

Retrofitting American Foodralism

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I. INTRODUCTION

Food policy action on the state and local levels is necessary and important for at least two reasons. First, the complexity and breadth of our nation's food system requires layered policy and regulation: the system's functioning needs both national uniformity and local distinctions. Second, there are crucial gaps in national regulation that provide rich opportunities for state and local action. These gaps, in areas such as the regulation of antibiotics in animal feed and the oversight of food additives, are not priorities of the federal agencies that oversee food. Although the Food and Drug Administration (FDA) has made nutrition policy a priority for 2018,¹ the current administration's explicitly anti-regulatory agenda makes it unlikely that it will address these previously under prioritized areas.²

State and local food policy action allow for regional difference, but also have the potential to spark national change. For example, at least eight localities have enacted controversial sugary drink taxes³ as a means of addressing the obesity crisis, although

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¹ See U.S. FOOD & DRUG ADMIN., HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP 7 (2018) (one of four strategic policy areas is to "Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease."); Scott Gottlieb, Comm'r, U.S. Food & Drug Admin., Reducing the Burden of Chronic Disease, Remarks at National Food Policy Conference (Mar. 29, 2018), <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm> [<https://perma.cc/4XDV-5KRJ>].

² See Diana R. H. Winters, *Food Law at the Outset of the Trump Administration*, 65 UCLA L. REV. DISC. 28, 30-37 (2017); Philip Rucker, *Bannon: Trump Administration Is in Unending Battle for 'Deconstruction of the Administrative State'*, WASH. POST (Feb. 23, 2017), https://www.washingtonpost.com/news/powerpost/wp/2017/02/23/bannon-trump-administration-is-in-unending-battle-for-deconstruction-of-the-administrative-state/?noredirect=on&utm_term=.99409262e767 [<https://perma.cc/9YPK-TBDQ>].

³ See Michael J. Bologna, *Cook County Puts Soda Tax on Ice in December*, DAILY TAX REPORT: STATE, Bloomberg BNA (Oct. 12, 2017), <https://www.bna.com/cook-county-puts-n73014470769/>

this strategy has not been embraced nationally. While all states have not embraced sugary drink taxes, they have embraced other initiatives, such as New York City’s trans-fat ban and menu labeling regulations, have been adopted as national policy.⁴ Subnational action, however, can also cause friction; state and local laws may interfere with federal authority and national regulatory uniformity, or with the methods by which other states or localities wish to regulate food.⁵

In this essay, we provide a brief overview of the food regulatory system in the United States and then describe several areas where states currently have the opportunity to act and fill federal gaps. We conclude by arguing for an approach that involves a retooling of American food policy to embrace a complementary regulatory relationship between the federal and state governments. We argue for one that respects the need for uniformity, but properly allows states and localities to more actively participate and to regulate public health, safety, and welfare in the interests of their citizens. In this “dynamic federalism,”⁶ the states can experiment with food p...olicy and function as the intended laboratories of democracy.⁷ This “foodralism”⁸ is not only in keeping with our country’s historic notions of federalism, but is practically necessary given current gaps in federal oversight.

II. CURRENT DIVISION OF AUTHORITY FOR FOOD REGULATION

Myriad federal laws and policies affect the United States food system due to its breadth and complexity.⁹ These include domestic and international laws and policies

[<https://perma.cc/UKU8-EYG5>] (“At least eight other localities have some tax on sweetened drinks. They are Seattle; Philadelphia; Boulder, Colo.; and four cities in California: San Francisco, Oakland, Berkeley, and Albany.”).

⁴ New York City banned trans fats in 2007. A national ban will go into place in 2018. See Nicholas Bakalar, *Trans Fat Bans Tied to Fewer Heart Attacks and Strokes*, N.Y. TIMES (Apr. 12, 2017), <https://www.nytimes.com/2017/04/12/well/eat/trans-fat-bans-tied-to-fewer-heart-attacks-and-strokes.html?login=smartlock&auth=login-smartlock> [<https://perma.cc/U8N6-ATYS>]. New York City put menu-labeling requirements for chain restaurants into place in 2008, and the Affordable Care Act codified it on a national basis in 2010, for implementation in 2018. See N.Y.C. Dep’t of Health & Mental Hygiene, *Calorie Posting: About*, NYC BUS., <https://www1.nyc.gov/nycbusiness/description/calorie-posting> [<https://perma.cc/X4VR-UVBQ>]; *Menu Labeling Requirements*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm> [<https://perma.cc/S7QA-7CWR>].

⁵ See Allan Erbsen, *Horizontal Federalism*, 93 MINN. L. REV. 493, 496, 500, 502-504 (2008); Diana R. H. Winters, *The Benefits of Regulatory Friction in Shaping Policy*, 71 FOOD & DRUG L.J. 228, 228-229, 238-239 (2016).

⁶ Also referred to as “empowerment federalism,” “polyphonic federalism,” “interactive federalism,” and “vertical regulatory competition.” See Kirsten H. Engel, *Harnessing the Benefits of Dynamic Federalism in Environmental Law*, 56 EMORY L.J. 159, 161 (2006) (“Absent constitutional changes that would lock in a specific allocation of authority, broad, overlapping authority between levels of government may be essential to prompting regulatory activity at the preferred level of government.”).

⁷ See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (A phrase made famous by Justice Brandeis describing the ability of the states to experiment with laws and policies without harm to the nation at large).

⁸ A term developed by the authors to describe the relationship between different levels of government as it pertains to the regulation of food in the United States.

⁹ See, e.g., MAGGIE GOSSELIN, INST. FOR AGRIC. & TRADE POLICY, *BEYOND THE USDA: HOW OTHER GOVERNMENT AGENCIES CAN SUPPORT A HEALTHIER, MORE SUSTAINABLE FOOD SYSTEM* 3 (Feb. 2010) (citing myriad governmental departments and agencies beyond the FDA and the USDA with roles in regulating the food system, including the EPA, Department of Defense, Department of Interior, Department of Commerce, Department of Transportation, Department of Housing and Urban Development, Department of Energy, Department of Homeland Security, and the Department of Labor, among others).

addressing trade, the environment, public health, and national security. Even when considering a relatively discrete issue like food safety, there are “as many as 15 federal agencies, including the FDA and the [USDA’s Food Safety Inspection Service], collectively administering at least 30 laws.”¹⁰ The FDA and USDA share primary responsibility for regulation of food products at the federal level. Specifically, the FDA regulates the safety and labeling of most foods other than meat, and approves the use of additives in food pursuant to the Federal Food, Drug and Cosmetic Act (FDCA).¹¹ The USDA regulates the safety and labeling of most meat and unshelled egg products under several major federal laws, including the Federal Meat Inspection Act,¹² the Poultry Products Inspection Act,¹³ and the Egg Products Inspection Act.¹⁴

The food industry is largely responsible for the passage of the first federal food laws, as members of the food industry worked closely with Congress to draft many of the original provisions and subsequent amendments.¹⁵ Participation by industry was both useful and necessary to the passage of a uniform national law that addressed the mounting concerns in the United States over adulterated and misbranded food and drugs.¹⁶ However, prior to the creation of a federal food law, the states were regulating food safety within their own borders, and relied heavily on the English common law as their guide.¹⁷

During colonial times, state food laws were focused largely on exports, although this changed as urban centers developed and the need for laws addressing local food concerns increased.¹⁸ In 1785, Massachusetts enacted the first adulteration law that applied to all food commodities with many states following suit thereafter.¹⁹ By 1850, however, the public identified food adulteration as an issue of concern, and called for the creation of health boards at the state and local levels.²⁰ While many states had developed their own broad food and drug legislation by this point, they failed to enforce them.²¹ States also recognized the need to continue to develop laws aimed at individual products and, eventually, for products not intended for export to protect local citizens.²² Scholars suggest that the second half of the nineteenth century was a time of considerable expansion of state food regulation²³, attributable to several factors: (1)

¹⁰ See RENEÉ JOHNSON, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 1 (2016).

