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Book Review

JOSEPH A. PAGE*

FOOD LAW IN THE UNITED STATES. By Michael T. Roberts. New York, NY: Cambridge University Press. 2016. Pp. xiv, 471. \$74.99.

Interest in food law has been proceeding apace for the past decade or so,¹ a phenomenon evidenced by 2016 events such as: a “Vote Food 2016: Better Food, Better Health” conclave sponsored by the O’Neill Institute for National and International Health at the Georgetown University Law Center;² a UCLA-Harvard Conference on “Food Marketing to Children: The Current Reality and What Can Be Done;”³ a Food Law Student Leadership Summit held at the Drake Law School;⁴ a fall symposium on “Law and Food Systems: Institutional Pathways Toward a New Paradigm?,” papers from which appear elsewhere in this number of the *Food and Drug Law Journal*; and the appearance of the first treatise on the subject, entitled *Food Law in the United States* (hereinafter *Food Law*), and authored by Michael T. Roberts, a pioneer in the field.⁵

Written with clarity and precision (and a user-friendliness exemplified by helpful features such as a detailed table of abbreviations), Roberts’ opus represents an admirable effort to impose intellectual discipline on a field marked by unruly growth and yet to emerge from a formative stage. Indeed, as no good deed goes unpunished,

* Professor Emeritus, Georgetown University Law Center. I would like to thank my colleague Lisa Heinzerling and Stephen Migala, the first student editor-in-chief of the *Food and Drug Law Journal*, for their helpful comments.

¹ Compare Baylen J. Linnekin & Emily M. Broad Leib, *Food Law & Policy: The Fertile Field’s Origins and First Decade*, 2014 WISCONSIN L. REV. 557, 584–95 (2014) (discussing the history of food law), with Stephanie Tai, *Food Systems Law from Farm to Fork and Beyond*, 45 SETON HALL L. REV. 109, 124–30 (2015).

² The goal of the gathering was to identify and discuss solutions to problematic legal and regulatory issues affecting food systems in the United States. See *Vote Food 2016*, O’NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW, <http://www.law.georgetown.edu/oneillinstitute/research/Food2016.cfm> (last visited Feb. 16, 2017).

³ See *3rd Annual UCLA-Harvard Food Law and Policy Conference Food Marketing to Children: The Current Reality and What Can be Done*, UCLA LAW: RESNICK PROGRAM FOR FOOD LAW & POLICY, <http://www.chlpi.org/wp-content/uploads/2015/06/2016-FLSLS-Flyer-1.pdf> (last visited Feb. 16, 2017).

⁴ The meeting brought together representatives from a few food-law student societies, all of them part of a national network. See *About FLSN*, FOOD LAW STUDENT NETWORK, <http://foodlawstudentnetwork.org/about/> (last visited Feb. 16, 2017).

⁵ See Linnekin & Leib, *supra* note 1, at 590 (“We mark the birth of the field of FL&P [food law and policy] as 2004, when Michael T. Roberts taught the first course entitled ‘Food Law and Policy’ to students in the Agricultural Law LL.M. Program at the University of Arkansas School of Law . . .”). Roberts now serves as the Executive Director of the Resnick Program for Food Law and Policy at the UCLA School of Law. See *About the Resnick Program for Food Law & Policy*, UCLA LAW: RESNICK PROGRAM FOR FOOD LAW & POLICY, <https://law.ucla.edu/centers/social-policy/resnick-program-for-food-law-and-policy/about/> (last visited Feb. 16, 2017) (hereinafter UCLA LAW).

the seemingly ceaseless publicity afforded food-related issues that either do or might have food law or policy implications may well consign Roberts to the constant updating (and possible rethinking) of his book.⁶

A legal treatise generally seeks to provide comprehensive coverage of a particular subject area, a proposition that bestows on treatises of first impression like *Food Law* a pair of limiting mechanisms that enable authors to cabin their work within manageable and sensible dimensions.⁷ The first is an opportunity to define, either explicitly or implicitly, the subject matter to be covered. The second is the capacity to make decisions about how comprehensive to be. *Food Law*, however, abstains from offering readers a precise definition of the field it sets out to cover, but instead presents coverage of what might be deemed traditional food law—and also includes a generous sampling of food-related topics and issues that have attracted widespread attention in legal and policy circles over the past decade or two. It is in addition selective in the depth of its treatment of these matters, with more space and depth allocated to more complex and controversial subjects.⁸

The conventional method of conceptualizing food law has been to regard it as a subset of food and drug law,⁹ the latter an established area of legal practice¹⁰ and one taught at various law schools for many years.¹¹ This approach derives from the food-related provisions of the federal Food, Drug, and Cosmetic Act (FDCA)¹² and from

⁶ For examples of articles published in the New York Times alone, see Anahad O’Conner, *In the Shopping Cart of a Food Stamp Household: Lots of Soda*, N.Y. TIMES, Jan. 14, 2017, at A1 (discussing U.S. Department of Agriculture disclosure that households receiving food stamps spent 10 percent of their food dollars on unhealthy soft drinks); Kenneth Chang, *Dinner Is Being Tweaked*, *id.*, Jan. 10, 2017, at D1 (stating that a new generation of gene-edited foods falls outside new federal labeling law); Thomas Fuller, *Healthy Food Everywhere But on the Table*, *id.*, Nov. 24, 2016, at A19 (finding that California farmworkers who help grow healthful fruits and vegetables unable to afford healthy diet, suffer high rates of malnutrition and obesity); Stephanie Strom, *Is It Organic? Ground Rules May Be Changing*, *id.*, Nov. 16, 2016, at A1 (discussing controversy over whether vegetables and fruit not grown in dirt should be termed “organic”); Ian Urbina, *U.S. Closing a Loophole on Products Tied to Slaves*, *id.*, Feb. 16, 2016, at A8 (discussing legislative efforts to ban U.S. imports of fish caught by forced labor in Southeast Asia).

⁷ Legal treatises first covered common-law subjects, which because of their nature created a need for systemization and explication of principles and rules derived from case law. On the evolution of legal treatises, see generally LAW BOOKS IN ACTION: ESSAYS ON THE ANGLO-AMERICAN LEGAL TREATISE (Angela Fernandez & Markus D. Dubber eds., 2012).

⁸ See, e.g., MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES § 3.08(2)(b) (2016) (hereinafter cited as FOOD LAW) (discussing a World Trade Organization dispute involving European union ban on beef treated with growth hormones).

⁹ See Linnekin & Leib, *supra* note 1, at 562–79 (discussing food law as a subcategory of food and drug law).

