

DRAFT

Retooling American Foodralism Laurie J. Beyranevand and Diana Winters

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 articulated anti-regulatory agenda makes it unlikely that these previously under prioritized areas will be addressed.²

State and local food policy action allows for regional difference, but also has 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, a strategy that has not been embraced nationally, while 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 take action to fill federal gaps. We conclude by arguing for an approach that involves a retooling of American foodralism⁶ to embrace a complementary regulatory relationship between the federal and state governments that respects the

¹ See Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap, available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf> (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."); Reducing the Burden of Chronic Disease, remarks by Commissioner Scott Gottlieb, Mar. 29, 2018, available at <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>.

² See 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-fordeconstruction-of-the-administrative-state/?utm_term=.41e5ce69fe24; Diana R. H. Winters, *Food Law at the Outset of the Trump Administration*, 64 UCLA L. Rev. Disc. 28, 31-37 (2017).

³ Michael J. Bologna, "Cook County Puts Soda Tax on Ice in December," Bloomberg BNA (Oct. 12, 2017), available at: <https://www.bna.com/cook-county-puts-n73014470769/> ("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 Trans Fat Bans Tied to Fewer Heart Attacks and Strokes, N.Y. Times, Apr. 12, 2017. 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 Calorie Posting, NYC Business, available at <https://www1.nyc.gov/nycbusiness/description/calorie-posting>; FDA, Menu Labeling Requirements, available at

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm>.

⁵ See Allan Erbsen, Horizontal Federalism, 93 MINN. L. REV. 493, 500 (2008); Diana R. H. Winters, *The Benefits of Regulatory Friction in Shaping Policy*, 71 Food and Drug L. J. 228, 238-239 (2016).

⁶ 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.

need for uniformity, but properly allows states and localities to more actively participate and regulate in the interests of their citizens for the benefit of the public health, safety, and welfare. In this “dynamic federalism,”⁷ the states can experiment and function as the intended laboratories of democracy.⁸ This 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 food system due to its breadth and complexity.⁹ These include domestic and international laws and policies 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, however, 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, poultry 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 many of the original provisions and subsequent amendments were proposed by members of the food industry who worked closely with Congress.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 In 1785, Massachusetts enacted the first adulteration law that applied to all food commodities with many states following suit thereafter.¹⁸

⁷ Also referred to as “empowerment federalism,” “polyphonic federalism,” “interactive federalism,” and “vertical regulatory competition.” Kirsten H. Engel, *Harnessing the Benefits of Dynamic Federalism in Environmental Law*, 56 Emory L.J. 159 (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.”).

⁸ *New State Ice Co. v. Liebmann*, 285 U.S. 262 (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.).

⁹ See e.g., Maggie Gosselin, *Beyond the USDA: How Other Government Agencies Can Support a Healthier, More Sustainable Food System* (Feb. 2010) (citing myriad governmental departments and agencies beyond the FDA and the USDA with a role in regulating the food system, including the EPA, Department of Interior, Department of Defense, 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).

¹⁰ Rénee Johnson, *The Federal Food Safety System: A Primer*, Congressional Research Service (Jan 17, 2014) <https://www.fas.org/sfp/crs/misc/RS22600.pdf>.

¹¹ See Richard A. Merrill and Jeffrey K. Francer, *Organizing Food Safety Regulation*, 31 Seton Hall L. Rev. 61, 90 (2000).

¹² 21 U.S.C. §§ 601 et seq.

¹³ 21 U.S.C. §§ 451 et seq.

¹⁴ 21 U.S.C. §§ 1031 et seq.; see Richard A. Merrill and Jeffrey K. Francer, *Organizing Food Safety Regulation*, 31 Seton Hall L. Rev. 61, 90 (2000).

¹⁵ See Dunn, Charles Wesley, *The Federal Act and the Food Industry*, 3 FOOD DRUG COSM. L.Q. 166, 171 (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, 153 (1948).

¹⁶ See generally Dunn, Charles Wesley, *The Federal Act and the Food Industry*, 3 FOOD DRUG COSM. L.Q. 166, 171 (1948).

¹⁷ See generally, Peter Barton Hutt and 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 40.

