Articles

Genetic Modification and Food Irradiation: Are Those Strictly on a Need-to-Know Basis?

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Abstract

Under the longstanding FDA policy, the use of genetic engineering in the production of food products generally does not require disclosure in labeling, though sellers would have to reveal if the process introduced any special risks or other material changes. Commentators who criticize this policy often point to the agency's purportedly contrary "precedent" in requiring disclosure whenever foods undergo irradiation. That old FDA rule deserves much of the blame, however, for the fact that irradiation remains seriously underutilized as an effective tool for guarding against foodborne pathogens. If routine GMO food labeling ever became mandatory under either federal or state law, then a similar fate might well befall this newer technology, which is precisely what opponents who involve a "right to know" hope to accomplish.

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Where ignorance is bliss, / 'Tis folly to be wise.[1]

For the last quarter of a century, a debate has raged over whether sellers should have to reveal the use of genetic engineering in the production of food products. So far, proponents of mandatory disclosure for genetically engineered (GE) or genetically modified (GM) foods have failed to convince policymakers, but the tide may have begun to turn. Given the prevalence of these techniques in American agriculture, the imposition of labeling requirements may have little impact at this late date. Nonetheless, the policy question has become salient again. This Article confronts the issue somewhat obliquely, however, by considering the very different trajectory of labeling disclosure requirements for another food production technology. Proponents of mandatory GM food disclosure often invoke the earlier decision by the U.S. Food and Drug Administration (FDA) to demand that labeling reveal the use of irradiation in food processing. While conceding that efforts to distinguish the two situations may lack persuasiveness, this Article suggests that the experience with the food irradiation requirement demonstrates precisely why policymakers should not embrace a similar mandate for GM foods. Indeed, the FDA has expressed repeated misgivings about its irradiation labeling rule but seems incapable of overcoming inertia.

I. GENETIC MODIFICATION IN FOOD PRODUCTION

Since the early 1980s, the FDA has struggled to define a sensible regulatory approach to genetically modified organisms (GMOs) used in food production.[2] In 1986, after convening an interagency working group, the White House Office of Science and Technology Policy (OSTP) issued a guideline entitled "The Coordinated Framework for Regulation of Biotechnology," which included separate policy statements from the different agencies that had participated and would have primary

1. Thomas Gray, *Ode on a Distant Prospect of Eton College* (1747).

2. *See* Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, ¶¶ 26–44 (2006) [hereinafter Noah, *Managing Biotechnology's [R]evolution*]; *id.* ¶ 31 n.110; Lars Noah, *Whatever Happened to the "Frankenfish"?: The FDA's Foot-Dragging on Transgenic Salmon*, 65 ME. L. REV. 606, 611 & n.36 (2013).

roles to play in its implementation, including the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the FDA.[3] The guideline emphasized that, for the most part, the government would regulate the products rather than the processes of biotechnology,[4] adding that it "sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[5] In its contribution to the Coordinated Framework, the FDA summarized the ways in which its existing controls for food products might apply to GMOs without, however, making any reference to possible labeling or other disclosure requirements.[6]

Six years after publication of the coordinated framework, the OSTP called upon the agencies to update their policies.[7] The FDA did so with regard to bioengineered food crops, issuing a policy statement addressing "Foods Derived from New Plant Varieties" in 1992.[8] The agency decided that it need not develop a distinctive regulatory approach for foods derived from genetically engineered crops; instead, it preferred to "utiliz[e] an approach identical in principle to that applied to foods developed by traditional plant breeding."[9] If transferred genetic material

3. *See* 51 Fed. Reg. 23,302 (June 26, 1986).

4. *See id.* at 23,306–07.

5. *Id.* at 23,302–03; *see also id.* at 23,303 ("Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately."). For critical assessments of the OSTP's framework (as applied to foods) and its subsequent implementation by the three designated agencies, see Jennifer Kuzma et al., *Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms*, 37 J.L. MED. & ETHICS 546, 547–50 (2009); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2216–59 (2004); Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003).