¹⁰ On the food-and-drug bar, see *id.* at 567. For an account of the career of a leading practitioner, see Ervin M. Griswold, Stanley M. Temko & Peter Barton Hutt, *A Tribute to H. Thomas Austern*, 39 FOOD DRUG COSM. L.J. 121 (1984). For a critical assessment, see JOSEPH C. GOULDEN, THE SUPERLAWYERS: THE SMALL AND POWERFUL WORLD OF THE GREAT WASHINGTON LAW FIRMS Ch. 5 (1972).

¹¹ For a list of law schools where the course has been offered, see Linnekin & Lieb, *supra* note 1, at 599–602. The most comprehensive casebook in the field is FOOD AND DRUG LAW: CASES AND MATERIALS (Peter Barton Hutt et al. eds., 4th ed. 2014).

¹² Pub. L. No. 75-717, 52 Stat. 1040 (1938), *codified as amended* at 21 U.S.C. §§ 301–1012 (2014) (hereinafter cited as FDCA). Chapter IV of the Act contains most of its specifically food-related provisions. The majority relate to safety. For a discussion of these provisions, see Fred H. Degnan et al., *Food Safety*, in FOOD AND DRUG LAW AND REGULATION Ch. 2 (David G. Adams et al. eds., 3d ed. 2015). Provisions elsewhere in the Act generally apply to all products (food, drugs, cosmetics, medical devices,

the food-related regulatory initiatives undertaken by the Food and Drug Administration (FDA),¹³ with an appropriate nod toward food-related areas responsibility for which Congress has vested in other agencies. These would include, *inter alia*, meat-and-poultry safety inspections conducted by the Department of Agriculture¹⁴ and food advertising, which the Federal Trade Commission regulates.¹⁵

What I have just described amounts to a relatively circumscribed (some might say cramped, others might say practical) way of thinking about food law—primarily responsive to the needs of practitioners who represent companies or industries subject to the FDCA as well as consumers and consumer groups; federal regulators charged with administering and enforcing the Act; and, congressional members and staffers involved in the processes of amending and overseeing the administration of the Act. This “FDA-centric” approach has shaped not only food-and-drug-law courses that seek primarily to prepare law students for food-and-drug-related employment,¹⁶ but also academic scholarship in the field.¹⁷

Another way of looking at the subject might, at least theoretically, take an all-encompassing approach¹⁸ and incorporate the full sweep of directives (legal and non-legal) arising from the production, marketing, distribution, consumption and disposal of both edibles and potables.¹⁹ This could include fields such as agricultural law,²⁰ and

tobacco) regulated by the statute. *See, e.g.*, FDCA Ch. III, 21 U.S.C. §§ 331–337A (2014) (prohibited acts and penalties).

¹³ *See* JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION* Chs. 10–11 (3d ed. 2007). On the structure and functions of FDA, *see* FDA, <http://www.fda.gov/>.

¹⁴ *See* Brett T. Schwemer & Jolyda O. Swaim, *Food: Meat and Poultry Inspection*, in *FOOD AND DRUG LAW AND REGULATION*, *supra* note 12, Ch. 5.

¹⁵ *See* Anne V. Maher & Lesley Fair, *FTC Regulation of Advertising*, in *FOOD AND DRUG LAW AND REGULATION*, *supra* note 12, Ch. 24.

¹⁶ The academic study of food and drug law need not be limited to the goal of professional preparation. It also lends itself nicely to nuanced and in-depth exploration of topic-specific aspects of traditional upper-class subjects such as administrative law, statutory drafting and construction, the legislative process and constitutional law.

¹⁷ For articles by professors and student notes dealing with food law and published in the 1970s, *see* Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 MICH. L. REV. 171 (1979); Richard A. Merrill & Earl M. Collier, “Like Mother Used to Make”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561 (1974); Note, *Health Regulation of Naturally Hazardous Foods: The FDA Ban on Swordfish*, 85 HARV. L. REV. 1025 (1972); Gary Laden, Note, *FDA Rule-Making Hearings: A Way Out of the Peanut Butter Quagmire*, 40 GEO. WASH. L. REV. 726 (1972).

¹⁸ This would be consistent with the definition of a legal treatise as “[a] scholarly legal publication containing all the law relating to a particular area.” *See* DAVID M. WALKER, *THE OXFORD COMPANION TO LAW* 1234 (1980) (emphasis added).

¹⁹ FDCA § 201(f)(1) (defining “food” as “articles used for food *or* drink . . .”) (emphasis added); 21 U.S.C. § 321(f)(1) (2014).

²⁰ “A true understanding of food law and policy . . . includes, for example, issues relating to the ownership of agricultural property, the water rights needed to sustain agriculture, tax incentives to preserve family farms, agricultural research and education, governmental economic programs to prevent agricultural surplus and to stabilize agricultural prices, food distribution programs for schoolchildren and the poor, programs to provide nutrition education and to prevent obesity, and a host of other policies that impinge on food and agriculture.” Peter Barton Hutt, *Food Law & Policy: An Essay*, 1 J. FOOD L. & POL’Y 1, 2–3 (2005); *see also* Neil D. Hamilton, *Keeping the Farm and Farmer in Food Policy and Law*, 11 FOOD L. & POL’Y 9 (2015). One area of agricultural law that might arguably not be included in food law would relate to the farming of plants such as cotton, whose fibers are put to non-food uses.

significant portions of animal-rights,²¹ antitrust,²² environmental²³ and public-health law²⁴ to the extent they impact food. But running off in every food-related direction risks converting a treatise into an amorphous mega-encyclopedia, without a unifying core.²⁵

Roberts has positioned his treatise on a middle ground that enables him to preserve much of his subject's traditional "FDA-centricity" yet, at the same time, to recognize and incorporate new thinking about the importance of food law. He confronts the relationship between food law and agricultural law by pointing out differences between them²⁶ and then by noting a modern tendency to include some farm-related issues within the scope of general concerns about food.²⁷ However, Roberts does not provide any rule-of-thumb, bright-line or otherwise, to determine which elements of agricultural law might fall properly within the ambit of a new approach to food law.²⁸ He merely postulates that his book "lays out the law governing food in order to equip the practitioner and scholar with an expanded legal framework to address the complexities and challenges of the modern food system."²⁹ This lets him pay special heed to how the structure of food law has expanded and has raised new legal issues associated in a very broad sense with the production, marketing and consumption of food.