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.¹⁹ By 1850, however, food adulteration was identified as an issue of public concern, leading to calls 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 them²¹ and also recognized the need to continue to develop laws aimed at individual products and, eventually, for those 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 regulation attributable specifically to the existence of several factors: (1) “specialization and urbanization” which caused consumers to purchase foods from “impersonal markets”; (2) technological innovations in food production that created new products, but also “increased product complexity”; (3) “the rise of analytic chemistry” which allowed for the adulteration of foods in ways that consumers could not easily identify; and (4) the market’s diminished ability to address adulteration issues that relied on consumer identification of problems.²³ Because of these advances in technology and commerce, the states continued to develop laws to prevent adulteration.²⁴

Contemporaneously, the federal government was considering national legislation to address the issue of food adulteration. In 1906, President Roosevelt signed the Pure Food and Drugs Act²⁵ into law after the introduction of many unsuccessful bills.²⁶ Many questioned why Congress waited over a half century prior to enacting 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.²⁷ Some suggest that the law exemplified regulatory capture and was enacted to appease large food manufacturers who sought federal legislation as a means of disadvantaging small, local producers.²⁸ However, most scholars cite the publication of Upton Sinclair’s *The Jungle* as the catalyst that eventually forced President Roosevelt’s hand.²⁹ The 1906 Act created a national scheme for the regulation of food,

¹⁹ *Id.* at 39.

²⁰ *Id.*

²¹ See Charles Wesley Dunn, *Its Legislative History*, 1 Food Drug Cosm. L.Q. 297, 306 (1946).

²² *Id.* at 42-43.

²³ Marc T. Law, *History of Food and Drug Regulation in the United States*, available at: <http://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states/> (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 and Robert Gallman eds., University of Chicago Press) (1986); SUSAN STRASSER, *SATISFACTION GUARANTEED: THE MAKING OF THE AMERICAN MASS MARKET* (Pantheon Books) (1989); JAMES H. YOUNG, *PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906* (Princeton Univ. Press) (1986); LORINE S. GOODWIN, *THE PURE FOOD, DRINK, AND DRUG CRUSADERS, 1879-1914* (McFarland & Co.) (1999); and DONNA J. WOOD, *THE STRATEGIC USE OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA* (Pitman Publishing) (1986)).

²⁴ 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.” Marc T. Law, *History of Food and Drug Regulation in the United States*, available at: <http://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states/>.

²⁵ 21 U.S.C. §11 (1906), *repealed by* 21 U.S.C. § 392(a), Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

²⁶ See Charles Wesley Dunn, *Original Federal Food, and Drugs Act of 1906, As Amended: Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297 (1946) (Prior to the passage of the Act, 103 bills were introduced to and defeated in Congress.).

²⁷ See Charles Wesley Dunn, *Its Legislative History*, 1 Food Drug Cosm. L.Q. 297, 307 (1946).

²⁸ Gabriel Kolko, *The Triumph of Conservatism: A Reinterpretation of American History* (McMillan) (1967).

²⁹ See e.g. U.S. FOOD AND DRUG ADMIN., FDA’S ORIGIN AND FUNCTIONS: FDA HISTORY, PART I, FDA.gov, available at: <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (“In fact, the nauseating condition of the meat-

but suffered from significant failings, and the FDA began to advocate for legislation to fill its gaps soon after its passage.³⁰ In 1938, Congress enacted the Food, Drug, and Cosmetic Act. The FDCA gave the FDA more authority over food labeling, and required the issuance of legal standards for foods, among other measures.³¹ Practically speaking, however, on the food side of the Act, industry is largely self-regulating with few exceptions. Although the FDCA has been amended over 100 times since 1938, its basic structure still stands.³²

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.³³ Moreover, while national uniformity was a rallying cry for industry to urge pass of the Federal Food, Drug, and Cosmetic Act, scholars posit that courts only consider uniformity as a means of fulfilling the Act's "overriding policy of improving consumer protection."³⁴ 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.³⁵ The existence of specific express preemption provisions within the Act has led courts to conclude that other matters were not to be preempted.³⁶ Moreover, the courts have confirmed the states' legitimate interest in protecting the public from "fraud and deception" related to food products.³⁷

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.").

³⁰ Peter Barton Hutt, Richard A. Merrill, Lewis A. Grossman, *Food and Drug Law Cases and Materials*, 4th Ed., Foundation Press (2014) at 9.

³¹ *Id.* at 10-11.

³² *Id.* Hutt, Merrill, and Grossman note that the Act today is "more than 30 times the length it was in 1938." *Id.* at 11.

³³ See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 230 (18947)(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 intent of Congress."); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144, 83 S. Ct. 1210, 1218 (1963) (Supreme Court upheld a state law that rejected avocados based on maturity which federal law deemed marketable holding that "the 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 Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718, 105 S. Ct. 2371, 2377 (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.")