¹¹ See Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 85, 92 (2000).

¹² 21 U.S.C. §§ 601-695 (2012 & Supp. II 2014).

¹³ *Id.* §§ 451-472.

¹⁴ *Id.* §§ 1031-1056.

¹⁵ See Charles Wesley Dunn, *The Federal Food, Drug, and Cosmetic Act and the Food Industry*, 3 FOOD DRUG COSM. L.Q. 166, 167 (1948); Ole Salthe, *A Brief Review of the Legislative History of the Federal Food, Drug, and Cosmetic Act*, 3 FOOD DRUG COSM. L.Q. 148, 152-53 (1948).

¹⁶ See generally Dunn, *supra* note 15, at 167-71.

¹⁷ See generally Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2 (1984).

¹⁸ *Id.* at 39.

¹⁹ *Id.* at 40.

²⁰ *Id.* at 39.

²¹ See Charles Wesley Dunn, *Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297, 306 (1946).

²² See *id.* at 42-43; Hutt & Hutt, *supra* note 17.

²³ See Marc T. Law, *History of Food and Drug Regulation in the United States*, EH.NET ENCYCLOPEDIA (Oct. 11, 2004), <http://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states> [<https://perma.cc/X8MZ-D7EF>].

“specialization and urbanization” that caused consumers to purchase foods from “impersonal markets”²⁴; (2) technological innovations in food production that created new products, but also “increased product complexity”²⁵; (3) “the rise of analytic chemistry” which allowed for the adulteration of foods in ways that consumers could not easily identify²⁶; and (4) the market’s diminished ability to address adulteration issues that relied on consumer identification of problems.²⁷ To address these advances in technology and commerce, states continued to develop laws to prevent adulteration.²⁸

Contemporaneously, the federal government considered passing national legislation to address the issue of food adulteration. In 1906, President Roosevelt signed the Pure Food and Drugs Act²⁹ into law after the introduction of many unsuccessful bills.³⁰ Many questioned why Congress waited over a half century after the identification of food adulteration as a public concern to enact the original federal Food, Drug and Cosmetic Act in 1906, but some attribute it to the fact that Congress was just beginning to enact laws broadly regulating commerce coupled with a strong sense that responsibility for food regulation and policy resided exclusively within the states.³¹ Some suggest that the law exemplified regulatory capture and that Congress enacted to appease large food manufacturers who sought federal legislation as a means of disadvantaging small, local producers.³² However, most scholars cite the publication of Upton Sinclair’s *The Jungle* as the catalyst that eventually forced President Roosevelt’s hand.³³ The 1906 Act created a national scheme for the regulation of food, but suffered from significant shortcomings. The FDA then began to advocate for legislation to fill its gaps soon after its passage.³⁴ In 1938, Congress enacted the Food, Drug, and Cosmetic Act (“FDCA”). The FDCA gave the FDA more authority over food labeling, and required the issuance of legal standards for foods, among other measures.³⁵ Practically

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* (citing John J. Wallis & Douglass C. North, *Measuring the Transaction Sector of the American Economic, 1870-1970*, in LONG TERM FACTORS IN AMERICAN ECONOMIC GROWTH 95-148 (Stanley Engerman & Robert E. Gallman eds., 1986); SUSAN STRASSER, SATISFACTION GUARANTEED: THE MAKING OF THE AMERICAN MASS MARKET (Pantheon Books 1989) (1989); JAMES H. YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 (1986); LORINE S. GOODWIN, THE PURE FOOD, DRINK, AND DRUG CRUSADERS, 1879-1914 (1999); and DONNA J. WOOD, STRATEGIC USES OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA (1986)).

²⁸ By way of example, states were grappling with food adulteration issues that had long plagued food consumers such as “water . . . added to wine, cream skimmed from milk, and chalk added to bread.” Law, *supra* note 23.

²⁹ 21 U.S.C. §11 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

³⁰ See Charles Wesley Dunn, *Original Federal Food, and Drugs Act of 1906, As Amended: Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297, 299 (1946) (noting that prior to the passage of the Act, 103 bills were introduced to and defeated in Congress).

³¹ See *id.* at 307.

³² GABRIEL KOLKO, THE TRIUMPH OF CONSERVATISM: A REINTERPRETATION OF AMERICAN HISTORY 103 (McMillan 1967) (noting that meat packers already experiencing regulations were eager to ensure that their competitors were also made to comply with regulations).

³³ See e.g. *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054819.htm> [<https://perma.cc/XGD4-S3GK>] (“In fact, the nauseating condition of the meat-packing industry that Upton Sinclair captured in *The Jungle* was the final precipitating force behind both a meat inspection law and a comprehensive food and drug law.”).

³⁴ See Hutt & Hutt, *supra* note 17, at 9-10.

³⁵ *Id.* at 10-11.

speaking, however, the industry is largely self-regulating with respect to food. Although Congress has amended the FDCA over 100 times since 1938, its basic structure still stands.³⁶

While federal laws and policies largely govern food regulation in the United States, most allow significant room for the states to regulate pursuant to their ability to develop laws and policies to protect the public, health, safety and welfare of their citizens.³⁷ Moreover, while national uniformity was an industry rallying cry for passage of the FDCA, scholars posit that courts only consider uniformity as a means of fulfilling the Act's "overriding policy of improving consumer protection."³⁸ Consequently, the Act contains few express preemption provisions related to food products, with the major exception being nutrition labeling information which benefits both manufacturers and consumers by providing national labeling uniformity.³⁹ The existence of specific express preemption provisions within the Act has led courts to conclude that other matters were not to be preempted.⁴⁰ Moreover, the courts have confirmed the states' legitimate interest in protecting the public from "fraud and deception" related to food products.⁴¹

There are instances, however, where courts federal law, either expressly or impliedly, preempts state or local regulation of food policy. Express preemption occurs when federal legislation or regulation contains language expressly preempting state law.⁴² An example of express preemption is the Nutrition Labeling and Education Act

³⁶ *Id.* at 11, 13 (the Act today is "more than 30 times the length it was in 1938" and that while there have been some "departures" from the original food and drug legislation, there has not been a "fundamental shift in legislative policy.").

³⁷ *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (holding that when Congress legislates in an area historically regulated by the states, courts start with the assumption that Congress did not intend to displace state authority "unless that was the clear and manifest purpose of Congress."); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) (upholding a state law that rejected avocados based on maturity, which Federal law deemed marketable, holding that "[T]he supervision of the readying of foodstuffs for market has always been deemed a matter of peculiarly local concern. Many decades ago, for example, this Court sustained a State's prohibition against the importation of artificially colored oleomargarine (which posed no health problem), over claims of federal preemption and burden on commerce."); *Hillsborough Cty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985) ("Given the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, we will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety.").

³⁸ Charles P. Mitchell, *State Regulation and Federal Preemption of Food Labeling*, 45 FOOD DRUG COSM. L.J. 123, 139 (1990).