The standard structure for early publications dealing with "FDA-centric" food law (as a component part of food and drug law) tracked the organization of the Food, Drug,

²¹ For an article involving animal-rights law and recently published in this journal, see Rita-Marie Cain, *The Chicken and the Egg—Animal Welfare, Food Safety and Federalism*, 71 FOOD & DRUG L.J. 1 (2016).

²² For a critical examination of the concentration of corporate power in the food industry and of the lack of antitrust enforcement that might curb resulting excesses, see PHILIP H. HOWARD, CONCENTRATION AND POWER IN THE FOOD SYSTEM: WHO CONTROLS WHAT WE EAT? Ch. 2 (2016).

²³ For a comprehensive discussion of EPA's authority to regulate pesticide use, see 3 LAW OF ENVIRONMENTAL PROTECTION §§ 17.47–61, Westlaw (Stanley Abramson et al. eds., database updated Oct. 2016).

²⁴ A recently published text on public-health law discusses several food-related issues in a chapter on "Promoting Healthier Lifestyles: Noncommunicable Disease Prevention." LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT Ch. 12 (3d ed. 2016).

²⁵ Lisa Heinzerling makes this point in a different context, the structuring of a law-school food-law course to meet appropriate intellectual and pedagogical standards within curricular time constraints. See LISA HEINZERLING, FOOD LAW: CASES AND MATERIALS 7 (2015). An excellent example of the eclectic, core-less nature of an all-embracing approach may be found in CECIL C. KUHNE III, THE LITTLE BOOK OF FOODIE LAW (2012) (offering accounts of legal decisions with no link to one another other than the fact that they involve food); *id.* Ch. 1 (discussing a libel suit arising from a critical restaurant review; *id.* at Ch. 3 (discussing a suit against a shipper for the spoilage of caviar during an ocean voyage); *id.* at Ch. 4 (discussing a trademark-infringement and unfair competition suit over the use of the name "Cordon Bleu"); *id.* Ch. 13 (discussing a legal challenge under the dormant Commerce Clause to restrictions of wine imported into the state of Texas).

²⁶ FOOD LAW, *supra* note 8, § 1.01(3)(b).

²⁷ *Id.* at § 1.01(3)(c). For the inclusion of some of these same issues in a text on agricultural law, see FOOD, FARMING, AND SUSTAINABILITY: READINGS IN AGRICULTURAL LAW Chs. VI, VIII, X (Susan A. Schneider ed., 2011) (analyzing the coverage of agricultural labor law, animal welfare, and certain food-related issues, such as safety). For a brief history of agricultural law, see Linnekin & Lieb, *supra* note 1, at 579–84.

²⁸ For a carefully considered effort to elucidate the difference between food law and agricultural law, see Tai, *supra* note 1, at 116–30.

²⁹ FOOD LAW, *supra* note 8, § 1.02.

and Cosmetics Act.³⁰ Later works made modifications, reflecting the need to present a more coherent order than the framework Congress had imposed on the structure of the statute.³¹ How to position topics of across-the-board relevance, such as enforcement and administrative rulemaking, has also produced divergences, since they can be addressed either before or after coverage of substantive food law.³²

In its organizational design, *Food Law* partially breaks from the traditional approach. An introductory chapter covers general matters such as the statutory definition of food,³³ principles of administrative law applicable to food regulation³⁴ and the regulatory roles played by international legal arrangements,³⁵ state and local governments,³⁶ litigation,³⁷ and self-governance.³⁸ It then identifies five overarching themes. Four incorporate, expand upon, and, to an extent, reorder—and even modify—the conventional view of food law as part of food and drug law. They are the protection and promotion of food commerce;³⁹ the safeguarding of the food supply from the risks of contamination and harmful added substances;⁴⁰ transmission of food-related information to consumers via truthful, non-deceptive labeling and advertising;⁴¹ and the encouragement of good nutrition.⁴² The fifth lends the treatise its most innovative

³⁰ See, e.g., HARRY AUBREY TOULMIN, A TREATISE OF THE LAW OF FOODS, DRUGS AND COSMETICS 27–35 (2d ed. 1963).

³¹ See, e.g., FOOD AND DRUG LAW 14–15 (Richard M. Cooper ed., 1991) (covering the substantive regulation of food in a chapter on labeling, followed by a chapter on food safety); FOOD AND DRUG LAW: CASES AND MATERIALS 35–40 (Richard A. Merrill & Peter Barton Hutt eds., 1980) (covering food sanitation, safety of food constituents, indirect food additives, food labeling, food identity and quality and nutrition in that order).

³² Compare Ann. H. Wion, FDA Administrative Procedures, in FOOD AND DRUG LAW AND REGULATION, *supra* note 12, Ch. 20, and Brooke Courtney & Elizabeth Sadove, *Medical Countermeasures: Emergency Preparedness and Response Roles and Authorities*, in FOOD AND DRUG LAW AND REGULATION, *supra* note 12, Ch. 22, with FOOD AND DRUG LAW: CASES AND MATERIALS, *supra* note 11, Chs. 2, 4, and FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE §§ 1.4 (Neal D. Fortin ed., 2d ed. 2017).

³³ FOOD LAW, *supra* note 8, § 1.02.

³⁴ *Id.* § 1.03(1)(b), 18. This section touches upon the transitions from formal to informal rulemaking by FDA, and from the latter to informal guidances, as a primary administrative tool. It does not, however, mention the many burdens imposed on administrative agencies by Congress and ultimately forcing FDA to abandon informal rulemaking as too costly and time-consuming. For a useful summary, see Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 438–40 (2008). For an excellent and indispensable historical analysis, placing these measures in the context of a systematic ideological and political campaign to undercut federal safety regulation, see THOMAS O. MCGARITY, *FREEDOM TO HARM: THE LASTING LEGACY OF THE LAISSEZ FAIRE REVIVAL* Ch. 7 (2013).

³⁵ FOOD LAW, *supra* note 8, § 1.03(3).

³⁶ *Id.* § 1.03(5).

³⁷ *Id.* § 1.03(6).

³⁸ *Id.* § 1.03(4) (also referred to as “new governance”).

³⁹ *Id.* § 2.

⁴⁰ *Id.* § 3.

⁴¹ *Id.* § 4. For a recent critique of the performance of federal agencies in exercising their responsibility to promote the conveyance of information to consumers of food products, see Lisa Heinzerling, *The Varieties and Limits of Transparency in U.S. Food Law*, 70 FOOD & DRUG L.J. 11 (2015).