³⁴ Charles P. Mitchell, *State Regulation and Federal Preemption of Food Labeling*, 45 Food Drug Cosm. L.J. 123, 139 (1990).

³⁵ Nutrition Labeling Education Act, 21 U.S.C. § 343; see also Charles P. Mitchell, *State Regulation and Federal Preemption of Food Labeling*, 45 Food Drug Cosm. L.J. 123, 129 (1990) ("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."); "[M]anufacturers do not have to 'print 50 different labels' and consumers who buy food in more than one state do not have to discern different labels." *Sciortino v. Pepsico, Inc.* 108 F. Supp. 3d 780, 796-797 (2015) (citations omitted).

³⁶ Diana R. H. Winters, *The Magical Thinking of Food Labeling*, 89 Tulane L. Rev. 815, 832-833 (2014). One court commented, "[a]s 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 nonpreemption." *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 121 Cal. Rptr. 2d 749, 755 (Ct. App. 4th 2002); 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." (citing *Setser v. United States*, 566 U.S. —, —, 132 S.Ct. 1463, 1469–1470, 182 L.Ed.2d 455 (2012) (applying principle of *expressio unius est exclusio alterius*)).

³⁷ See *Florida Lime*, 373 U.S. at 144, 145 ("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."); *Id.* at 145 ("Federal regulation by means of minimum standards of the picking, processing, and transportation of agricultural commodities, however comprehensive for those purposes that regulation may be, does not of itself import displacement of state control over the distribution and retail sale of those commodities in the interests of the consumers of the commodities within the State.")

There are instances, however, where courts find state or local regulation of food policy to be preempted by federal law, either expressly or impliedly. Express preemption occurs when federal legislation or regulation contains language expressly preempting state law.³⁸ An example of this is the Nutrition Labeling and Education Act (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 label requirements and the listing of product ingredients.³⁹ It also prohibits state and local requirements that are not identical to federal requirements on nutrient content and health claims, although until the passage of the Patient Protection and Affordable Care Act, states could establish requirements as to nutrient content claims for restaurant and retail chains.⁴⁰

Implied preemption can manifest in three ways: when Congress occupies the entire field of regulation, when state law and federal law actually conflict, and when state law interferes with the “purposes and objectives” of Congress in establishing regulation.⁴¹ 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.”⁴² In a case of conflict preemption, a regulated entity cannot simultaneously comply with both federal and state obligations. Finally, in objectives and purposes preemption, the state law requirement interferes with the objectives and purposes of Congress in passing federal legislation. Discerning whether this type of preemption exists is a delicate task.⁴³

The complexity of the layered food regulation scheme in the United States also 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.⁴⁴ Historically, the states and localities have assisted the federal government in food regulation primarily by implementing federal standards, performing inspections and engaging in limited enforcement activities, but there has been criticism that states duplicate federal efforts in some

³⁸ *Hillsborough Cty., Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985) (explaining preemption doctrine).

³⁹ “[N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section . . . [or] any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section . . . [or] any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title” 21 U.S.C. §§ 343-1(a)(2), (3) (4)(2010).

⁴⁰ 21 U.S.C. § 343-1(a)(4), (5)(2010). This exemption allowed localities, such as New York City, to establish menu-labeling requirements for certain restaurants. See *New York State Restaurant 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. 21 U.S.C. § 343-1(a)(4)(2010).

⁴¹ *Hillsborough Cty.*, 471 U.S. at 715; *Jones v. Rath*, 430 U.S. at 525; *Florida Lime*, 373 U.S. at 146.

⁴² *Hillsborough Cty.*, 471 U.S. at 713 (citation omitted).

⁴³ 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.*, 2011 WL 2418628 at *8 (Conn. Super. Ct. 2011).

⁴⁴ See e.g., *Nat’l Meat Ass’n v. Harris*, 132 S. Ct. 965, 970-71 (2012) (Court struck 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.); *Jones v. Rath*, 430 U.S. 519 (1977) (Invalidating 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.).

instances, and are sometimes inconsistent in their regulation of certain aspects of the food system.⁴⁵ 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.⁴⁶

Some might suggest the Food Safety Modernization Act (FSMA) provides an example of the beginnings of the type of shared state-federal regulatory space called for in this Essay given the Act's many provisions related to federal-state integration. 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.⁴⁷ The Act reflects the largest reform of federal food safety regulation in seven decades, substantially expanding the scope of the Food and Drug Administration'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.⁴⁸ Passage of FSMA⁴⁹ 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.⁵⁰ While collaboration among different agencies at varying levels occurred, researchers called for a federal mandate to develop an "integrated food safety system."⁵¹

However, 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

⁴⁵ Robert B. Wallace and Maria Oria, *Enhancing Food Safety: The Role of the Food and Drug Administration* (2010), available at: http://www.nap.edu/catalog.php?record_id=12892&utm_expid=4418042-5.krRTDpXJQISoXLpdo-1Ynw.0&utm_referrer=http%3A%2F%2Fwww.nap.edu%2Fopenbook.php%3Frecord_id%3D12892%26page%3D217.