³⁹ *See* Nutrition Labeling Education Act, 21 U.S.C. § 343(q)(4)(A) (2012) (stating that the FDA Secretary will issue both mandatory and voluntary nutritional guidelines. *See also* Mitchell, *supra* note 38, at 130 ("Far from discerning 'clear and manifest' intent to exclude state regulation, courts interpreting the Act have found only silence and have declined to find wholesale preemption."); *Sciortino v. Pepsico, Inc.* 108 F. Supp. 3d 780, 796-797 (N.D. Cal. 2015).

⁴⁰ *See* Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. 815, 832-833 (2014); *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 121 Cal. Rptr. 2d 749, 755 (Cal. Ct. App. 2002) ("As far as the Food, Drug, and Cosmetic Act is concerned, it would be more accurate to say that the act evidences, far from implied preemption, an instance of implied *non*preemption."). *See also* *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) ("By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources.").

⁴¹ *See Florida Lime*, 373 U.S. at 144-145 (stating "the States have always possessed a legitimate interest in 'the protection of . . . [their] people against fraud and deception in the sale of food products' at retail markets within their borders.").

⁴² *Hillsborough Cty.*, 471 U.S. at 713 (explaining preemption doctrine).

(NLEA), which amended the FDCA in 1990. The NLEA contains an express preemption provision prohibiting the establishment of any state or local requirements that are not identical to federal requirements regarding labeling and the listing of product ingredients.⁴³ It also prohibits state and local requirements that are not identical to federal requirements on nutrient content claims and health claims,⁴⁴ although, prior to passage of the Patient Protection and Affordable Care Act, states could establish requirements regarding nutrient content claims made by restaurant and retail chains.⁴⁵

Implied preemption can manifest in three ways: (1) when Congress occupies the entire field of regulation, (2) when state law and federal law actually conflict, and (3) when state law interferes with the “purposes and objectives” of Congress in establishing regulation.⁴⁶ Field preemption is rare, and only takes place when “the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress ‘left no room’ for supplementary state regulation.”⁴⁷ In comparison, conflict preemption takes place when a regulated entity cannot simultaneously comply with both federal and state obligations. Finally, in objectives and purposes preemption occurs when the state law requirement interferes with the objectives and purposes of Congress in passing federal legislation.⁴⁸ Discerning whether this type of preemption exists is a delicate task.⁴⁹

The complexity of the layered food regulation scheme in the United States leads to instances where courts find federal laws preempt states from enacting laws that arguably would provide better protection for the citizenry, in the interest of achieving national uniformity or preventing interference with interstate commerce.⁵⁰ However, people have also criticized the states for duplicating federal efforts in some instances and sometimes acting inconsistently in their regulation of certain aspects of the food

⁴³ 21 U.S.C. §§ 343-1(a)(2)-(4) (2012).

⁴⁴ *Id.* §§ 343-1(a)(4)-(5).

⁴⁵ *Id.* This exemption allowed localities, such as New York City, to establish menu-labeling requirements for certain restaurants. See *New York State Rest. Assoc. v. New York City Board of Health*, 556 F.3d 114, 120 (2d Cir. 2009) (“Though appearing complex, this scheme is simple when it comes to restaurant food – the NLEA does not regulate nutrition information labeling on restaurant food, and states and localities are free to adopt their own rules.”). This exemption has been narrowed, however, by the Patient Protection and Affordable Care Act, which imposes menu-labeling requirements on larger chain restaurant establishments. § 343-1(a)(4).

⁴⁶ *Hillsborough Cty.*, 471 U.S. at 714, 716; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525-26 (1977); *Florida Lime*, 373 U.S. at 146.

⁴⁷ *Hillsborough Cty.*, 471 U.S. at 713.

⁴⁸ *Id.* (“Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent it actually conflicts with federal law. . . . [including] when state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”) (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

⁴⁹ For example, a state trial court in Connecticut found that the plaintiff could not use state law to impose labeling requirements regarding allergens different than those found in the FDCA because “it would be an obstacle to the accomplishment and execution of the purposes and objectives of Congress in the field of labeling food products containing potential food allergens.” *Cardinale v. Quorn Foods, Inc.*, No. X05CV096002022S, 2011 WL 2418628, at *8 (Conn. Super. Ct. May 19, 2011).

⁵⁰ See e.g., *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 458-62 (2012) (striking down a state law that prohibited the holding, processing, or butchering of a nonambulatory animal on the basis that the Federal Meat Inspection Act and its implementing regulations preempted more restrictive state proscriptions); *Rath Packing Co.*, 430 U.S. at 540-43 (invalidating a California law regulating labeling and weights of food products as preempted by the Federal Meat Inspection Act and an obstacle to fulfillment of the Fair Packaging and Labeling Act).

system.⁵¹ To address these issues, some have called for an integrated regulatory structure that leverages the strengths of state and local agencies to provide more comprehensive regulation, particularly with regard to food safety.⁵²

Some might suggest the Food Safety Modernization Act (FSMA), given the Act's many provisions related to federal-state integration, provides an example of the type of shared regulatory space called for in this essay given the Act's many provisions related to federal-state integration.⁵³ However, FSMA also provides an example of overreaching federal regulation that removes authority from the states and would have benefitted from enhanced state participation at the outset.⁵⁴ FSMA's⁵⁵ passage was precipitated by a rash of serious foodborne illness outbreaks, but was also due to the fact that there were myriad agencies at the state and federal levels tasked with cooperatively administering thirty different laws pertaining to food safety.⁵⁶ The Act reflects the largest reform of federal food safety regulation in seven decades,⁵⁷ substantially expanding the scope of the FDA's regulatory authority by allowing the agency to monitor on-farm food safety, implement preventive controls at facilities, increase inspections, issue mandatory recalls, and exercise increased oversight of foreign food facilities importing into the United States.⁵⁸ While collaboration among different agencies at varying levels of government has occurred under the FSMA, researchers

⁵¹ INST. OF MED. & NAT'L RESEARCH COUNCIL, ENHANCING FOOD SAFETY: THE ROLE OF THE FOOD AND DRUG ADMINISTRATION 43-51, 212 (Robert B. Wallace & Maria Oria eds., 2010).

⁵² *Id.* at 205-12. See also Jennifer L. Pomeranz et al., *The Potential for Federal Preemption of State and Local Sugar-Sweetened Beverage Taxes*, 53 AM. J. PREVENTIVE MED. 740 (2017) (discussing the rationale for federal preemption of sugar-sweetened beverage taxes and concluding that these taxes should not be preempted).

⁵³ Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885; 29 C.F.R. § 1987.100 (2012).

⁵⁴ See e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-425, FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED 16 (2016) (State officials contacted by the GAO regarding whether the FDA met its mandate to coordinate with state departments of agriculture had mixed opinions about the efficacy of the agency's communication. "Specifically, officials from 2 departments characterized the quality as very good, 3 characterized it as good, 2 characterized it as moderately good, and 1 characterized it as very poor. Officials from one of the departments that characterized the coordination as very good explained that FDA was very open to discussing states' concerns. One of the officials that characterized the coordination as moderately good stated that FDA did not seek as much input from states as the official would have liked. The official that characterized the coordination as very poor noted that states had many outstanding concerns that had not been addressed, including the produce rule's complexity and compliance costs."). See also Laura Fisher, *Administrative Law - All (Food) Politics Is Local: Cooperative Federalism, New England Small Farms, and the Food Safety Modernization Act*, 37 W. NEW ENG. L. REV. 337, 367 (2015) (arguing that FSMA should embrace true cooperative federalism and allow the states to develop workable plans based on regional differences that implement the broader goal of food safety); Emily Walters, *The Food Safety Modernization Act's True Implications for Sustainable Agriculture*, 4 WASH. & LEE J. ENERGY, CLIMATE & ENV'T 391, 406 (2013) (by broadening the FDA's reach under FSMA, the Act has taken away authority from the states in areas they historically regulated).