6. *See* 51 Fed. Reg. 23,309, 23,312–13 (June 26, 1986). The earlier draft of this policy statement barely even mentioned foods, focusing instead on therapeutic products and animal feeds. *See* 49 Fed. Reg. 50,878, 50,878–80 (Dec. 31, 1984); *id.* at 50,878 ("The implementing regulations for food . . . additive petitions and for affirming generally recognized as safe (GRAS) food substances are sufficiently comprehensive to apply to those involving new biotechnology.").

7. *See* 57 Fed. Reg. 6753, 6758–59 (Feb. 27, 1992). This document, which reiterated previous concerns about imposing excessive regulatory burdens and the need to focus on the nature of the product rather than the underlying process, called for regulating only "unreasonable" risks, subjecting products to no greater restrictions than unmodified but otherwise similar products, and exempting classes of products likely to pose minimal risks. *See id.* at 6756–57.

8. *See* 57 Fed. Reg. 22,984 (May 29, 1992).

9. *Id.* at 22,984–85 ("The method by which food is produced or developed may . . . help to understand the safety or nutritional characteristics of the finished food. However,

introduced an unusual protein and/or altered a metabolic pathway to produce a new carbohydrate or other substance, then the FDA might call for the submission of a food additive petition.[10] The policy invited companies unsure about a new product's regulatory status to consult with the agency on an ad hoc basis.[11]

The 1992 policy statement rejected suggestions that all bioengineered foods disclose their origin in labeling.[12] The FDA explained that it would, however, require disclosure if the insertion of genetic material from another source altered the nutritional profile of the food or introduced a risk of allergenicity. By way of illustration, it noted that, "if a tomato has had a peanut protein introduced into it and there is insufficient information to demonstrate that the introduced protein could not cause an allergic reaction in a susceptible population, a label declaration would be required to alert consumers who are allergic to peanuts so they could avoid that tomato."[13] The agency reiterated this point one year later in a notice that solicited public comments on the GMO labeling question.[14] Although a number of groups continue to

the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.").

10. *See id.* at 22,990.

11. *See id.* at 22,985; *see also* 77 Fed. Reg. 45,622 (Aug. 1, 2012) (explaining that a different "guidance, entitled 'Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,' [71 Fed. Reg. 35,688 (June 21, 2006),] continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein"); 76 Fed. Reg. 9020 (Feb. 16, 2011) (announcing an updated "Guidance on Consultation Procedures: Foods Derived from New Plant Varieties," which had originally appeared in 1997); Leila Abboud, *Makers of Modified Crops Faulted on Safety Data Submitted to FDA*, WALL ST. J., Jan. 7, 2003, at A3 (reporting criticisms of the consultation process in practice).

12. *See* 57 Fed. Reg. at 22,991; *see also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 178–81 (D.D.C. 2000) (rejecting various substantive challenges to this aspect of the 1992 policy statement); *id.* at 172–75 (rejecting procedural objections to the policy statement as a whole); *cf. id.* at 174 ("Evidencing this non-binding effect is the FDA's 1993 decision to open the labeling issue for further discussion, requesting additional public comment on the possible implementation of a general labeling requirement.").

13. 57 Fed. Reg. at 22,991.

14. *See* 58 Fed. Reg. 25,837, 25,840 (Apr. 28, 1993) ("Under FDA's policy, such foods will be required to be labeled to alert consumers to potential allergenic substances derived from commonly allergenic foods, unless the developer can demonstrate scientifically that the introduced substance is not allergenic in the new food."). Congress subsequently mandated clearer allergenicity labeling of processed foods. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, tit. II, 118 Stat. 891, 905 (codified at 21 U.S.C. §§ 321(qq), 343(w) (2012)); *see also* 73 Fed. Reg. 46,302 (Aug. 8, 2008) (requesting comments on implementation issues). *See generally* Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65

insist that GM foods pose various hazards,[15] the current consensus among respected organizations that take a balanced (as opposed to ideologically driven) approach to reviewing the evidence finds nothing to fear.[16]

In the waning days of the Clinton Administration, the FDA proposed a set of rules that would have required the submission of a "premarket biotechnology notice" (PBN).[17] Its position on mandatory disclosure had not changed.[18] Instead, in tandem with its notice of proposed rulemaking, the agency published a draft guidance document on *voluntary* labeling of foods as either GM or non-GM.[19] The

(2006). In the two decades since the first GM food came to market, the FDA has never mandated allergenicity labeling.