⁴⁶ *Id.* See also Jennifer L. Pomeranz, Dariush Mozaffarian, Renata Micha, *The Potential for Federal Preemption of State and Local Sugar-Sweetened Beverage Taxes*, *Am. J. Prev. Med.* 2017;53(5):740–743 (discussing the rationale for federal preemption of sugar-sweetened beverage taxes and concluding that these taxes should not be preempted).

⁴⁷ See e.g., Government Accountability Office, "FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed" 16 (May 2016), available at: <https://www.gao.gov/assets/680/677463.pdf>. (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).

⁴⁸ Johnson R. Food safety issues for the 113th Congress. Congressional Research Service Report, R42885, 2013 Jan 9.

⁴⁹ Food Safety Modernization Act of 2011, P.L. No. 111-353, 124 Stat. 3885 (2011).

⁵⁰ Government Accountability Office, *Federal Food Safety and Security Systems: Fundamental Restructuring is Needed to Address Fragmentation and Overlap* (2004), GAO-04-588T, available at: <http://www.gao.gov/assets/120/110801.pdf>.

⁵¹ Government Accountability Office, "FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed" 16 (May 2016), available at: <https://www.gao.gov/assets/680/677463.pdf>. 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. [Francer, GAO, blog post]

regulated parties, as well as the regulators. As required,⁵² the agency performed preliminary regulatory impact analyses of several of its proposed rules prior to their promulgation.⁵³ 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 year⁵⁴ with net benefits amounting to \$582.63 million per year.⁵⁵ However, the FDA calculated its anticipated benefits based on the avoided costs associated with prevented foodborne illness outbreaks, but notes that will be dependent on effective implementation of the rule.⁵⁶ 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.”⁵⁷

Consequently, critics argue that FSMA embodies a regulatory response where the costs may far exceed the benefits and potentially imposes unnecessary burdens while diverting resources from other necessary food system priorities.⁵⁸ In addition, the states have identified a number of issues in need of

⁵² “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.”). Reference 43 FDA, “Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption,” re Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Available from: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-1018>.

⁵³ See Reference 43 FDA, “Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” re Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Available from: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-1018>; FDA, “Tab C Final Regulatory Action as Cleared by OIRA, and a Final Version of the Materials Required by the Executive Order (Supp PRIA) OMB Executive Order 12866 Regulatory Planning and Review re Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Supplemental Proposed Rule)” (Sept. 29, 2014), <https://www.regulations.gov/document?D=FDA-2011-N-0920-1584>.

⁵⁴ FDA Proposed Amendments to Rule. Standards for the growing, harvesting, packing and holding of produce for human consumption. ID: FDA-2011-N-0921-0973. Available from: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0973>.

⁵⁵ Reference 43 FDA, “Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption,” re Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 298, 302. Available from: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-1018>.

⁵⁶ Reference 43 FDA, “Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption,” re Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 301.

⁵⁷ FDA, “Tab C Final Regulatory Action as Cleared by OIRA, and a Final Version of the Materials Required by the Executive Order (Supp PRIA) OMB Executive Order 12866 Regulatory Planning and Review re Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Supplemental Proposed Rule)” (Sept. 29, 2014) 6, <https://www.regulations.gov/document?D=FDA-2011-N-0920-1584>

⁵⁸ See e.g., Richard Williams, *Regulations Implementing the Food Safety Modernization Act* (Aug. 2015), <https://www.mercatus.org/system/files/Williams-FSMA-Regulations.pdf>; and James L. Gattuso and Diane Katz, *Red Tape Rising 2016: Obama Top Regs Top \$100 Billion Annually* (May 23, 2016), <http://www.heritage.org/research/reports/2016/05/red-tape-rising-2016-obama-regs-top-100-billion-annually> (“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” (Nov. 1,

resolution associated with the state-federal relationship contemplated under the statute: (1) clarification of roles and responsibilities; (2) regular communication between 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.⁵⁹