⁵⁵ Food Safety Modernization Act of 2011.

⁵⁶ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEMS: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP (2004).

⁵⁷ RENEE JOHNSON, CONG. RESEARCH SERV., R42885, FOOD SAFETY ISSUES FOR THE 113TH CONGRESS (2013).

⁵⁸ *Id.*

have continued to call for a federal mandate to develop an “integrated food safety system.”⁵⁹

Despite its lofty goals, the FDA’s own estimates suggest that the benefits associated with implementation of FSMA are relatively small when compared with the costs and burdens on both the regulated parties and the regulators. As required,⁶⁰ the agency performed preliminary regulatory impact analyses of several of its proposed rules prior to their promulgation.⁶¹ In its analysis of the proposed rule setting “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” the agency estimated that the rule would have an annualized cost of \$459.56 million per year⁶² with net benefits amounting to \$582.63 million per year.⁶³ However, the FDA calculated its anticipated benefits based on the avoided costs associated with prevented foodborne illness outbreaks, and noted that benefits would be dependent on effective implementation of the rule.⁶⁴ Similarly, the agency’s analysis of its “Preventive Control Rule” reflects annualized costs of \$471 million per year in the first year, and \$459 million per year thereafter, with benefits accruing in the form of prevented illnesses, although the agency noted it “lack[ed] sufficient information to fully estimate the proposed rule’s likely benefits.”⁶⁵

Consequently, critics argue that FSMA embodies a regulatory response with costs that may far exceed the benefits and that potentially imposes unnecessary burdens while diverting resources from other food system priorities.⁶⁶ In addition, the states have

⁵⁹ U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 54, at 16. There have also been repeated calls for, at the very least, a simplification and rationalization of federal food systems oversight, by combing all federal food oversight into one agency, but this idea has not gained much traction.

⁶⁰ “The FDA has examined the impacts of the proposed rule under Executive Order 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.” U.S. FOOD & DRUG ADMIN., ANALYSIS OF ECONOMIC IMPACTS – STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION 2 (2014).

⁶¹ *See id.*; U.S. FOOD & DRUG ADMIN., FDA-2011-F-0171, REGULATORY IMPACT ANALYSIS – FOOD LABELING: CALORIE LABELING OF ARTICLES OF FOOD IN VENDING MACHINES (2014).

⁶² U.S. FOOD & DRUG ADMIN., *supra* note 60, at 301.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 79 Fed. Reg. 58,524 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pts. 1, 16, & 117).

⁶⁶ *See e.g.*, Richard Williams, *Regulations Implementing the Food Safety Modernization Act*, (Mercatus Working Paper, 2015); James Gattuso & Diane Katz, *Red Tape Rising 2016: Obama Top Regs Top \$100 Billion Annually*, THE HERITAGE FOUND. (May 23, 2016), <https://www.heritage.org/government-regulation/report/red-tape-rising-2016-obama-regs-top-100-billion-annually> [https://perma.cc/64ZV-LLM2] (“Foodborne illness is indeed a public health concern. However, America’s food supply is remarkably safe, and yet the Food and Drug Administration (FDA) has cast an exceedingly broad regulatory net rather than focusing on the biggest risks. That means higher food costs across the board without regard to consumer benefit. In addition to consumers, the biggest burden will fall on small farms and “local” food producers who are forced to implement controls, training, and record-keeping systems fashioned for much larger operations. And because the rules are rigid, producers of specialty crops are particularly concerned that advances in food science and technology will become more difficult to adopt.”); Baylen Linnekin, *The Feds Modernize Food Safety Without Making Food Safer*, REASON (Nov. 1, 2014.), <http://reason.com/archives/2014/11/01/fdas-fsma-modernizes-food-safety-without> [https://perma.cc/U5D4-

identified a number of unresolved issues in the federal-state relationship contemplated under the Act including: (1) clarification of roles and responsibilities; (2) regular communication between the FDA and the states; (3) comprehensive funding to assist the states in their implementation efforts; (4) creation of an information sharing system regarding industry compliance; (5) process by which the FDA responds to questions related to the regulations; and (6) a dispute resolution mechanism to resolve disputes related to rule interpretation.⁶⁷

Moreover, in response to the FDA's proposed rules to implement FSMA, advocates for small and mid-sized producers noted that a "one-size fits all" approach to food safety has the practical effect of eroding localized and more sustainable food systems because the measures proposed are overly burdensome and cost prohibitive for smaller operations.⁶⁸ As a result of the individual meetings, the FDA held wider meetings to receive feedback on its proposed rules from interested parties. After reviewing the public comments, the agency recognized the need to tailor its regulations to regional, state, and local differences, such as various production methods based on local growing seasons and other factors.⁶⁹ Because of the significant feedback the agency received regarding the need to diversify its regulations to account for the vast differences among agricultural regions in the United States, the FDA is currently in the process of revising its rules and contemplates an active role for states and localities in the revisions.⁷⁰

Here, we advocate an approach that differs from the cooperative one reflected in the FSMA, and which would strengthen the states' roles to a degree while still relying largely on states for enforcement and implementation of rules and standards developed by the federal government. States should have the authority to more actively craft and execute food policy regulation to reflect local difference and/or attempt to drive national

PZGDJ] ("Even giving the FDA the maximum possible benefit of the doubt—even if I assume that the FDA will prevent every single one of the illnesses the agency itself doesn't expect to prevent—the maximum benefit of these FSMA rules would be a reduction of 5.4 percent of food-borne illnesses. Meanwhile, the agency also floats a break-even figure of reducing 228,000 cases of food-borne illness under the manufacturing rules. This would mean the two rules, taken together, would reduce cases of food-borne illness by up to 3.7 percent.").

⁶⁷ U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 54, at 32-37.

⁶⁸ National Sustainable Agriculture Coalition, Comment Letter on Proposed Rule for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Nov. 15, 2013), <http://sustainableagriculture.net/wp-content/uploads/2008/08/NSAC-Produce-Rule-Comments-FINAL-11-15-13.pdf> ("Regulations must be scale- and supply-chain appropriate to be effective; a one-size-fits-all approach will put small and mid-sized farms and processors out of business, undermining public health goals, such as increased production of, availability of, and access to healthy foods, as well as economic opportunity, equity, and job-creation goals."). See also Diana R.H. Winters, *From Industrial to Artisanal: A New Regulatory Framework for a Changing Food Landscape* 10-11 (Ind. Univ. Robert H. McKinney Sch. of Law Research Paper No. 2013-23, 2013) (arguing that the complexity of regulation makes it difficult for small food producers to enter the market, even if they are exempted from FSMA rules).

⁶⁹ See e.g., Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 76 Fed. Reg. 58,433 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 112) (proposing to amend provisions addressing microbial standards for agricultural water and minimum time intervals for the application of raw manure to account for regional growing conditions and practices); *FSMA Strategy for Engaging Stakeholders*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm564350.htm> [<https://perma.cc/K5WK-HVH3>] ("Meeting with the people on the front lines who would be covered by FSMA rules definitely helped educate our staff. The issues that face each region of the country are unique. We received a lot of useful information during our outreach, including local, regional, and commodity-specific concerns.").