15. *See* Henry I. Miller, *The Use and Abuse of Science in Policymaking: The Regulation of Biotechnology Provides a Cautionary Tale of Politicized Science*, REGULATION, Summer 2012, at 26, 30 (objecting that the media "consistently len[t] exaggerated credibility and ink to the alarmist claims of anti-biotech activists"); Noah, *Managing Biotechnology's [R]evolution*, *supra* note 2, ¶ 62 & nn.227–28.

16. *See* Andrew W. Torrance, *Planted Obsolescence: Synagriculture and the Law*, 48 IDAHO L. REV. 321, 324–27 (2012); *id.* at 327 (explaining that "the community of biological experts is approaching a consensus that neither GMOs nor food derived from them represent dangers to human health or the environment"); Amy Harmon, *On Hawaii, a Lonely Quest for Fact*, N.Y. TIMES, Jan. 5, 2014, at A1 ("Some [researchers] compare the hostility to G.M.O.s to the rejection of climate-change science, except with liberal opponents instead of conservative ones."); Tamar Haspel, *Does What You Know About GMOs Pass Go?*, WASH. POST, Oct. 16, 2013, at E1 ("The National Academies [of Sciences], the American Medical Association, the World Health Organization, the Royal Society and the European Commission . . . all agree that there's no evidence that it's dangerous to eat genetically modified foods."); Rosie Mestel, *In Defense of Modified Foods; Despite Popular Suspicion, Scientists Widely Agree That Genetically Altered Crops Are Safe as Any*, L.A. TIMES, Oct. 25, 2012, at A1; *see also Controversial GMO Cancer Study Is Retracted*, WASH. POST, Nov. 30, 2013, at A4.

17. *See* 66 Fed. Reg. 4706, 4730 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592); *see also* Andrew Pollack, *F.D.A. Plans New Scrutiny in Areas of Biotechnology*, N.Y. TIMES, Jan. 18, 2001, at A12 ("The [proposed] rules have been expected since May, when the F.D.A. announced its intentions. The agency had conducted three public hearings late in 1999 and received more than 35,000 written comments.").

18. Although it discussed the use of special labeling to address concerns about allergenicity or changes in nutritional content, *see* 66 Fed. Reg. at 4710, 4728, the preamble to the proposed rule explained that the agency would not use this rulemaking to impose general disclosure requirements, *see id.* at 4708 n.5; *id.* at 4711 (noting that the FDA is not "proposing an across-the-board requirement that all [GE] foods bear special labeling"). The agency decided to abide by its existing policy on labeling notwithstanding the results of focus group studies that it had commissioned. *See* Marc Kaufman, *Consumers Want Engineered Food Labeled; Shoppers Express "Outrage" That Product Choices Aren't Clear, FDA Reports*, WASH. POST, Feb. 13, 2001, at A9.

19. *See* 66 Fed. Reg. 4839 (Jan. 18, 2001) (announcing a draft guidance entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering"); *id.* at 4840 ("reaffirming [its] decision to not require special labeling of all bioengineered foods"); *see also* Frank J. Miskiel, Comment, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public*

rulemaking exercise soon stalled,[20] and the FDA subsequently reiterated its preference for the existing informal consultation process.[21] Moreover, the 2001 draft guidance on voluntary labeling was never finalized, and the agency has yet to take any formal action more than two years after the filing of yet another citizen petition that requested rulemaking to require routine disclosure.[22]

No doubt in part as a consequence of the FDA's decision against across-the-board labeling, GMOs have become ubiquitous in the American diet.[23] Indeed, if the agency decided to reverse course now, essentially all processed foods would have to declare the presence of some genetically engineered ingredient.[24] Given the difficulties of segregating major crops, food processors might resort to the increasingly popular but somewhat unhelpful "may contain" disclaimers used to disclose the possible presence of allergens.[25] In contrast, more than a decade ago the European Union (EU) imposed a sweeping disclosure

Policy, 38 CAL. W. L. REV. 223 (2001); Marc Kaufman, *FDA Issues Biotech Food Rules: Proposals Address Labeling, Advance Notice of New Products*, WASH. POST, Jan. 18, 2001, at E3 (describing reactions to the draft guidance).