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.⁶⁰ As a result of the individual meetings the FDA held to receive feedback on its proposed rules from interested parties, and after reviewing the public comments, the agency came to discover the need to tailor its regulations based on differences among regions, states, and localities, and the various production methods around the country, based on growing seasons in addition to other factors.⁶¹ 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.⁶²

Here we advocate a different approach than the one reflected in the Food Safety Modernization Act, which strengthens the states' roles to a degree, but still relies on them largely 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 policy. It is appropriate for states to act in areas that would benefit the public health, safety, and welfare and where the federal government has not acted. Any cost to national

2014), <http://reason.com/archives/2014/11/01/fdas-fsma-modernizes-food-safety-without> ("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.").

⁵⁹ Government Accountability Office, "FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed" 32-37 (May 2016), available at: <https://www.gao.gov/assets/680/677463.pdf>.

⁶⁰ National Sustainable Agriculture Coalition, *Comments on the Proposed Rule for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Nov. 15, 2013), available at: <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 Winters, Diana R. H., *From Industrial to Artisanal: A New Regulatory Framework for a Changing Food Landscape* (April 30, 2013), at 10-11. Indiana University Robert H. McKinney School of Law Research Paper No. 2013-23. Available at SSRN: <https://ssrn.com/abstract=2283213> or <http://dx.doi.org/10.2139/ssrn.2283213> (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).

⁶¹ See e.g., Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption - Supplemental Notice of Proposed Rulemaking, 76 Fed. Reg. 58433 (proposed Sept. 29, 2014) (FDA proposed 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.); Food and drug Administration, *Our Strategy for Engaging Stakeholders*, available at: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm564350.htm> ("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.").

⁶² *Id.*

uniformity is outweighed in these cases by the benefit to the public, and can be remedied by Congress in any event.

II. 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, which is often cited as a leader in state regulation that is strongly protective of the public,⁶³ has joined the lead in the context of food policy as well. This section will consider various state initiatives, both underway and under consideration, that can be viewed as pushing the bounds of federalism and that may ultimately provide for a safer food system.

A. Substances Generally Recognized as Safe

As mentioned above, 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 additives⁶⁴ in the American food supply.⁶⁵ 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.⁶⁶ 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.⁶⁷

Under the FAA, all additives proposed for use in the food supply are presumed unsafe⁶⁸ and must receive pre-market approval by the FDA⁶⁹ unless they have been exempted as prior approved⁷⁰ or generally recognized as safe (GRAS) substances.⁷¹ For a substance that would otherwise be subject to the food additive pre-approval process to be considered GRAS and excluded from regulation as a food additive, it must be “recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under

⁶³ See e.g., Madison Park, “California Sets Trends in Health Regulation,” CNN (Feb. 10, 2012, available at:

<http://www.cnn.com/2012/02/10/health/california-leads-health-laws/index.html> (“The state has been first to pass major public health initiatives that have spread throughout the country.”); Charles W. Schmidt, “ENVIRONMENT: California Out in Front.” 115 *Environmental Health Perspectives* 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.).

⁶⁴ 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) (2006); 21 C.F.R. § 170.3(e) (2012).

⁶⁵ *Developments in the Law: The Federal, Food, Drug, and Cosmetic Act*, 67 Harv. L. Rev. 632, 634 (1954).

⁶⁶ Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended at 21 U.S.C. §§ 301–399. (2006)).

⁶⁷ See e.g., Complaint at 1, CENTER FOR FOOD SAFETY, BREAST CANCER PREVENTION PARTNERS, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, ENVIRONMENTAL DEFENSE FUND, and ENVIRONMENTAL WORKING GROUP v. TOM PRICE, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; SCOTT GOTTLIEB, COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION; and UNITED STATES FOOD AND DRUG ADMINISTRATION, S.D.N.Y. (No. 1:17-cv-03833) (“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 (“FDCA” or “the Act”), 21 U.S.C. §§ 342(a), 348; the Administrative Procedure Act (“APA”), 5 U.S.C. § 701 et seq; and the U.S. Constitution.”); Erin Quinn and Chris Young, “Why the FDA Doesn’t Really Know What’s in Your Food,” The Center for Public Integrity (Apr. 14, 2015), available at: <https://www.publicintegrity.org/2015/04/14/17112/why-fda-doesnt-really-know-whats-your-food>.

⁶⁸ 21 U.S.C. § 348(a).