⁴² FOOD LAW, *supra* note 8, at § 5.

aspect, confronting the legal issues generated by debate over the roles food should play and actually does play in contemporary life in the United States and globally.⁴³

The chapter on commerce departs somewhat from the usual way of thinking about this aspect of food law. The FDCA specifically prohibits enumerated instances of adulteration that need not pose a threat of physical harm to consumers and might be described as economic adulteration.⁴⁴ The primary purpose would seem to be the protection of consumers' pocketbooks and wallets, since the law aims to prevent economic loss incurred when hidden changes to products cause prices to exceed actual value or when consumers' reasonable expectations are not met in marketplace transactions.⁴⁵ Moreover, the government need not prove intentional or negligent wrongdoing to establish this (or, for that matter, any type of) adulteration.⁴⁶ FDA has not found economic adulteration effective to protect food supply integrity.⁴⁷ Instead, it has resorted first to the establishment of standards of identity, and then to the use of mandatory labeling⁴⁸ as better ways to protect the interests of consumers (or, at least, to enable consumers to protect themselves).

Food Law notes a fundamental change that has resulted in a vertiginous increase of food imports into the United States and an outpouring of standards, rules, and laws to promote fairness in international trade.⁴⁹ In turn, this has given rise to a substantial uptick in food fraud on the part of distributors and sellers, in the form of "padding, diluting, and substituting of food products for the purpose of economic gain."⁵⁰ A new term of art, "economically motivated adulteration," describes this phenomenon, and Roberts devotes much of this chapter to describe and analyze how international agreements are addressing it.⁵¹

The chapter on food safety covers both traditional FDCA substantive provisions that might justify enforcement measures against food bearing harmful added or non-

⁴³ This framework, of course, is specifically suitable for a treatise, which provides comprehensive coverage of a topic. For a more streamlined vision, developed for the purpose of putting together teaching materials for a law-school course, see LISA HEINZERLING, *supra* note 25, at 7 (structure based on three goals of food law—to inform consumers about the food they purchase and ingest, to assure food safety, and to provide citizens with reliable access to sufficient and nutritious alimentation). For the recognition of "food defense" as a separate category of food law, see FOOD REGULATION, *supra* note 32, Ch. 13 (statutory protection of food supply against terrorist acts and criminal tampering by individuals).

⁴⁴ FDCA § 404(b), 21 U.S.C. § 341(b), summarized in FOOD LAW, *supra* note 8, at § 2.02(2).

⁴⁵ Economic adulteration may also cause physical harm. See *id.* at 41 (substitution of cheap ingredients in milk leading to contamination that killed thousands of children in New York), 42 (addition of melamine to infant formula hospitalizing thousands of infants in China). A more appropriate response to such situations might be to consider such cases as involving the adding of a harmful substance and therefore subject to regulation as a safety violation. See *infra* notes 52–67 and accompanying text.

⁴⁶ The Act does make one reference to intentional adulteration, in the context of providing protections against the risks of terrorism. See FDCA § 420, 21 U.S.C. § 350I.

⁴⁷ "FDA has virtually abandoned enforcement of section 402(b) except in cases of outright fraud, which are rare." FOOD AND DRUG LAW: CASES AND MATERIALS, *supra* note 11, at 379.

⁴⁸ For an excellent historical overview of FDA regulation of food identity, quality and labeling, as well as of the common or usual names of food products and the use of the designator "imitation," see *id.* at 325–32, 350–52, 362, 369.

⁴⁹ On the growth of food imports, see *Challenges Facing Import Regulation*, FOOD REGULATION, *supra* note 32, at 334; see also FOOD LAW, *supra* note 8, § 3.08 (discussing international food-safety regulation).

⁵⁰ FOOD LAW, *supra* note 8, § 2.02(1)(a).

⁵¹ *Id.* § 2.02.

added substances⁵² (including food additives,⁵³ substances generally recognized as safe,⁵⁴ food contact materials,⁵⁵ color additives⁵⁶ and residues of pesticides⁵⁷ and animal drugs⁵⁸) as well as present-day controversies generated by genetically modified or engineered food,⁵⁹ animal cloning,⁶⁰ irradiation⁶¹ and nanotechnology.⁶² Roberts places special emphasis on changes brought by the Food Safety Modernization Act of 2011.⁶³ He then presents, in some detail, enforcement tools available to the federal government⁶⁴ and supplementary mechanisms provided by state laws,⁶⁵ international treaties,⁶⁶ private standards⁶⁷ and tort litigation.⁶⁸

⁵² *Id.* § 3.04. The one type of safety-related food adulteration to which Roberts gives short shrift (for a passing reference, *see id.* § 3.03) arises from the provision that defines a food as adulterated “if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. FDCA § 402(a)(3), 21 U.S.C. § 342(a)(3). This has inspired the use of the euphemism “aesthetic adulteration” to describe food containing such “yuck” as insect fragments and excreta, a rhetorical device aimed at promoting a particular point of view (here a “no-big-deal” attitude toward certain kinds of natural filth) and comparable to the use of such terms as “intelligence community” and “correctional facility.” On FDA’s practice of setting defect action levels for filth in food, *see* Fred H. Degnan et al., *supra* note 12, at 37–38.

⁵³ FOOD LAW, *supra* note 8, § 3.05(2).

⁵⁴ *Id.* § 3.05(3).

⁵⁵ *Id.* § 3.05(4).

⁵⁶ *Id.* § 3.05(5).

⁵⁷ *Id.* § 3.05(7).

⁵⁸ *Id.* § 3.05(8).

⁵⁹ *Id.* § 3.05(9). FDA took the position that substances added to food during these processes were similar enough to commonly added substances such as protein and fat that they could be considered generally recognized as safe. Hollywood ridiculed the alarmist attitude toward genetic engineering in a hilarious horror-movie spoof. *See* THE ATTACK OF THE KILLER TOMATOES (1978).

⁶⁰ FOOD LAW, *supra* note 8, § 3.05(10). This and the previous section deal only with the safety issues raised by animal cloning and genetic engineering. Whether labeling should inform consumers of the use of these processes in the production of food items they are purchasing is covered in the next chapter. *See infra* notes 55 and 56 and accompanying text. Cross-references in these footnotes would have been helpful.

⁶¹ *Id.* § 3.05(11).

⁶² *Id.* § 3.05(12).

⁶³ *See id.* §§ 3.02(3), 3.06.

⁶⁴ *Id.* § 3.06(9). Roberts does not devote one single chapter to enforcement, but rather opts for a fragmented approach that inserts enforcement descriptions at various parts of his treatments of substantive food law. *See, e.g., id.* § 2.03(3), (listing regulatory tools dealing with economically motivated adulteration); § 4.02(5) (warning letters for food labeling violations).

