (iv) centralized assessment of local performance and revising of initial benchmarks as necessary.[93] Any democratic experimentalist approach, whether domestic or international, will track on to this blueprint.

The first step is a centralized institution setting a common goal. In the international context, the best institutional candidate is the OIE (the World Organization for Animal Health). OIE is an intergovernmental organization with institutional and financial

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

93 Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 GEO. L.J. 53, 54–55 (2012); Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267, 316–17 (1998).

autonomy recognized by the WTO (and by others) as the international authority responsible for addressing animal disease control and improving animal health worldwide.[94] OIE is a reference organization for the WTO, meaning it sets the principal international reference standards for sanitary measures to facilitate safe international trade of animals and animal products.[95] It is governed by a committee of delegates from each of its 180 contracting member governments.[96] Delegates meet once a year in a General Assembly to run the organization and update standards based on the best scientific information available.[97] OIE already does significant work around antibiotics resistance. It has several resolutions related to the use of antibiotics in food-producing animals as well as a section on antibiotics use in each of its two published codes. OIE has identified reducing antibiotics resistance in humans and animals by reducing or eliminating subtherapeutic antibiotic use in animals as an important central goal and is committed to helping its member countries achieve this goal.[98]

The second step is the delegation of experimentation to sub-jurisdictions to achieve the central goal. In the case of international democratic experimentalism, there is no strict delegation because intergovernmental organizations do not delegate powers to sovereign nations. However, the point of this step in this case is less about delegation per se and more about ensuring that sub-levels experiment and that the central institution performs data collection to compare and assess performances. As long as there is a mechanism for ensuring the sub-levels provide data on their experimentation and the central institution collects and assesses this data, the framework achieves the purposes of the second step of democratic experimentalism.

To fulfill the third step—experimentation at the local level followed by centralized data collection by the overarching institution—the OIE can condition yearly participation at the General Assembly on members providing data on whatever efforts are occurring in their home countries. Under this proposal, the data that OIE would collect would take three forms. First, OIE would collect rates of antibiotic use in food-producing animals in each country—in other words, basic tracking or surveillance data. To have a seat at the table and vote on standards that will determine food animal trade policies, member states would be required to share data they collect on their countries' antibiotics use in livestock. In this way, the OIE data collection mechanism would ensure that at the very least members track this phenomenon at the local level so that the extent of the problem can be understood. At present, for example in the United States, there is no surveillance data of this type.[99] It is more difficult to address a problem when the exact details and extent of the problem is unknown.

The second form of data would be any policies or efforts being undertaken in the country to decrease the use of antibiotics in food-producing animals, along with any

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94 OIE: WORLD ORGANIZATION FOR ANIMAL HEALTH, *About Us*, http://www.oie.int/about-us/ (last visited Jan. 10, 2017).

95 *Id.*

96 *Id.*

97 *Id.*

98 *Id.*

99 When California law S.B. 27 comes into effect in 2018, it will be the only law in the United States to require data collection. *See* S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015). At present, the only data available are sales data of the number of antibiotics sold each year for use in food-producing animals.

assessments of the efficacy of the interventions. This requirement will be nil in a country with no regulations or ongoing efforts. To be clear, under this proposal, OIE would not require countries to experiment, it would simply require them to collect and bring data on any efforts that are ongoing. This type of data collection would help ensure that the standards developed at each OIE general meeting do in fact reflect the best scientific evidence available, in keeping with the mandate of OIE.

Finally, the third form of data collection would track the rates of antibiotic-resistant infections in humans. Doing so would not only help maintain an accurate global account of the problem and track its trends, it would also help track the impacts (or lack thereof) of any domestic policies.

Collecting data on use, ongoing efforts, and human infection rates would, at the very least, help OIE to piece together an accurate picture of the current state of antibiotic resistance, which is critical when attempting to devise solutions. Although OIE would not mandate any experimentation per se, this data collection could help spur member states to experiment to try to reduce their antibiotic use.

In the final step, the central body assesses local performance by comparing pooled data. It then sets new benchmarks based on these data, resulting in a continuous learning process. In this context, the proposed step four would take two forms, in line with the types of data collected as delineated above. First, OIE members would use the data collected across countries to update OIE code provisions on the acceptable levels of use of antibiotics in food-producing animals. As a result, the updated code provision could then be based on the best scientific evidence available annually, improving OIE's standard-setting process. Second, as the central data pooler, OIE would provide a means to allow countries to compare their experiences as desired. By creating a centrally accessible database of experiences, OIE could assist countries to learn from other similarly situated countries and to assess and adopt best practices, facilitating better and more efficient progress via a centralized formalized mechanism. This product of international democratic experimentalism crucially acknowledges that not every Netherlands has a Denmark it knows to look to; it helps develop a more diverse experiential database to begin to fill this gap.

This schema thus offers structured, disciplined action while still flexibly accounting for local variance and circumstances. A prime difficulty of governance at the international level is the difficulty of meaningfully translating experience across contexts, as what works in one region or country may not be replicable in another. Although this problem will never be fully addressed, an international democratic experimentalist approach administered through the OIE offers perhaps the best available mechanism to maximize replicability by broadening, centralizing, and streamlining the process of comparison.