⁶⁹ *Id.* § 348(b).

⁷⁰ A list of prior approved substances is included in Food and Drugs, 21 C.F.R. §§ 181.1–181.34 (2012).

⁷¹ 21 U.S.C. § 321(s) (2006).

the conditions of its intended use.”⁷² Such general recognition of safety may be demonstrated either through “scientific procedures”⁷³ or, for those substances commonly used prior to the passage of the FAA in 1958, “experience based on common use in food.”⁷⁴ 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.⁷⁵

Based on official statements made by the FDA, 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 that had been used as additives without evidence they produced acute harm.⁷⁶ However, it is estimated that there are presently over 1,000 chemicals that have been deemed GRAS and used in foods without FDA oversight or notification.⁷⁷ Consequently, despite the existence of seemingly rigid federal standards, there are many substances continuously affirmed as GRAS and effectively left unregulated, while few are delisted in light of evolving science suggesting some substances are not, in fact, safe.⁷⁸

In 1997, the FDA informally replaced its GRAS petition process with a voluntary notification program.⁷⁹ Because the process is completely voluntary, companies submitted just 274 GRAS determination notifications to the agency from 1998 to 2008.⁸⁰ After years of failing to promulgate a final rule replacing the petition process with a notification process, in 2016, the agency formally replaced the voluntary

⁷² *Id.*

⁷³ *Id.*; 21 C.F.R. § 130.70(a) (2012).

⁷⁴ 21 U.S.C. § 321(s); 21 C.F.R. § 130.70(c)(1).

⁷⁵ 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) 5 (2010), available at <http://www.gao.gov/products/GAO-10-246> (Concluding that “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, Heather M. Alger, James T. O’Reilly, Sheldon Krinsky, Lisa A. Bero, Maricel Maffini, “Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe,” 173 JAMA Intern. Med. 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.”).

⁷⁶ See Substances Generally Recognized as Safe, 62 Fed. Reg. 18938, 18939 (April 17, 1997) (“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 (2012) (as amended at 21 C.F.R. §§ 152, 182) (“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. Degnan, *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.”).

⁷⁷ Pew Charitable Trusts, “Fixing the Oversight of Chemicals Added to Our Food” 1 (Nov. 2013), available at: http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content_level_pages/reports/foodadditivescapstonereportpdf.pdf.

⁷⁸ 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 (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).

⁷⁹ 62 FR 18938 (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.

⁸⁰ U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note --, at 6.

petition process with a voluntary notification process, but strongly encouraged companies to contact the agency when making GRAS determinations.⁸¹ In response to comments arguing that the agency's proposal was arbitrary and capricious because the FDA was failing to fulfill its mandate to "oversee food additives," the agency responded by noting that although the Food, Drug, and Cosmetic Act requires a premarket approval process for additives, the statute does not require industry to notify the agency regarding the use of GRAS substances.⁸² The FDA has been criticized for its lack of knowledge about the existence and safety of certain GRAS substances in the market place,⁸³ as well as the agency's inability to monitor the continued safety of those substances.⁸⁴

Not surprisingly, some advocates were disappointed with the FDA's final regulation and have since sued, alleging that because the agency is relying on a completely voluntary process, the plaintiff organizations lack information about GRAS determinations made independently of FDA oversight.⁸⁵ The agency's action and the resulting lawsuit, however, call into question whether federal law would preempt state action in this area; because the FDA has effectively chosen not to regulate an entire category of substances that would otherwise be subject to significant agency oversight, can a state choose to disallow the inclusion of substances independently deemed GRAS without FDA oversight in its food supply?

For example, assuming a state chose to ban GRAS substances that have been independently tested and approved without FDA oversight, would that be preempted? While most states have substantially adopted the text of the Federal Food, Drug, and Cosmetic Act, which includes language exempting GRAS substances from the additive pre-approval process, California's Sherman Act⁸⁶ is a notable exception. Under California's law, added substances are considered unsafe unless a regulation "limits the quantity and the use, or intended use, of the substance to the terms prescribed by the regulation."⁸⁷ 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

⁸¹ Food and Drug Administration, "Substances Generally Recognized as Safe", 81 F.R. 54960, 54966 (2016).

⁸² 81 FR 54960, 54971.

⁸³ Carrie A. Scufari, Esq., *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 *244 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."); Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. Rev. 329, 443 (1998).

⁸⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note ---, 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.").