20. The agency initially extended the comment period, *see* 66 Fed. Reg. 17,517 (Apr. 2, 2001), and the next year's Unified Regulatory Agenda showed no anticipated date for finalization, *see* 67 Fed. Reg. 33,071, 33,073 (May 13, 2002), before references to it disappeared entirely. As a consequence, the FDA continues to govern GM foods entirely through technically nonbinding announcements. *See* Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. (forthcoming Aug. 2014) (evaluating the agency's growing reliance on guidance documents in this and other areas).

21. *See* Jonathan D. Rockoff, *Bioengineering Guides Issued: FDA Asks Companies to Vouch for Genetically Modified Plants' Safety*, BALT. SUN, June 22, 2006, at 4A; *supra* note 11.

22. *See* Bruce Horovitz, *Labels Sought for Food That's Modified; Foodmakers Don't Have to Warn Consumers*, USA TODAY, Oct. 4, 2011, at 1B.

23. *See* Sandi Doughton, *I-522: Claims Conflict on Safety of Engineered Foods*, SEATTLE TIMES, Oct. 13, 2013, *available on* Westlaw, 2013 WLNR 25650140 ("About 90 percent of corn, soy beans, cotton and sugar beets grown in the U.S. are genetically engineered, and at least one of those crops shows up in the vast majority of chips, cereals, soft drinks, crackers and other processed foods."); Julia Moskin, *Modified Crops Tap a Wellspring of Protest*, N.Y. TIMES, Feb. 8, 2012, at D3 ("Common ingredients like corn, vegetable oil, maltodextrin, soy protein, lecithin, monosodium glutamate, cornstarch, yeast extract, sugar and corn syrup are almost always produced from transgenic crops.").

24. *See* Rosie Mestel, *Genetically Modified Foods and Free Speech*, L.A. TIMES, Feb. 23, 2013, at AA1 ("Since most processed foods contain oil, sugar, syrups, emulsifiers, flour, cornmeal and protein that are derived from GM crops, virtually every [processed food] product sold in the last 15 years would have carried a [disclosure] label.").

25. *See* Alan McHughen, *Food Labeling: Uninformation and the Choice Paradox*, 18 NATURE BIOTECH. 1018, 1019 (2000); *see also* Derr, *supra* note 14, at 86–88, 151–52 (discussing allergen disclaimers); Julie Schmit, *More Food Labels Take an Ominous Tone on Allergens; Foodmakers Don't Want to Chance It*, USA TODAY, Dec. 27, 2007, at 4B.

requirement for GMOs used in food production,[26] which has resulted in the nonavailability of GE foods in those markets.[27]

In light of the FDA's position and the repeated failure of labeling proposals introduced in Congress,[28] activists have turned their attention to the states.[29] Recently, Connecticut and Maine enacted legislation to mandate GMO labeling, but these laws will only take effect if a handful of neighboring states pass comparable requirements,[30] while ballot initiatives to demand routine disclosure failed in California and

26. *See* Valery Federici, Note, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 BROOK. J. INT'L L. 515, 518 (2010) (explaining that the EU "requires that plant foods with more than 0.9% genetically modified content be labeled as 'genetically modified'"); *id.* at 542–45 (detailing evolution in the EU's labeling requirements); *see also id.* at 516–17 ("The E.U.'s anti-GM attitude has spread to other countries, including Australia, New Zealand, Japan, Indonesia, and South Korea, all of which currently have some form of GM-labeling law in place."); *id.* at 545 (elaborating).

27. *See id.* at 541, 546. Evidently, the EU intended precisely this result, which it can no longer pursue directly after the World Trade Organization ruled against earlier European moratoria on the use and sale of GMOs. *See id.* at 528–29; *see also* Scott Miller, *EU's New Rules Will Shake up Market for Bioengineered Food*, WALL ST. J., Apr. 16, 2004, at A1 (discussing Greenpeace's tactics after GM foods could be sold in Europe subject to mandatory labeling disclosure).