This schema also satisfies the need for a transnational governance structure that is democratic. OIE is democratically governed by a committee of delegates of 180 contracting member governments who meet yearly to run the organization, it has institutional and financial autonomy, and it is internationally recognized as the authority on animal disease control and improving animal health worldwide. As an intergovernmental reference organization for the WTO, which itself has enforcement capabilities, it also has a degree of authority and even indirect enforcement capacity because the standards and codes it sets for sanitary measures on international trade of animals and animal products become enforceable at the WTO level. The democratic governance of this organization ensures that, through the democratic experimentalist approach, the standards OIE promulgates will reflect the best known general scientific understanding, rather than the lowest common denominator, an unrealistic heightened standard, or a standard that is unsubstantiated scientifically. OIE's authority and democratic governance structure are rare, and position it uniquely to be able to credibly and effectively take on the task of reducing antibiotics resistance at the international level via a democratic experimentalist framework.

Ensuring that OIE standards reflect the best scientific evidence available could have significant impact on international activity to reduce the subtherapeutic use of antibiotics. Because OIE is a WTO reference organization, when individual countries set their sanitary measures to be in accordance with OIE's codified standards, they are presumptively in compliance with WTO requirements. If desired, these countries with OIE-sanctioned heightened standards could refuse to import meat that does not meet these standards and they would not face WTO challenges or a threat of trade retaliation. If important enough players raised their standards, other countries would feel pressure to keep up with the heightened standards or else lose important trading partners. Achieving this result does depend on influential players increasing their trade standards. However, given the strong movement in Europe around antibiotics, and even the mounting popular movement in the United States against the misuse of antibiotics in animals, which has led to several companies pledging to phase out their antibiotics use, it is not unreasonable to expect this result could occur.

Finally, this framework also better ensures that scientific understanding improves. This result is critical. Strong scientific evidence is arguably the best weapon for advocating for better policies, especially considering the powerful pharmaceutical and producer interests on the side of maintaining, or increasing, the current uses of antibiotics in food-producing animals. To sway policy-making in the right direction, there must be clear scientific support. On this topic that is so critical to human health, it is imperative that the scientific evidence—whatever it should find—guide the policy, and not emotions, musings, or speculations on what sounds reasonable.

IV. ANTICIPATING AND ADDRESSING POTENTIAL COUNTER-ARGUMENTS

A. Democratic Experimentalism and Command-and-Control Regulation

Democratic experimentalism is not mutually exclusive with command-and-control regulation. In fact, it will surely involve comparing various command-and-control measures across localities, along with other types of policies and efforts. In addition, the democratic experimentalist approach may—perhaps even optimally—result in some command-and-control measures once understanding of effective approaches improves. The hallmark of democratic experimentalism is systematized, formalized data collection, comparison, and benchmarking and re-benchmarking—this process is agnostic as to which types of policies may work best in a given scenario, whether command-and-control or otherwise.

B. Developing a List of Best Practices is Insufficient

Another potential counterargument is whether democratic experimentalism is *necessary* for addressing antibiotics resistance, as opposed to simply one potential method for doing so. Put another way, why not just assemble a list of best practices over time as they arise, make them publicly available, and encourage countries and states to adopt those? The answer is that the issue is so context-specific and knowledge-intensive that it requires a lot of information to solve, and it is so time sensitive that it requires that information very quickly. For both effectiveness and efficiency reasons, democratic experimentalism is necessary.

First, democratic experimentalism is critical to achieving effective policies. Reducing overuse of antibiotics is very context- and animal-specific. At present, there is not enough information to know what works best in various contexts, or really in any context not similar to Denmark. The Denmark experience may not be generalizable to all other countries. Denmark is a pork-producing country, for one, so its approaches may not be as effective for poultry or cattle. Denmark's policies also operate within a distinctive northern European communitarian political and cultural context. Its methods may not be socially acceptable or politically feasible elsewhere. In addition, the EU example shows how wildly different policy implementation and results can be in different countries, even those subject to identical policies such as the EU-wide ban. Democratic experimentalism allows for and even systematizes nuanced comparison via a knowledgeable central institution. Without this systematized data collection, a list of best practices would fall short and risk glossing over the nuanced analysis required.

Second is the efficiency component. Some problems are less time sensitive and can afford to wait for voluntary action to generate enough information to elucidate best practices. Antibiotics resistance is not one of those problems. The rapid proliferation of resistant bacteria and the disastrous potential effects mean there is no time to waste on encouraging voluntary action, particularly given the projections for increased use in India, Brazil, and China. Using democratic experimentalism to spur international action on this issue can lead to more efficient, critical solutions. Centralized data collection and systematized continuous learning represent the fastest, most efficient way to inform code- and policy-setting, which is a large reason why democratic experimentalism is so compelling. The time is up to continue to let this problem and its solutions unfold informally, without concerted international effort and public accountability.

CONCLUSION

Antibiotic resistance in humans is a mounting problem with grave potential consequences. It is imperative to have public action immediately to address this problem or else, as many have warned, we risk approaching a post-antibiotic world in which basic infections result in death and complex procedures are rendered impossible. Democratic experimentalism offers a promising potential framework for addressing this problem not only at the domestic level, but also internationally under the auspices of the OIE. This approach satisfies important considerations when regulating at the international level, including effectiveness, efficiency, and democratic governance in addressing this complex and global problem.

A critical theme that cannot be stressed enough is that democratic experimentalism is an important theoretical framework for addressing this problem in large part because of its formalized and systematized data collection and pooling requirements that result in unparalleled effectiveness and efficiency. The reasons for this are fourfold. First, this approach ensures as much as possible that policies reflect the best scientific evidence available. Second, it allows countries to compare experiences meaningfully, and therefore help solve the problem more effectively. Third, it acknowledges the necessity of scientific evidence to sway policy-making in an informed direction. Finally, it helps ensure as quick and efficient action as possible, which is critical for this urgent threat to public health. Implementing a global concerted effort based on democratic experimentalism can help ensure the ongoing viability of the global public good of antibiotics and help protect global public health.