Erin Quinn and Chris Young, "Why the FDA Doesn't Really Know What's in Your Food," The Center for Public Integrity (Apr. 14, 2015), available at: <https://www.publicintegrity.org/2015/04/14/17112/why-fda-doesnt-really-know-whats-your-food>. ("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.").

⁸⁵ Compl. Center for Food Safety v. Price, No. 1:17-cv-03833 (S.D.N.Y. May 22, 2017).

⁸⁶ CA Health & Safety Code, Div. 104, Part 105.

⁸⁷ CA Health & Safety Code, Div. 104, Part 105, § 110445.

act.”⁸⁸

Neither the Food Additives Amendment nor the federal Food, Drug, and Cosmetic Act 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 statute - the Delaney Clause nor the Color Additives Amendment - contained an express preemption provision.⁸⁹ 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.⁹⁰ Despite the fact that the FDA made a determination about the additive’s safety within the framework of the Food, Drug, and Cosmetic Act, that safety finding did not preclude California from requiring a warning label under state law based on safety concerns.⁹¹ 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.”⁹² 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 [w]hich are matters traditionally left to state regulation.”⁹³ 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 goes into effect, which will be 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 Food and Drug Administration for its failure to more closely monitor and control the use of antibiotics in food-producing animals in the face of 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 that antibiotics be prescribed by licensed veterinarians.⁹⁴ The Bill also provides for data collection regarding the prescription and use of antibiotics.⁹⁵

The history of 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

⁸⁸ CA Health & Safety Code, Div. 104, Part 105, § 110085.

⁸⁹ *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 806 (2015).

⁹⁰ *Sciortino*, 108 F. Supp. 3d at 806-807.

⁹¹ *Sciortino*, 108 F. Supp. 3d at 807.

⁹² *Sciortino*, 108 F. Supp. 3d at 809 (citing *Wyeth v. Levine*, 555 U.S. at 582)).

⁹³ *Sciortino*, 108 F. Supp. 3d at 811.

⁹⁴ S.B. 27, 2015 Leg. Reg. Sess. (Cal. 2015-2016).

⁹⁵ *Id.*

production.⁹⁶ 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.⁹⁷ 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.⁹⁸ 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.⁹⁹

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,¹⁰⁰ these hearings were never held and the 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 FDA, alleging that FDA had “withheld agency action,” by not withdrawing the approval for these animal drugs, and had therefore violated the FDCA and the APA.¹⁰¹ In March 2012, the district court granted summary judgment for the plaintiffs, writing, “For 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.”¹⁰² 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.¹⁰³

In 2013, while the case was on appeal, the FDA announced a program asking industry to voluntarily reduce the use of subtherapeutic antibiotics in animal feed.¹⁰⁴ 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

⁹⁶ See *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 131 (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).

⁹⁷ *Natural Res. Def. Council*, 884 F. Supp. 2d at 129.

⁹⁸ Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444–45 (proposed Feb. 1, 1972) (to be codified at 21 C.F.R. pt. 135).

⁹⁹ 21 C.F.R. § 558.15 (2013).

¹⁰⁰ Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264 (Oct. 21, 1977); Drugs for Human Use; Drug Efficacy Study Implementation; Certain Anticholinergic Drugs Containing Tridihexethyl Chloride; Withdrawal of Approval, 48 Fed. Reg. 4554 (Feb. 1, 1983); New Animal Drugs for Use in Animal Feeds; Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 48 Fed. Reg. 4490 (proposed Feb. 1, 1983) (to be codified at 21 C.F.R. pt. 558).

¹⁰¹ *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 130 (S.D.N.Y. 2012).

¹⁰² *Natural Res. Def. Council, Inc. v. FDA*, 872 F. Supp. 2d 318, 341 (S.D.N.Y. 2012), rev’d, 760 F.3d 151 (2d Cir. 2014).

¹⁰³ *Natural Res. Def. Council, Inc. v. FDA*, 760 F.3d 151 (2d Cir. 2014). The dissent points out 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. *Id.* at 177 (Katzmann, J., dissenting).