28. Over the course of a dozen years, then-Congressman Dennis Kucinich (D-OH) repeatedly (and fruitlessly) introduced his "Genetically Engineered Food Right to Know Act." *See* H.R. 3553, 112th Cong. (2011); H.R. 5577, 111th Cong. (2010); H.R. 6636, 110th Cong. (2008); H.R. 5269, 109th Cong. (2006); H.R. 2916, 108th Cong. (2003); H.R. 4814, 107th Cong. (2002); H.R. 3377, 106th Cong. (1999); *see also* S. 2080, 106th Cong. (2000) (companion bill introduced by Senator Barbara Boxer (D-CA)). Even after his retirement, other members of Congress continued introducing the bill. *See* S. 809, 113th Cong. (2013); H.R. 1699, 113th Cong. (2013); *cf.* S. 248, 113th Cong. (2013) (proposing to require labeling of GE fish). *But cf.* H.R. 4432, § 104, 113th Cong. (2014) (seeking to preempt state GM disclosure requirements).

29. *See* Amy Harmon & Andrew Pollack, *Battle Brewing over Labeling of Genetically Modified Food*, N.Y. TIMES, May 25, 2012, at A1; Elizabeth Weise, *GMO Battle Hits Wash. State; Voters Will Decide Next Month Whether Genetically Modified Foods Have to Be Labeled as Such*, USA TODAY, Oct. 9, 2013, at 3A.

30. *See* Ariana Eunjung Cha, *New Salvo Launched in GMO Labeling Debate*, WASH. POST, Oct. 20, 2013, at A3 ("In June, Connecticut and Maine became the first states to pass legislation requiring labeling of GMO foods, although they are delaying implementation until more nearby states do the same. At least 20 other states are considering similar bills."); *cf.* ALASKA STAT. § 17.20.040(a)(14) (2012) (mandating disclosure at retail when selling transgenic fish). Many years earlier, Vermont had mandated disclosure of the use of recombinant bovine somatotropin (rBST) in dairy cattle, but milk producers successfully challenged the disclosure requirement as an abridgement of their First Amendment rights. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73–74 (2d Cir. 1996) (granting a preliminary injunction, concluding that the purported "right to know" failed to qualify as a substantial interest: "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement"). *See generally* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COLUM. J. ENVTL. L. 227 (1997); Terence J. Centner & Kyle W. Lathrop, *Labeling rbST-Derived Milk Products: State Responses to Federal Law*, 45 U. KAN. L. REV. 511 (1997).

Washington.[31] In the absence of governmental requirements, a few grocery store chains have announced plans to insist on such labeling for food products that they carry.[32] With the prospect of such varying requirements, some observers have speculated that the industry may soon embrace a uniform federal disclosure rule.[33]

The labeling issue has received a fair amount of attention in the scholarly literature.[34] Some authors have defended the FDA's

31. *See* Andrew Pollack, *After Loss, the Fight to Label Modified Food Continues*, N.Y. TIMES, Nov. 8, 2012, at B4; Stephanie Strom, *Food Companies Claim Victory Against Labeling Initiative in Washington State*, N.Y. TIMES, Nov. 7, 2013, at A21. One decade earlier, Oregon voters rejected a similar referendum. *See* Bob Condor, *Round 1 Defeats Rules for Labeling Gene-Altered Food*, CHI. TRIB., Nov. 10, 2002, at Q9.