⁷⁰ *Id.*

policy. It is appropriate for states to act in areas that would benefit the public health, safety, welfare, and where the Federal government has not acted. The benefit to the public outweighs any cost to national uniformity, and Congress retains the ability to remedy any issues through the legislative process.

III. REGULATORY GAPS LEFT FOR STATE ACTION

Given the dearth of preemption provisions included in some of the major federal food laws, there is space for states and localities to develop laws and policies addressing public health, safety, and welfare. The State of California, often cited as a leader in state regulation that is strongly protective of the public,⁷¹ has joined the lead in developing food policy as well. This section reviews various state initiatives, both underway and under consideration, that are pushing the bounds of federalism and ultimately may provide for a safer food system.

A. SUBSTANCES GENERALLY RECOGNIZED AS SAFE

As mentioned above, concerns about potentially unsafe additives⁷² primarily motivated the passage of the Pure Foods and Drugs Act of 1906, which ultimately became the Federal Food, Drug, and Cosmetic Act, was motivated in large part by concerns about potentially unsafe additives⁷³ in the American food supply.⁷⁴ Two decades after the enactment of the 1938 Act, Congress passed the Food Additives Amendment of 1958 (FAA) giving the Food and Drug Administration the ability to require pre-market approval of additives based on their intended use.⁷⁵ While the FAA arguably gave the FDA much needed authority to control food safety, concerns over the use of unsafe substances in food production persist.⁷⁶

⁷¹ See e.g., Charles W. Schmidt, *ENVIRONMENT: California Out in Front*, 115 ENVTL. HEALTH PERSP. A144 (2007) (Frustrated with the lack of progress at the Federal level to combat global warming, California's legislature has responded with some of the nation's strongest environmental laws); Madison Park, *California Sets Trends in Health Regulation*, CNN (Feb. 10, 2012), <https://www.cnn.com/2012/02/10/health/california-leads-health-laws/index.html> [<https://perma.cc/R2DH-K3C6>] ("The state has been first to pass major public health initiatives that have spread throughout the country.").

⁷² The definition of what constitutes an additive in the food supply is broad. Under Federal law, an additive is any substance that "may reasonably be expected to result, directly or indirectly, either in [its] becoming a component or otherwise affecting the characteristics of any food. 21 U.S.C. § 321(s) (2012).

⁷³ The definition of what constitutes an additive in the food supply is broad. Under Federal law, an additive is any substance that "may reasonably be expected to result, directly or indirectly, either in [its] becoming a component or otherwise affecting the characteristics of any food. 21 U.S.C. § 321(s) (2012).

⁷⁴ *Developments in the Law: The Federal, Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 634 (1954).

⁷⁵ Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended at 21 U.S.C. §§ 301-399 (2006)).

⁷⁶ See e.g., Complaint at 1, *Ctr. for Food Safety v. Price*, No. 1:17-cv-03833 (S.D.N.Y. May 22, 2017) ("The GRAS Rule allows potentially unsafe food additives to be used in the food supply (human and animal) without FDA review, approval, oversight, or knowledge, in violation of the Federal Food, Drug, and Cosmetic Act . . ."); Erin Quinn & Chris Young, *Why the FDA Doesn't Really Know What's in Your Food*, *CTR. FOR PUB. INTEGRITY* (Apr. 14, 2015, 5:00 AM), <https://www.publicintegrity.org/2015/04/14/17112/why-fda-doesnt-really-know-whats-your-food> [<https://perma.cc/V9SL-CP4G>].

The FAA presumes that all additives proposed for use in the food supply are unsafe⁷⁷ and must receive pre-market approval by the FDA⁷⁸ unless the FDA previously approved them⁷⁹ or they are generally recognized as safe (GRAS) substances.⁸⁰ For FDA to exclude food additives as GRAS, experts “qualified by scientific training and experience to evaluate its safety” must find the additives “safe under the conditions of its intended use.”⁸¹ Experts can determine safety through “scientific procedures,”⁸² or for those substances commonly used prior to the passage of the FAA in 1958, “experience based on common use in food.”⁸³ In other words, these substances escape the pre-approval process, leading some to suggest they are not subject to an appropriate level of scrutiny by the agency.⁸⁴

Based on official statements made by the FDA, it only intended the GRAS exemption was intended to apply to those substances that were commonly considered “safe additives” prior to passage of the FAA — for example, salt, sugar, and other substances previously used as additives without evidence they produced acute harm.⁸⁵ However, it is estimated that there are presently over 1,000 chemicals classified as GRAS and used in foods without FDA oversight or notification.⁸⁶ Despite the existence of seemingly rigid federal standards, there are many substances continuously affirmed as GRAS and effectively left unregulated, while few substances get delisted in light of

⁷⁷ 21 U.S.C. § 348(a) (2012).

⁷⁸ *Id.* § 348(b).

⁷⁹ A list of prior approved substances is included in 21 C.F.R. §§ 181.1-181.34 (2012).

⁸⁰ *See* § 321(s).

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-246, FOOD SAFETY: THE FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 8 (2010) (“FDA reviews those GRAS determinations that companies choose to submit to the voluntary notification program. However, FDA generally does not have information about other GRAS determinations because companies are not required to inform the agency of their GRAS determinations. Furthermore, FDA has not taken certain steps that could help ensure the safety of GRAS determinations, particularly those for which the agency has not been notified. Notably, a trade association routinely informs FDA of its GRAS determinations, even though it does not submit notices to FDA’s voluntary notification program.”); Thomas G. Neltner, et al., *Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe*, 173 JAMA INTERNAL MED. 2032, 2032 (2013) (“Between 1997 and 2012, we found that financial conflicts of interest were ubiquitous in determinations that an additive to food was GRAS. The lack of independent review in GRAS determinations raises concerns about the integrity of the process and whether it ensures the safety of the food supply, particularly in instances when the manufacturer does not notify the FDA of the determination.”).

⁸⁵ *See* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (proposed April 17, 1997) (to be codified at 21 C.F.R. pts. 170, 184, 186, & 570) (“It is on the basis of the GRAS exemption to the food additive definition that many substances (such as vinegar, vegetable oil, baking powder, and many salts, spices, flavors, gums, and preservatives) are lawfully marketed today without a food additive regulation.”); 21 C.F.R. § 182.1(a) (2018) (“It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use.”). *See also* Frederick H. Degan, *Rethinking the Applicability and Usefulness of the GRAS Concept*, 46 FOOD DRUG COSM. L.J. 553, 580 (1991) (arguing that the agency should spend its scarce resources on “those substances truly in need of prompt agency attention” rather than the “thousands of other substances considered to be of little public health consequence”).