⁶⁵ *Id.* § 3.07. This is an area that assumes greater importance during periods marked by an anti-regulatory policy on the part of the federal government, which may insist that federal preemption bars certain state regulatory initiatives that run counter to this policy.

⁶⁶ *Id.* § 3.08.

⁶⁷ *Id.* § 3.09.

⁶⁸ *Id.* § 3.10. For a creative view of the role of tort law in improving the democratic deliberative process in the development of food law, *see* Melissa Mortazavi, *Tort as Democracy: Lessons from the Food Wars*, 57 ARIZ. L. REV. 929 (2015).

The chapter on food marketing covers the regulation of labels, labeling and advertising. It includes topics such as affirmative requirements for labels,⁶⁹ health claims that sellers may place on labels (and constitutional challenges to FDA's efforts to regulate them),⁷⁰ and legal issues resulting from labeling that informs consumers of facts unrelated to safety, like the use of genetic engineering in the production of a food,⁷¹ animal cloning,⁷² religious dietary labeling,⁷³ animal-raising claims⁷⁴ and country-of-origin labeling.⁷⁵ Regulation of advertising by the Federal Trade Commission,⁷⁶ the use of the Lanham Act by competitors alleging unfair competition⁷⁷ and food-disparagement laws are also covered.⁷⁸

The chapter on regulation of nutrition presents organizational problems. The prior chapter covers a critical aspect of nutrition regulation, namely FDA's promulgation of rules requiring food labels to display certain information about nutrition,⁷⁹ which would seem to belong here. Also, the principal "FDA-centric" material included in the nutrition chapter relates to the regulatory scheme for dietary supplements.⁸⁰ This is a somewhat *sui generis* subject that would probably stand better on its own, since it has a political and regulatory history that features disputes on how effective dietary-supplement regulation was meant to be and actually is.⁸¹ The chapter also deals with a potpourri of nutrition issues with which FDA does not deal or deals with only marginally. These include topics such as menu labeling,⁸² the marketing of food to children,⁸³ the banning of non-nutritious foods deemed harmful to health,⁸⁴ government nutrition programs,⁸⁵ public-health litigation dealing with the obesity

⁶⁹ FOOD LAW, *supra* note 8, § 4.03. The treatise does not, however, go into any detail about FDA's use of Section 201 of the FDCA to require labeling to bear important information, such as warnings, the absence of which would render the product misbranded. For an excellent discussion of Section 201, see FRED H. DEGNAN, *FDA'S CREATIVE APPLICATION OF THE LAW: NOT MERELY A COLLECTION OF WORDS* Ch. 9 (2d ed. 2006).

⁷⁰ FOOD LAW, *supra* note 8, § 4.04.

⁷¹ *Id.* § 4.05(3).

⁷² *Id.* § 4.05(4).

⁷³ *Id.* § 4.05(5).

⁷⁴ *Id.* § 4.05(9).

⁷⁵ *Id.* § 4.05(10). For a recent discussion of constitutional issues raised by country-of-origin labeling, see Rebecca Tushnet, *COOL Story: Country of Origin Labeling and the First Amendment*, 70 FOOD & DRUG L.J. 25 (2015).

⁷⁶ FOOD LAW, *supra* note 8, § 4.07.

⁷⁷ *Id.* § 4.08(4).

⁷⁸ *Id.* § 4.09.

⁷⁹ *Id.* § 4.03(2).

⁸⁰ *Id.* § 5.02(1).

⁸¹ On the history of dietary-supplement regulation, see Scott Bass, *Dietary Supplements: Populism and Pirandello*, in *FDA: A CENTURY OF CONSUMER PROTECTION* 219 (Wayne L. Pines ed., 2006). For a critical take on federal regulation of dietary supplements, see MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH* 219–93 (rev. ed. 2013).

⁸² FOOD LAW, *supra* note 8, § 5.03.

⁸³ *Id.* § 5.04.

⁸⁴ *Id.* § 5.05.

⁸⁵ *Id.* § 5.06.

epidemic,⁸⁶ and case studies of attempts to restrict the consumption of salt⁸⁷ and sugar.⁸⁸

The fifth chapter then shifts gears and reflects systemically on a different mode of thinking about food and food law, going far beyond the “FDA-centric” concerns that what we ingest for nourishment and taste should be “safe, wholesome, sanitary, and properly labeled.”⁸⁹ The new approach is holistic, in the sense that it insists on consideration of multiple perspectives in analyzing and developing solutions to food-related issues,⁹⁰ and tends to be less science-based.⁹¹ This approach identifies with the Food Movement,⁹² a heterogeneous group of activists, thinkers and food enthusiasts⁹³ who are critical of the industrialized production of food and its commercialization⁹⁴ and who have an abiding interest in how the process by which food travels from farm to fork affects not only them but also others involved in or touched by that process.⁹⁵ This knowledge, in turn, shapes ethical values and the direction of political activity, and it can enhance both the quality of individual life and the wellness of communities.⁹⁶

⁸⁶ *Id.* § 5.07.

⁸⁷ *Id.* § 5.08(1).

⁸⁸ *Id.* § 5.08(2). For a powerful set of arguments underscoring the adverse health effects attributable to sugar, see GARY TAUBES, *THE CASE AGAINST SUGAR* (2016), briefly noted in Joseph A. Page, *Short Takes, infra* at 376.

⁸⁹ FDCA § 1003(b)(2)(A), 21 U.S.C. § 393(b)(2)(A) (2012).

⁹⁰ It might be off the mark to suggest that FDA has never taken a holistic approach to any of its responsibilities. One author has argued that the White House Conference on Food, Nutrition and Health in 1969 “forced government and industry alike to look at the regulation of food in a holistic way.” FRED H. DEGNAN, *supra* note 69, at 135.

⁹¹ On the influence of scientific advances on the development of traditional food law and policy, see Peter Barton Hutt, *supra* note 20, at 8–11. For an introduction to the various ethical considerations that might inform food policy, see RONALD L. SANDLER, *FOOD ETHICS: THE BASICS* (2015).

⁹² On the birth and growth of the Food Movement, see Michael Pollan, *The Food Movement Rising*, N.Y. REV. (June 20, 2010), <http://www.nybooks.com/articles/2010/06/10/food-movement-rising/> (last visited Feb. 28, 2017).