32. *See* Tiffany Hsu, *Grocer to Require Stricter Labeling; Whole Foods Will Mandate Disclosure of Genetically Modified Products by 2018*, L.A. TIMES, Mar. 9, 2013, at B1; *see also* Brady Dennis, *Some Major Retailers Reject Transgenic Fish*, WASH. POST, Oct. 19, 2013, at A1; *cf.* David Barboza, *Modified Foods Put Companies in a Quandary*, N.Y. TIMES, June 4, 2000, § 1, at 1 (discussing limited earlier pledges by major food processors and fast food chains); Annie Gasparro & Leslie Josephs, *Whole Foods Plans to Drop Chobani Greek Yogurt*, WALL ST. J., Dec. 19, 2013, at B3 ("Many big food companies have said they won't voluntarily label GMOs because it is costly and they fear it will give consumers a misconception that GMOs are harmful."). Large retailers occasionally use their leverage in this manner. *See* Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 28 LAW & POL'Y 515, 525 (2006) ("Retailers use their economic power to impose retailer-owned food safety standards on suppliers."); Lyndsey Layton, *Wal-Mart Turns to "Retail Regulation" to Ban Flame Retardant*, WASH. POST, Feb. 27, 2011, at A4; *see also* David Carr & Constance L. Hays, *3 Racy Men's Magazines Are Banned by Wal-Mart*, N.Y. TIMES, May 6, 2003, at C1 ("The decision . . . is the latest in a series of moves by the company to limit distribution of entertainment products it judges too racy for its shoppers. . . . Wal-Mart Stores sell sanitized versions of albums, with some songs omitted or covers redrawn to pass muster with the chain's buyers.").

33. *See* Stephanie Strom, *Companies Weigh Federal Labels for Gene-Engineered Ingredients*, N.Y. TIMES, Feb. 1, 2013, at B1 (reporting that, with the growing threat of state disclosure requirements and pressures from major retailers, the food industry might welcome FDA-mandated labeling); *cf.* Mary Clare Jalonick, *Group Tries to Head off Label Fight: Wants the FDA to Have Final Say*, BOS. GLOBE, Feb. 7, 2014, at B7 (reporting that the industry is seeking legislation that would preempt state laws but not mandate labeling). If the FDA adopted a regulation, then it might displace state laws by virtue of the express preemption clause in the statute, *see* 21 U.S.C. § 343-1(a) (2012), but the existing draft guidance would not trigger preemption, *see* Holk v. Snapple Beverage Corp., 575 F.3d 329, 340–42 (3d Cir. 2009); *see also* Nutrition Labeling and Education Act of 1990, Pub. L. No 101-535, § 6(c)(2), 104 Stat. 2353, 2364 (savings clause for state warning label requirements); Burk, *supra* note 30, at 258–64, 268–75 (discussing preemption of rBST labeling).

34. *See generally* LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE (Paul Weirich ed., 2007); Jack A. Bobo, *Two Decades of GE Food Labeling Debate Draw to an End—Will Anybody Notice?*, 48 IDAHO L. REV. 251 (2012) (discussing the guidance developed by the Codex Alimentarius and its impact on trade disputes); Mikael Klintman, *The Genetically Modified (GM) Food Labelling Controversy: Ideological and Epistemic Crossovers*, 32 SOC. STUD. SCI. 71 (2002) (offering a sociological account of the debate).

approach,[35] while others have criticized the agency's position.[36] Proponents of routine disclosure often invoke a "right to know" as if that went without saying.[37] Twenty years ago I penned a lengthy article challenging this vague concept, offering in its place the notion of a "need to know."[38] The FDA's policy of requiring disclosure only if GMOs

35. *See, e.g.*, GARY E. MARCHANT ET AL., THWARTING CONSUMER CHOICE: THE CASE AGAINST MANDATORY LABELING FOR GENETICALLY MODIFIED FOODS (2010); J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105 (2000); Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717 (2000); Carl R. Galant, Comment, *Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure*, 42 HOUS. L. REV. 125 (2005).

36. *See, e.g.*, Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 458–64, 499–504, 510 (2002); Kirsten S. Beaudoin, Comment, *On Tonight's Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237 (1999); Michael A. Whittaker, Comment, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215 (1998); *see also* Margaret Gilhooley, *Reexamining the Labeling for Biotechnology in Foods: The Species Connection*, 82 NEB. L. REV. 1088, 1105–17, 1121–25 (2004) (proposing mandatory disclosure, though not in all cases of genetic modification, and preferring the use of a descriptor such as "enhanced" rather than some variant of "GM"); *id.* at 1091 ("The best case for additional labeling is when a gene has been transferred from a different plant or animal species [a so-called 'wide cross'] to a food to affect its taste or nutrition [as opposed to serving agronomic purposes].").