⁸⁶ THE PEW CHARITABLE TRS., FIXING THE OVERSIGHT OF CHEMICALS ADDED TO OUR FOOD 1 (2013).

evolving science suggesting they are no longer safe.⁸⁷

In 1997, the FDA informally replaced its GRAS petition process with a voluntary notification program.⁸⁸ Because the process is completely voluntary, companies submitted just 274 GRAS determination notifications to the agency from 1998 to 2008.⁸⁹ After years of failing to promulgate a final rule, the agency formally replaced the voluntary petition process with a voluntary notification process in 2016, but strongly encouraged companies to contact the agency when making GRAS determinations.⁹⁰ Comments in response to the Notice of Proposed Rulemaking argued that the agency's proposal was arbitrary and capricious because the FDA was failing to fulfill its mandate to "oversee food additives."⁹¹ The agency noted that although the FDCA requires a premarket approval process for additives, the statute does not require industry to notify the agency regarding the use of GRAS substances.⁹² Advocates have criticized the FDA for its lack of knowledge about the existence and safety of certain GRAS substances in the market place,⁹³ as well as the agency's inability to monitor the continued safety of those substances.⁹⁴

Not surprisingly, the FDA's final regulation disappointed some advocates who have since sued, alleging that the agency's voluntary process deprives the plaintiff

⁸⁷ See, e.g., Laurie J. Beyranevand, *Generally Recognized as Safe: Analyzing Flaws in the FDA's Approach to GRAS Additives*, 37 VT. L. REV. 887, 887-89 (2013) (arguing that the FDA needs to reevaluate its approach to regulating GRAS substances and consider "safety" in the broadest sense to more adequately protect consumers).

⁸⁸ See Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,938 (FDA proposed to revoke the petition process which required rulemaking for each GRAS substance and replace it with a notification procedure whereby individuals could notify the agency of GRAS determinations). This rule was never finalized until the recent 2016 rulemaking.

⁸⁹ U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 83, at 6.

⁹⁰ Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,966 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, & 570).

⁹¹ *Id.* at 54970-71.

⁹² *Id.*

⁹³ Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 443 (1998); Carrie A. Scrufari, *Substances Generally Recognized as Safe—Until They're Not: Challenges in Protecting the Food Supply in A Processed World*, 36 STAN. ENVTL. L.J. 219, 243-44 (2017)

("An examination of the FFCA and its attendant rules and regulations demonstrates that FDA is not regulating GRAS substances in any meaningful pre-market way, and for most intents and purposes, it is not regulating GRAS substances in a meaningful post-market way. In addition, because the safety of GRAS substances is already legally presumed, they appear to evade regulatory scrutiny by falling into another large loophole--one Congress intended to close in 1958 with the Delaney Clause.")

⁹⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 83, at 12. See also Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 339 (2016) ("The FDA's current inability to oversee the safety of food additives is amenable to a solution that promises significant benefit to consumers at a relatively low cost to producers and regulators. Simply put, the FDA should promulgate a regulation requiring producers to notify the FDA of all SRAS substances and the self- (or industry-) determinations of their safety before introducing them into the market. Producers ought to be required to monitor on an ongoing basis the safety of all substances in use in their products and to report credible adverse information to the FDA as that information develops."); Quinn & Young, *supra* note 75 ("Two industry consultants told Center for Public Integrity reporters that two-thirds of their safety reviews are never sent to regulators. An international food company told the GAO that it introduces five new ingredients yearly without telling the FDA.")

organizations of critical information about GRAS determinations made independently of FDA oversight.⁹⁵ The agency's action and the resulting lawsuit, however, call into question whether federal law would preempt state action in this area. Since the FDA has effectively chosen not to regulate a category of substances that could be subject to significant agency oversight, can a state choose to disallow the inclusion of substances independently deemed GRAS without FDA oversight or design a pre-approval process of its own? For example, does a state's decision to ban independently approved GRAS substances without FDA oversight or notification raise preemption issues.

While most states have substantially adopted the text of the FDCA, which includes language exempting GRAS substances from the additive pre-approval process, California's Sherman Act⁹⁶ is a notable exception. California law considers added substances unsafe unless a regulation "limits the quantity and the use, or intended use, of the substance to the terms prescribed by the regulation."⁹⁷ In other words, even where the FDA has developed a food additive regulation for substances not exempt, California has reserved the right to "prescribe conditions under which [the substance can be used] whether or not these conditions are in accordance with the regulations adopted pursuant to the Federal act."⁹⁸

Neither the FAA nor the federal FDCA contain any language expressly preempting the states from developing laws to address added substances, which would suggest the issue is ripe for state action. In a case considering whether the FDCA and the FDA's regulatory findings regarding the safety of a color additive pursuant to the Act, preempted a warning label required by California's Proposition 65, the Court found that neither of the two applicable parts of the federal statute - the Delaney Clause nor the Color Additives Amendment - contained an express preemption provision.⁹⁹ In reaching its conclusion that the state law was not preempted, the Court relied on "the plain language" of the statute, "the presumption against preemption" when states are acting in the interests of public health, safety, and welfare, and the lack of an express preemption provision related to this specific issue.¹⁰⁰ Despite the fact that the FDA made a determination about the additive's safety within the framework of the FDCA, that safety finding did not preclude California from requiring a warning label under state law based on safety concerns.¹⁰¹ In other words, "the [FDA's] safety determination and related decisions not to set limits on [the additive's] use under the Delaney Clause were intended to set only a regulatory floor, not a ceiling, that does not bar state law remedies."¹⁰² Finding no express, obstacle, or conflict preemption, the court affirmed "California's exercise of its police power to protect the health and safety of its citizens

⁹⁵ Complaint at 16, *Ctr. for Food Safety v. Price*, No. 1:17-cv-03833 (S.D.N.Y. May 22, 2017).

⁹⁶ CAL. HEALTH & SAFETY CODE, Div. 104, Part 105 (2018).

⁹⁷ *Id.* § 110445.

⁹⁸ *Id.* § 110085.

⁹⁹ *See Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 806 (N.D. Cal. 2015).

¹⁰⁰ *Id.* at 806-807.

¹⁰¹ *Id.* at 807.

¹⁰² *Id.* at 809 (citing *Wyeth v. Levine*, 555 U.S. at 582 (2009)).

.... [w]hich are matters traditionally left to state regulation.”¹⁰³ While California has not taken any significant steps with regard to more stringent regulation of unsafe GRAS substances, nothing in their state law appears to prohibit them from doing so in the event there is a scientific and evidentiary basis for the action.

B. ANTIBIOTICS AND FOOD PRODUCING ANIMALS

In January 2018, California’s SB-27 went into effect, becoming the nation’s strictest law regarding the use of antibiotics in food-producing animals. The federal government has historically regulated animal drugs, but observers and stakeholders have criticized the FDA for its failure to more closely monitor and control the use of antibiotics in food-producing animals - especially given the increased understanding about the role of these drugs in antibiotic resistance. California passed SB-27 in late 2015 to address the perceived shortcomings of federal regulation. The California law prohibits the use of antibiotics in food-producing animals for reasons other than disease prevention, and requires licensed veterinarians to prescribe antibiotics.¹⁰⁴ The Bill also provides for data collection regarding the prescription and use of antibiotics.¹⁰⁵

Historically, the regulation of antibiotics in animal feed has been marked by obfuscation and delay. The FDA approved new animal drug applications for several antibiotics in the 1950s following research that when administered in subtherapeutic doses (levels below those needed to fight disease), certain antibiotics could improve weight gain in food-producing animals and therefore speed up food production.¹⁰⁶ By the mid-1960s, the agency began to consider evidence that the subtherapeutic use of antibiotics in animal feed was contributing to antibiotic resistance in disease-causing organisms, and in 1972, a task force convened by the agency issued a report on this issue.¹⁰⁷ The report found that antibiotic resistance was increasing, and that animals that were given antibiotics were harboring antibiotic-resistant pathogens that may lead to human disease.¹⁰⁸ The task force also recommended that antibiotics used as human medicine be prohibited from subtherapeutic use in animals, and in 1973, the FDA issued a regulation proposing to revoke the approval of several of the antibiotics it had approved in the 1950s.¹⁰⁹

Although the FDA issued a notice that it would hold a hearing regarding the withdrawal of approval for these antibiotics in 1977, and denied petitions by industry in 1983 asking it to withdraw this notice for a hearing,¹¹⁰ the FDA never held these hearings

¹⁰³ *Id.* at 811.