⁹³ See Michael Pollan, *Big Food Strikes Back*, N.Y. TIMES MAG., Oct. 9, 2016, at 40, 41, 81 (describing the Food Movement as a “loose-knit coalition of environmental, public-health, animal-welfare and social-justice advocates” and “a collection of disparate groups that seek change in food and agriculture but don’t always agree with one another on priorities”); see also Michael Pollan, *supra* note 92, at 4 (detailing the conflict between food-safety advocates and local-food advocates; latter fearful that costs of safety regulation will adversely affect small-farm agriculture); Nicholas Obolensky, *The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad*, 17 ROGER WILLIAMS U.L. REV. 887 (2012) (criticizing the Food Safety Modernization Act for putting excessive regulatory burdens on small and mid-sized farms).

⁹⁴ On the Food Movement’s critique of and political struggle against corporate agriculture, see Michael Pollan, *supra* note 93. For a positive view of industrialized farming, see JASON LUSK, *UNNATURALLY DELICIOUS: HOW SCIENCE AND TECHNOLOGY ARE SERVING UP SUPERFOODS TO SAVE THE WORLD* (2016).

⁹⁵ Professor Heinzerling links consciousness of our ignorance about how the food we consume has reached our tables to the making of “transparency a core demand of the contemporary movement aimed at changing the industrial food system.” Heinzerling, *supra* note 41, at 11. For a cartoon poking gentle fun at the demand for food-related information, see THE NEW YORKER, Jan. 30, 2017, at 49 (restaurant patron asking waiter whether cows furnishing grass-fed beef on menu had been “forced to eat the grass”).

⁹⁶ The Food Movement’s primary emphasis on policy and political action differs from that of some early public-interest-law practitioners who worked on food-safety issues. The latter were not primarily concerned with opposing “big food” *per se*, and with the “big” questions relating to food policy, but rather

Roberts entitles this chapter “Regulation of Food Systems,” reflecting multiple (i.e. local, regional, national, and planetary) processes in the life cycles of food products,⁹⁷ the latter captured by the shorthand expression “farm-to-fork.”⁹⁸ He covers such areas as the promotion of local food production,⁹⁹ sustainability,¹⁰⁰ urban agriculture,¹⁰¹ food security,¹⁰² food sovereignty¹⁰³ and food justice,¹⁰⁴ with emphasis on attendant legal issues. For example, a desire to encourage the local growth of food might support an FDA regulation mandating the inclusion of the word “local” on labels, on the ground that the failure to do so might render the product misbranded; but, this would require a principled determination of what constitutes “local” food.¹⁰⁵ In addition, state as well as local governments wishing to encourage “farmers markets” by conferring special benefits or regulatory considerations would need to define that term to clarify which food-vending facilities qualify.¹⁰⁶

with providing the best possible legal assistance to consumers and consumer advocates in administrative proceedings, litigation, and efforts to enact or block legislation, where they opposed initiatives undertaken by industrialized food producers and in their view inimical to the interests of consumers. *See Note, The New Public Interest Lawyers*, 79 *YALE L. J.* 1069, 1103–06 (1970) (describing the above approach); *see also* Robert L. Rabin, *Lawyers for Social Change: Perspectives on Public Interest Law*, 28 *STAN. L. REV.* 207 (1976). At times, their work followed up on published investigative reports. For examples of the latter dealing with food, *see* JAMES S. TURNER, *THE CHEMICAL FEAST* (1970) (safety of food additives); HARRISON WELLFORD, *SOWING THE WIND* (1972) (meat and pesticide safety). For an example of litigation, *see* *Schuck v. Butz*, 500 F.2d 810 (D.C. Cir. 1974) (upholding Department of Agriculture denial of petition by consumer advocate and others to ban or restrict use of nitrite in meat). For an account of industry-supported social movements that successfully resisted several major FDA policy initiatives dealing with food, *see* Lewis Grossman, *FDA and the Rise of the Empowered Consumer*, 66 *ADMIN. L. REV.* 627, 646–51 (2014).

⁹⁷ *See* FOOD LAW, *supra* note 8, § 6.01(1)(a).

⁹⁸ For an account of the history of the concept of food systems, *see* generally Tai, *supra* note 1.

⁹⁹ FOOD LAW, *supra* note 8, § 6.02. This section covers farmers’ markets and mobile food sellers.

¹⁰⁰ *Id.* § 6.03. Included here are discussions of environmental programs affecting food, farm legislation, organic food, and the regulation of animal treatment, with a view toward preserving adequate food production for the planet’s inhabitants.

¹⁰¹ *Id.* § 6.04. This chapter treats the growing, processing, and distribution of food in or near urban areas.

¹⁰² *Id.* § 6.05. Food security refers to “the ongoing availability of food.” *Id.* at 443. It involves a right not only to food as sustenance, but also to nutritious food. For arguments urging recognition of a right to adequate nutrition under existing U.S. law, *see* Paul A. Diller, *Combating Obesity with a Right to Nutrition*, 101 *GEO. L.J.* 969 (2013).

¹⁰³ FOOD LAW, *supra* note 8, § 6.06 (positing that “every country and people must have the right and the ability to define their own food, farming and agricultural policies”).

¹⁰⁴ *Id.* § 6.07 (an “intentionally broad” notion that “covers all aspects of food law, from food safety to nutrition programs to farm worker rights to community supported agriculture . . . to environmental concerns to local food to urban agriculture to food access, but does so with the perspective and prism of equity”). For purposes of a treatise, it might have been more effective if Roberts had integrated equitable concerns into the materials covering the aspects of food law he enumerates here.

¹⁰⁵ *Id.* § 6.02(1)(b). Roberts identifies the issue as involving a determination whether the designation of a food as “local” is a “particular,” thereby rendering the label “misleading in any particular,” as required by FDCA § 403(a)(1), 21 U.S.C. § 343(a)(1). There might also be an issue under FDCA § 201(n), 21 U.S.C. § 321(n), as to whether failure to include the word “local” on a label might render a food product misleading because of its omission of a material fact.” On FDCA § 201(n), *see supra* note 69.

¹⁰⁶ *See* FOOD LAW, *supra* note 8, § 6.02(3)(b).