¹⁰⁴ See Phasing Out Certain Antibiotic Use in Farm Animals, FDA (Dec. 11, 2013), <http://www.fda.gov/forconsumers/consumerupdates/ucm378100.htm>.

potentially contentious withdrawal hearing.”¹⁰⁵ Despite the court’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 FDA’s voluntary policy.¹⁰⁶ 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.¹⁰⁷

The California bill addresses the shortcomings of FDA’s policy by prohibiting the use of antibiotics for routine disease prevention and increasing veterinary oversight.¹⁰⁸ In fact, Governor Jerry Brown vetoed an earlier version of the bill that would have incorporated FDA’s voluntary guidelines, writing that California needed to go farther to fight antibiotic resistance.¹⁰⁹ Before the law went into effect, commentators opined whether the law would be challenged on express or implied preemption grounds, but no suit has been brought.¹¹⁰

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’s 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,”¹¹¹ state regulation regarding food additives unregulated by the federal government could do the same. Due to the uncertainty of preemption law, however, state laws to fill in where the federal government has chosen not to act could be invalidated by courts. 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.”¹¹² Such uncertainty may deter states from legislating in important areas that have been left unregulated, and may also serve to sustain the idea that food policy is primarily regulated on the federal level. Ultimately, this default is detrimental to the rigorous experimentation needed in food policy today.

III. Retooling the Federal-State Relationship

¹⁰⁵ 760 F.3d at 175.

¹⁰⁶ See Lisa Heinzerling, *The FDA’s Continuing Incapacity on Livestock Antibiotics*, Stanford Environmental Law Journal, Vol. 33, 2014; Diana R. H. Winters, The inadequacy of voluntary measures to reduce the use of antimicrobials in animal feed, Bill of Health, Oct. 14, 2014, available at <http://blogs.harvard.edu/billofhealth/2014/10/04/the-inadequacy-of-voluntary-measures-to-reduce-the-use-of-antimicrobials-in-animal-feed/>. Heinzerling 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. Heinzerling at 333.

¹⁰⁷ The White House, National Strategy For Combating Antibiotic-Resistant Bacteria 5 (2014), available at http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf.

¹⁰⁸ S.B. 27, 2015 Leg., Reg. Sess. (Cal. 2015–2016); Emilie Aguirre, *Contagion Without Relief: Democratic Experimentalism and Regulating the Use of Antibiotics in Food-Producing Animals*, 64 UCLA L. Rev. 550, 578 (2017).

¹⁰⁹ 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 [<https://perma.cc/54URVZH5>]; Aguirre, 64 UCLA L. Rev. at 579.

¹¹⁰ Aguirre at 585-593. Aguirre concludes that a suit against the law on preemption grounds should fail. Aguirre at 592.

¹¹¹ Aguirre at 593.

¹¹² *Id.*

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.¹¹³ 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 federal Nutrition Labeling Education Act has largely failed to ameliorate in any demonstrable manner.¹¹⁴ 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.

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 they have the authority to act when the federal government has chosen not to and serve the important function of ensuring that someone is regulating in the public's interest. While the common concern about urging greater state action in a field with national reach relates to piecemeal law and policymaking, it is worth considering whether a fragmented regulatory approach to certain issues is preferable to the virtual inexistence of oversight. Moreover, such an approach can shift our perception of the proper authority to be the default regulator in the area of food policy.

This Essay considers two specific examples where the Food and Drug Administration 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 "nonadvisory preemption" or simply issue nonbinding agency guidance¹¹⁵ that does not preempt the states from regulating simultaneously.¹¹⁶ The states are then free to experiment and develop laws that benefit from the results of those efforts. While similar to agency guidance documents in their nonbinding effect, in the two examples discussed above, the agency has not only chosen not to regulate, but has formalized, through federal regulations, its intent not to enforce any standards. In part, the FDA has justified these regulations through its interpretations of the Food, Drug, and Cosmetic Act, which it argues does not explicitly direct the agency to mandate a course of action.

¹¹³ 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.");

¹¹⁴ See Jayachandran A. Variyam, "Do Nutrition Labels Improve Dietary Outcomes?", 17 Health Econ. 695 (2008); Richard Williams, "Why the New Nutrition Labels Won't Work," Politico, (May 23, 2016) ("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."). In response to this failure, FDA Commissioner Scott Gottlieb recently announced a "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. Food and Drug Administration, *FDA Nutrition Innovation Strategy* (Mar. 2018), available at: <https://www.fda.gov/Food/LabelingNutrition/ucm602651.htm>.

¹¹⁵ Exempt from the notice and comment requirements under 5 U.S.C. § 553.

¹¹⁶ Sarah E. Light, *Advisory Nonpreemption*, 95 Was. U. L. Rev. 327 (2017).

However, the approach to state regulation must be the same as with nonbinding agency guidance. In other words, even where the agency has formalized its nonregulation through regulations, absent some explicit intent to preempt the states clearly expressed in federal law, states should be free to regulate in the interests of public health, safety, and welfare and 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.