¹⁰⁴ See CAL. FOOD & AGRIC. CODE §§ 14402, 14401 (2016).

¹⁰⁵ See *id.* § 14405.

¹⁰⁶ See *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 341-42 (S.D.N.Y. 2012); Diana R. H. Winters, *Intractable Delay and the Need to Amend the Petition Provisions of the FDCA*, 90 IND. L. J. 1047, 1060 (2015).

¹⁰⁷ *Nat. Res. Def. Council, Inc.*, 872 F. Supp. 2d at 322-23.

¹⁰⁸ Dep’t of Health, Educ. & Welfare, *Antibiotic and Sulfonamide Drugs in Animal Feeds*, 37 Fed. Reg. 2411, 2444-45 (proposed Feb. 1, 1972) (to be codified at 21 C.F.R. pt. 135).

¹⁰⁹ See 21 C.F.R. § 558.15 (2013).

¹¹⁰ Dep’t of Health, Educ. & Welfare, *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); Dep’t of Health, Educ. & Welfare, *Drugs for Human Use; Drug*

and approval for these antibiotics was never withdrawn. In May 2011, the Natural Resources Defense Council (NRDC), the Center for Science in the Public Interest, the Food Animal Concerns Trust, Public Citizen, and the Union of Concerned Scientists, Inc. brought suit against the FDA, alleging that the FDA had “withheld agency action,” by not withdrawing the approval for these animal drugs, and therefore violated the FDCA and the APA.¹¹¹ In March 2012, the District Court granted summary judgment for the Plaintiffs, writing, “[f]or over thirty years, the Agency has been confronted with evidence of the human health risks associated with the widespread subtherapeutic use of antibiotics in food-producing animals, and, despite a statutory mandate to ensure the safety of animal drugs, the Agency has done shockingly little to address these risks.”¹¹² However, in July 2014, the Second Circuit overturned the District Court’s decision, finding that the FDA only had to withdraw approval for the animal drugs after it found the drugs unsafe at a formal hearing, which the agency had never held.¹¹³

In 2013, while the case was on appeal, the FDA announced a program asking the industry to voluntarily reduce the use of subtherapeutic antibiotics in animal feed.¹¹⁴ In its decision, the Second Circuit noted that although the members of the court were not experts in the area, “it is relatively easy for us to accept the FDA’s determination that its preferred program of voluntary compliance offers greater prospect for immediate and significant reductions in animal antibiotic use than the pursuit of a potentially contentious withdrawal hearing.”¹¹⁵ Despite the Second Circuit’s acknowledgment that the FDA was “‘encouraged’” by the ‘overwhelmingly cooperative’ reaction of the animal feed industry to the guidelines for voluntary compliance,” commentators have noted inconsistencies and loopholes in the FDA’s voluntary policy.¹¹⁶ And, while President Barack Obama issued a national strategy to combat antibiotic resistance in 2014, in the area of antibiotics in animal feed, this strategy relies on the FDA’s voluntary programs to reduce the use of antibiotics in animal feed.¹¹⁷

Efficacy Study Implementation; Certain Anticholinergic Drugs Containing Tridihexethyl Chloride; Withdrawal of Approval, 48 Fed. Reg. 4554, 4554 (Feb. 1, 1983); Dep’t of Health, Educ. & Welfare, Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264, 56,264 (Oct. 21, 1977); Dep’t of Health, Educ. & Welfare, Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43,772, 43,772 (Aug. 30, 1977).

¹¹¹ See *Nat. Res. Def. Council, Inc.*, 872 F. Supp. 2d at 329-30.

¹¹² *Id.* 341.

¹¹³ See *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.* 760 F.3d 151, 175 (2d Cir. 2014) (“[T]he decision whether to institute or terminate a hearing process that may lead to a finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA; *but see id.* at 177 (Katzmann, J. dissenting) (stating that any reading of the provision in its larger context would show that once FDA had made a preliminary finding that the drugs were unsafe, it was required to hold hearings on their withdrawal).

¹¹⁴ See *Phasing Out Certain Antibiotic Use in Farm Animals*, U.S. FOOD & DRUG ADMIN (Dec. 11, 2013), <http://www.fda.gov/forconsumers/consumerupdates/ucm378100.htm> [<https://perma.cc/6TA6-M9AQ>].

¹¹⁵ See *Nat. Res. Def. Council, Inc.*, 760 F.3d at 175.

¹¹⁶ See Lisa Heinzerling, *The FDA’s Continuing Incapacity on Livestock Antibiotics*, 33 STAN. ENVTL. L.J. 325, 333 (2014) (identifying identifies four specific problems with FDA’s voluntary approach: the reliance on industry cooperation, the fact that antibiotics can still be issued herd-wide for disease prevention, the weakening of the meaning of veterinary oversight, and the lack of transparency in the process); Diana R. H. Winters, *The Inadequacy of Voluntary Measures to Reduce the Use of Antimicrobials in Animal Feed*, BILL OF HEALTH (Oct. 14, 2014), <http://blogs.harvard.edu/billofhealth/2014/10/04/the-inadequacy-of-voluntary-measures-to-reduce-the-use-of-antimicrobials-in-animal-feed> [<https://perma.cc/2DXM-E359>].

¹¹⁷ See THE WHITE HOUSE, NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 13 (Sept. 5, 2014), <https://obamawhitehouse.archivesavailable> at <http://www.whitehouse.gov/sites/default/files/docs/carb>

The California bill addresses the shortcomings of the FDA's policy by prohibiting the use of antibiotics for routine disease prevention and increasing veterinary oversight.¹¹⁸ In fact, Governor Jerry Brown vetoed an earlier version of the bill that would have incorporated the FDA's voluntary guidelines, writing that California needed to go further to fight antibiotic resistance.¹¹⁹ Before the law went into effect, commentators opined whether people would challenge the law on express or implied preemption grounds, but no one has yet to bring a suit.¹²⁰

With both the regulation of food additives and antibiotics in the food supply, the federal government has chosen not to act vigorously to protect public health and safety. Disconcertingly, the Agency has ossified its inaction into a set of regulations. As a result, there is a significant opportunity for states to act in these areas, and California has done so in regards to antibiotic use in animal feed. Just as California law "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,"¹²¹ state regulation regarding food additives unregulated by the federal government could do the same. Due to the uncertainty of preemption law, courts could invalidate state laws enacted to fill in where the federal government has chosen not to act. As Emilie Aguirre writes in her compelling article discussing the justifications for California's antibiotics law to survive such a challenge, this "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."¹²² Such uncertainty may deter states from legislating in important areas that were previously unregulated, and may also serve to sustain the idea that food policy is primarily regulated on the federal level. Ultimately, this default to federal regulation is detrimental to the rigorous experimentation needed in food policy today.

IV. RETOOLING THE FEDERAL-STATE RELATIONSHIP

As the food landscape continually shifts at the local, state, national, and global level, federal law has struggled to keep pace. In other areas of law regulating industries and entities whose activities have the potential to impact public health, states and localities have demonstrated significant leadership where the federal government has fallen short.¹²³ In the food law and policy arena, there have been some notable developments at the state and local level, but arguably, there is much to be done. As mentioned previously, states and localities have taken active steps to address the obesity epidemic, which the NLEA has largely failed to ameliorate in any demonstrable

_national_strategy.pdf.