In this chapter, Roberts specifically addresses the question whether a food law treatise should examine the goals food law does and should serve, the links (or lack thereof) between substantive directives of food law and the results they do or might possibly bring about, and the efficacy of the processes meant to guide food law toward the purposes that undergird it—in a word, policy. The Food Movement itself is unabashedly policy-oriented. Much of the literature it has generated discusses issues relating to the goals that guide the regulation of the production, distribution, consumption and disposal of food products as well as those process issues dealing with how to reach those goals.¹⁰⁷ Examples abound: whether communitarian social values of farmers markets and local food distribution should trump agribusiness' lower food pricing and convenience; or how group viewpoints (such as low-income consumers) may be integrated into decision-making regarding food-distribution. These considerations would seem political in nature and thereby apt for only legislative or administrative solutions.¹⁰⁸

Here, Roberts displays ambivalence about the role of policy in his book. He posits that a food-systems focus “raises normative questions about what sort of food system is preferable,”¹⁰⁹ and he further notes these ultra-broad issues are “beyond the scope of this food law treatise.”¹¹⁰ Later he points out that the concepts behind food systems have “policy rationales” that are “well beyond the purview of this chapter.”¹¹¹ Nonetheless, he does discuss policies and principles underlying these concepts.¹¹²

This apparent hesitation might derive from disagreement in academic circles on how to conceptualize this new field of food law. In an exhaustive article describing the emergence of food law as a field of its own, Baylen Linnekin and Emily Broad Leib insist on referring to the field as “Food Law and Policy” or FL&P.¹¹³ They suggest that its policy focus sets FL&P apart from most other legal fields,¹¹⁴ including, presumably, “FDA-centric” food and drug law. FL&P's exceptionalism with regard to policy is actually a matter of degree. All legal fields serve purposes and implicate elements of policy. Indeed, it would seem difficult in this day and age to teach a law school course without engaging in policy discussions with students. This would be as

¹⁰⁷ See, e.g., MARION NESTLE, *SODA POLITICS: TAKING ON BIG SODA (AND WINNING)* (2015) (providing thorough presentation of strategies and tactics consumer advocates can employ to confront the soda industry for the purpose of reducing or putting to an end the sale of soft drinks harmful to public health). On the general subject, see PARKE WILDE, *FOOD POLICY IN THE UNITED STATES: AN INTRODUCTION* (2013).

¹⁰⁸ For an example of a set of food-related controversies that ended up in political settlements, see MICHAELA DESOUCY, *CONTESTED TASTES: FOIE GRAS AND THE POLITICS OF FOOD* (2016) (offering an account of political struggles in France and the United States over animal cruelty in the production of fattened duck and goose liver for human consumption).

¹⁰⁹ *FOOD LAW*, *supra* note 8, § 6.01.

¹¹⁰ *Id.* He does briefly advert to one of the most contentious, the controversy over the obesity epidemic, in which public-health considerations have clashed with arguments based on the value of promoting personal responsibility in making food choices. See *id.* § 1.01.

¹¹¹ *Id.* § 6.03.

¹¹² See, e.g., *id.* §§ 6.05(1) (food security), 6.06(1) (food sovereignty).

¹¹³ Linnekin & Leib, *supra* note 1, at 560, 560 n.9. The use of the ampersand instead of the word “and” avoids an acronym that some might deem less than totally positive.

¹¹⁴ *Id.* at 585.

true in regard to torts as to traditional food and drug law.¹¹⁵ Therefore, to make the “and Policy” tag, at least in the curricular context, more meaningful than a marketing device, it would be necessary to invest in FL&P a treatment of policy that would make it unique.

On the other hand, Stephanie Tai makes the case for calling the new field “Food Systems Law,” on the ground that this captures what is novel about contemporary legal studies relating to food—a type of holistic thinking that examines the “complex interrelationships between [sic] the relevant laws, the legal institutions, parties, and circumstances, as well as the overall function of the system.”¹¹⁶ Coherence and distinctiveness, as well as an ability to articulate the needs of affected parties heretofore outside the scope of traditional food law, provide the basis for arguments in favor of elevating food systems to titular prominence.¹¹⁷ She claims that her preferred term does not differ in any significant way from FL&P, but the implication lurks that in her view it goes without saying that policy plays a key part in any treatment of food systems.

Roberts, who has long labored professionally in the vineyard of food law and policy,¹¹⁸ deftly guides his book through this uncertain terrain. He has written a legal treatise in a field that has become increasingly policy-focused, yet maintains a degree of “FDA-centricity” that contains much of the substance of food law. His solution is to paint lightly with a policy brush and to devote an entire section of the treatise to legal issues that arise from policy innovation associated with present-day food-systems concerns. The material in this section is so cutting edge that one wishes he had devoted more space to it. Hopefully, he will consider doing this in his next edition.

One notable process-related policy issue that is not new, and continues to stimulate discussion, is whether the goals of food law are so ill-served by its location within the embrace of the FDCA and by a unitary FDA that authority to regulate comestibles should be consolidated and relocated within a single, newly created federal food agency. Roberts spells out the pros and cons of the debate,¹¹⁹ thereby engendering reflection, especially considering the capacious approach a systems orientation adopts toward food law.

It seems highly unlikely that if one were to wipe the slate clean and design a system of federal food regulation from scratch, food would find itself lumped together with pharmaceuticals, medical devices, cosmetics, and tobacco products. Historical forces combined to merge food and drug regulation within a single agency in 1906,¹²⁰ and this conjunction has survived to the present day. Yet contemporary political realities (especially in light of the 2016 election results and their immediate aftermath) would make it highly improbable that Congress will pass legislation creating a new food agency, and give it the authority and funding it would need to meet, what its

¹¹⁵ For an example of policy-related material in the leading food-and-drug-law casebook, see *The Deterioration of the Food Additive Approval Process*, in FOOD AND DRUG LAW, *supra* note 11, at 603–07 (critical assessment of FDA regulation of food additives).

¹¹⁶ Tai, *supra* note 1, at 161.

¹¹⁷ *Id.* at 159–69.

¹¹⁸ See UCLA LAW, *supra* note 5.

¹¹⁹ FOOD LAW, *supra* note 8, § 1.03(1)(c).

¹²⁰ For the historical background of the 1906 Act, see Richard M. Cooper, *The Struggle for the 1906 Act*, in FDA: A CENTURY OF CONSUMER PROTECTION 25–70 (Wayne L. Pines, ed. 2006).

proponents would identify as the major challenges food production and marketing will face in the twenty-first century.¹²¹

The administrative-structure debate does, however, raise intriguing and relatively unexplored questions about the relationship between FDA food and medical product regulation programs. Within FDA, for example, food regulation seems to be a junior partner to the regulation of medical products (drugs and devices) in terms of budgetary allocation¹²² and administration.¹²³ Does food really enjoy a subordinate status, and if so, has this prejudiced the regulation of food, and how much improvement would a “divorce” produce? In addition, do FDA’s food-safety programs benefit or suffer from public successes and failures of drug and device regulatory successes or failures? Another way of putting it would be whether the reputational effects of FDA’s medical-product initiatives carry over to its food programs.¹²⁴

The call for a unitary system for food regulation is consistent with the study of food law that divorces the latter from the law dealing with medical, personal-care, and tobacco products. Yet this ignores food law as it is rather than as it might be under an ideal regime that incorporates a food-systems approach to the subject. Divorcing food law from the law regulating other products under FDA jurisdiction will weaken an appreciation of aspects of the regulatory process that apply across the board, and will also eliminate a grasp of important cross-over effects that each has had on the other. Indeed, it is legitimate to ask whether one can fully understand important aspects of food law under the FDCA without a comprehension of related developments under other areas of food and drug law, and vice versa.¹²⁵

Examples of what might be deemed the cross-over phenomenon abound. On a very basic level, food labeled as intended for consumption for the purpose of curing, treating, mitigating, or preventing a disease will be regarded as a drug,¹²⁶ subject to all the onerous safety and efficacy requirements the FDCA imposes on pharmaceuticals,¹²⁷ and hence an understanding of the latter would be essential for an appreciation of what is at stake in food classification disputes. Legal doctrine confronting the problem of

¹²¹ On the absence of food issues from the 2016 platforms of both the Democratic and the Republican Parties, see Kim Severson, *Putting Food Issues on Politician’s Plates*, N.Y. TIMES, July 27, 2016, at D1.

¹²² For fiscal year 2017, the agency requested \$1.5 billion for food safety, and \$2.8 billion for medical-product safety and availability. Department of Health and Human Services, *Fiscal Year 2017: Food and Drug Administration: Justification of Estimates for Appropriations Committees* 7, 9, <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM485237.pdf> (last visited Feb. 28, 2017).

¹²³ Over the past half century, of 14 past FDA Commissioners, there have been eleven physicians, a veterinarian, a pharmacist and a neurophysiologist. See *Commissioners*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/history/leaders/commissioners/default.htm> (last visited Jan. 29, 2017).

¹²⁴ For a magisterial study of the reputational impact FDA’s pharmaceutical regulation has had on the agency’s capacity to carry out its mission to assure the safety and effectiveness of drug products, see DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* (2010).

¹²⁵ A practical problem arises in the matter of law-school curricula. If food-law courses cover FDA regulation of food products, students wishing to take both food law and food and drug law may run up against an administrative determination that this would create coverage duplication that could prevent them from enrolling in both offerings.

¹²⁶ See FOOD LAW, *supra* note 8, § 1.02(2).

¹²⁷ On the new-drug approval process, see O’REILLY, *supra* note 13, §§ 13:78–13:132.

agency delay,¹²⁸ the phenomenon of interim approval of regulated products without explicit statutory authorization,¹²⁹ FDA's experience with formal rulemaking,¹³⁰ the ethical obligations of attorneys toward client behavior that might violate important social norms,¹³¹ and the constitutional barriers to FDA regulation of product labeling,¹³² all span product categories under food and drug law. For that reason, attorneys representing clients in matters governed by the Act should have a holistic understanding of the Act and FDA's administration of it. The same would be true of those participating in the legislative process as it relates to the FDCA, as it is currently structured. Indeed, even those engaged in a radical restructuring that would place food products under the jurisdiction of a separate agency, if that should ever happen, would be well served by a familiarity with the traditional substance of food and drug law.

Nonetheless, *Food Law in the United States* provides valuable insights into fresh ways of thinking about twenty-first-century food policy as it may affect the scope and substance of the law governing what we consume for nourishment and taste. We are clearly on the cusp of an era of change. This will undoubtedly need more time for momentum to gather. In the meantime, Roberts' treatise is an indispensable roadmap for serious study and reflection.

¹²⁸ See *Comment: Regulatory Delay*, FOOD AND DRUG LAW, *supra* note 11, at 1557–60. On unsuccessful efforts to force FDA to terminate provisional listings of color additives, *see id.* at 446–47.

¹²⁹ On FDA's resort to "creativity" in temporarily permitting the marketing of added substances that would be considered food additives under a straightforward application of the law, *see* Degnan et al., *supra* note 12, at 66–67 (agency's use of interim food additives). For judicial invalidation of an FDA policy to allow on an interim basis the continued marketing of over-the-counter drugs whose safety and/or efficacy had not been established, *see* *Cutler v. Hayes*, 818 F.2d 879 (D.C. Cir. 1987).

¹³⁰ The nightmare of the peanut-butter hearing, a formal proceeding required by law when FDA tried to set a standard of identity that would mandate peanut butter to contain 90% peanuts (industry fought for 87%) took 30 days of hearings and a total elapsed time of more than 57 months to complete. *See* Robert W. Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132, 1151 (1972). FDA probably had this experience in mind when it developed imaginative summary-judgment procedures to help avoid formal hearings requested by pharmaceutical companies whose drugs the government sought to remove from the market for lack of efficacy, utilizing retroactive authority granted by the 1962 Drug Amendments. On the effect of this legislation, *see* Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L. REV. 185 (1971). The United States Supreme Court ultimately upheld these procedures. *Weiburger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973).

¹³¹ *See* Kelly D. Brownell & Kenneth E. Warner, *The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar Is Big Food?*, 87 MILBANK Q. 259 (2009) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879177/pdf/milq0087-0259.pdf> (last visited Feb. 28, 2017) (comparing highly questionable behavior by the tobacco industry and similar behavior by the food industry in responding to public—health initiatives against their products); *see also* Rohit Malik, Note, *Catch Me If You Can: Big Food Using Big Tobacco's Playbook?*, <https://dash.harvard.edu/bitstream/handle/1/8965631/Malik%20Rohit.pdf?sequence=1> (last visited Feb. 28, 2017). For a trial judge's trenchant criticism of the conduct of attorneys representing the tobacco industry, *see* *United States v. Philip Morris, USA, Inc.*, 449 F. Supp. 2d 1, 87–110, 832–39 (D.D.C. 2006).

¹³² Constitutional challenges asserting commercial-speech protections have restricted FDA regulatory initiatives to restrict health claims for food and dietary supplements, to limit the dissemination of truthful information about unapproved uses of drugs and to require graphic images on cigarette packs. *See* FOOD LAW, *supra* note 8, at § 4.04(2)(b) (challenging health claims for food and dietary supplements); *Caronia v. United States*, 703 F.3d 149 (2d Cir. 2012) (setting aside conviction of drug-company employee and holding that government infringing on his constitutional rights by prosecuting him for truthful speech about an unapproved use of a new drug); *R. J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012) (setting aside as unconstitutional FDA regulations requiring cigarette packages to bear highly graphic images depicting the kinds of harm cigarettes can inflict on smokers).