¹¹⁸ Livestock: Use of Antimicrobial Drugs, 2015 Cal. Stat. ch. 675 (2015) (codified at CAL. FOOD & AGRIC. CODE §§ 14400-14408 (2017)); Emilie Aguirre, *Contagion Without Relief: Democratic Experimentalism and Regulating the Use of Antibiotics in Food-Producing Animals*, 64 UCLA L. REV. 550, 578 (2017).

¹¹⁹ See Aguirre, *supra* note 118; 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.

¹²⁰ See Aguirre, *supra* note 118, at 592 (concluding that a suit against the law on preemption grounds should fail).

¹²¹ *Id.* at 593.

¹²² *Id.*

¹²³ See Kirsten H. Engel, *Harnessing the Benefits of Dynamic Federalism in Environmental Law*, 56 EMORY L.J. 159, 168 (2006) (noting that states, most often California, "impose standards on nationally distributed products to address and environmental health or safety problem.").

manner.¹²⁴ Yet, some might argue the states' attempts at filling gaps left by federal law have not gone far enough or represent clumsy efforts that fail to yield substantial impact.

Others may suggest more regulation is not necessarily the answer, particularly as it pertains to the food industry where consumers have played a strong role in driving product reformulations or labeling disclosures to meet changing demand.¹²⁵ However, market-based responses to public health concerns presuppose consumers have access to information that may affect their purchasing decisions. Regulation, on the other hand, is justified and necessary when it protects the public's health from harms imposed by others.¹²⁶ While controversial, public health regulation is also justified on the basis of risk to self, also referred to as paternalism, where government interferes with individual decision making to provide some benefit or prevent harm.¹²⁷ Those who suggest government should refrain from paternalistic regulation argue that individuals should be free to engage in potentially harmful activities assuming they are aware of the risks.¹²⁸ Laws intended to prevent consumers from engaging in activities that might harm them, such as purchasing products with potentially unsafe ingredients are clearly justified as non-paternalistic, particularly when information about the product's safety is completely in the control of the producer.¹²⁹ In fact, there is a general acceptance that the market cannot adequately protect consumers from potentially unsafe products leaving responsibility in the hands of regulators.¹³⁰

¹²⁴ See Jayachandran A. Variyam, *Do Nutrition Labels Improve Dietary Outcomes?*, 17 HEALTH ECON. 695, 704 (2008); Richard Williams, *Why the New Nutrition Labels Won't Work*, POLITICO: THE AGENDA, (May 23, 2016), <https://www.politico.com/agenda/story/2016/05/the-nutrition-facts-panel-failed-policy-000125> [<https://perma.cc/6RFS-2MUJ>] (“How am I so sure that the nutrition facts panel has been a failure? Because I made all of the upbeat predictions about how helpful it would be when, in 1993, we implemented the Nutrition Labeling and Education Act of 1990. That law created, among other things, the Nutrition Facts Panel that you see on the back of packaged food. At the time, I was the chief economist at the Center for Food Safety and Applied Nutrition in the FDA and I asserted that people would see this information and use it to make wise, healthy choices, which would lead to better health outcomes for the nation. We thought we would see about 40,000 fewer cases of cancer and heart disease over the next 20 years and prevent 13,000 deaths.”); *but see FDA Nutrition Innovation Strategy*, U.S. FOOD & DRUG ADMIN. (Oct. 18, 2018), <https://www.fda.gov/Food/LabelingNutrition/ucm602651.htm> [perma.cc/DV4B-S22V] (detailing FDA Commissioner Scott Gottlieb's recently announced “Nutrition Innovation Strategy” as part of the agency's “Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap” focused on prioritizing science based food label claims, cleaning up the ingredients label for greater consumer understanding, reconsidering existing standards of identity in light of updated nutrition science, implementing the enacted changes to the nutrition facts panel and menu labels, and voluntary measures to reduce sodium in food products, in response to the failed nutrition labels).

¹²⁵ See, e.g., DELOITTE, CAPITALIZING ON THE SHIFTING CONSUMER FOOD VALUE EQUATION 4 fig. 4 (2016), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/consumer-business/us-fmi-gma-report.pdf>; Beth Kowitz, *Special Report: The War on Big Food*, FORTUNE (May 21, 2015), <http://fortune.com/2015/05/21/the-war-on-big-food/> [<https://perma.cc/3KWN-M2JG>] (“We look at our business and say, ‘How can we remake ourselves?’” said Richard Smucker, CEO of [Smuckers].”); Hans Taparia & Pamela Koch, Opinion, *Real Food Challenges the Food Industry*, N.Y. TIMES, Nov. 8, 2015, at SR4 (“[F]ood manufacturers are reacting [to changing consumer demand] by cleaning up their ingredient labels, acquiring healthier brands and coming out with a prodigious array of new products.”).

¹²⁶ See generally Lawrence O. Gostin, *General Justifications for Public Health Regulation*, 121 PUB. HEALTH 829 (2007) (examining three general justifications for government intervention: (1) risk to others; (2) protection of incompetent people; and (3) risk to self).

¹²⁷ *Id.* at 831.

¹²⁸ *Id.*

¹²⁹ See David B. Resnik, *Paternalistic Food and Beverage Policies: A Response to Conly*, 7 PUB. HEALTH ETHICS 170, 171 (2014).

¹³⁰ Gostin, *supra* note 126, at 831, 833.

The notion of a retooled foodralism, or one where state and federal regulatory authority over food issues that impact public health, safety, and welfare is blended, could remedy this by assuring the states of their authority to act when the federal government has chosen not to, serving the important function of ensuring that some authority is regulating in the public's interest. While the common concern over urging greater state action in a field with national reach relates to piecemeal law and policymaking, it is worth considering that a fragmented regulatory approach to certain issues may be preferable to the virtual inexistence of oversight. Moreover, such an approach can shift our perception of the proper default regulatory authority in the area of food policy.

This essay considers two specific examples where the FDA opted for a regulatory approach to important public health issues that encourages rather than mandates compliance with a set of federal norms. Some commentators have argued that when agencies are faced with regulatory situations involving rapidly changing technologies or scientific uncertainty, they should engage in "non-advisory preemption" or simply issue nonbinding agency guidance¹³¹ that does not preempt the states from regulating simultaneously.¹³² The states are then free to experiment and develop laws that benefit from the results of those efforts. While nonbinding in their effect, the two examples above have shown that the agency has not only chosen not to regulate in one instance, but has formalized, through federal regulations, its intent not to enforce any standards in the other. In part, the FDA has justified these regulations through its interpretations of the FDCA, which it argues does not explicitly direct the agency to mandate a course of action.

Even where the agency has formalized a decision not to regulate, absent some explicit intent to preempt state action, states should be free to regulate in the interests of public health, safety, and welfare, and to mandate compliance where the federal government has chosen not to. An approach to food regulation that does not question the states' ability to regulate where the federal government has chosen not to does not create a conflict between state and federal law, but rather serves to fulfill the overarching objectives of our federal food laws to provide a safe food supply for consumers. This will allow food law and policy to be more responsive to changing conditions and the local landscape, while also providing varied models for possible emulation at the national level.

¹³¹ Nonbinding agency guidance is exempt from the notice and comment requirements under Title V of the United States Code section 553. See 5 U.S.C. § 553 (2012).

¹³² See generally Sarah E. Light, *Advisory Nonpreemption*, 95 WASH. U. L. REV. 327 (2017) (describing advisory nonpreemption).