37. *See, e.g.*, Matthew Rich, Note, *The Debate over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 904–06, 908, 915 (2004); Jamie E. Jorg Spence, Note, *Right to Know: A Diet of the Future Presently upon Us*, 39 VAL. U. L. REV. 1009, 1048–53 (2005). A couple of commentators have suggested peculiar constitutional foundations for this "right to know" that would obligate government to require that sellers disclose the use of genetic engineering in food production. *See* Cynthia D. Fisher, Note, *The Genie Is out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods*, 4 J. LEGAL ADVOC. & PRAC. 88, 117–18 (2002) (due process clause); *id.* at 121 (concluding that the FDA's policy "infringes on our personal autonomy by diminishing or eliminating our choices in determining what foods we choose"); David Alan Nauheim, Comment, *Food Labeling and the Consumer's Right to Know: Give the People What They Want*, 4 LIBERTY U. L. REV. 97, 99–101, 128 (2009) (free speech clause); *id.* at 98 ("[T]he First Amendment requires that government protect the consumers' right to receive accurate non-misleading information that they reasonably desire."). These commentators utterly failed to comprehend the profound difference between so-called "negative" rights (namely, against government interference)—which, for instance, sellers successfully have invoked against state disclosure requirements, *see supra* note 30—and affirmative entitlements (to government assistance).

38. *See* Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 341–43, 381–401 (1994); *id.* at 384 ("[I]nappropriate [consumer] responses to risk labeling may outweigh the anticipated benefits of warning efforts, particularly when the primary purpose of such efforts is nothing more than fulfilling an amorphous 'right to know.'"); *see also* Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49 (1997); *cf.* Burk, *supra* note 30, at 308–15 (evaluating dormant commerce clause objections to origin-of-food labeling premised on nothing more than a

pose allergenicity concerns or affect the composition of a food exemplifies a need-to-know approach.

Rather than revisiting that broad and largely inconclusive debate, let me instead offer a concrete illustration of this supposed "right to know" in action. Proponents of mandatory GM labeling repeatedly have emphasized that the FDA did precisely that in the case of irradiated foods.[39] Although one can distinguish this "precedent" in any number of ways,[40] I hope to show in the next Part that the experience with irradiation labeling demonstrates quite clearly the flaws of a generalized disclosure requirement for innovative food production technologies.[41]

consumers' "right to know"); *id.* at 291 ("When a consumer purchases milk, there is no telling whether it comes from farms owned by godless communists, is distributed by corporations with objectionable foreign investments, . . . or in some other way is associated with some political, economic, or social outcome that the consumer might find distasteful."). Although "paternalistic" in a sense, this approach raises potential First Amendment problems only if the state acts coercively by either prohibiting or requiring the disclosure of information by regulated entities. *See* Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31, 32–35 & n.2, 67, 85–89, 91–92 (2011).

39. *See, e.g.*, Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 526, 591–92 (2004); Marden, *supra* note 5, at 763; McGarity, *supra* note 36, at 459–60; Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667, 670, 672, 682–84, 686–88 (1999); Nauheim, *supra* note 37, at 109–10, 117–18, 124–26; Rich, *supra* note 37, at 903–04.

40. *See* 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993) (explaining that it does not require disclosure of irradiated ingredients); *id.* at 25,839 ("Further, FDA notes that plant breeding methods are applied in the earliest stages of development of new plant varieties and are not processes applied to the finished food."); Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 306 (2000). *See generally* Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 383–84 (2006) (explaining the limited force of objections premised on purported departures from agency precedent).

41. In contrast, one commentator who repeatedly drew this parallel seemed altogether sanguine about the experience with irradiation. *See* Winn, *supra* note 39, at 682–83 ("FDA, despite a recognition of potential disadvantages of an irradiation label, was confident that additional information provided on a voluntary basis by food producers would more than sufficiently curtail the potential problem of scaring consumers."); *id.* at 688 (discounting cost concerns). The experience of the last 15 years has hardly borne out such confident predictions. At the other extreme, an otherwise excellent recent treatment of the issue warned that mandatory GMO labeling would set an unfortunate "precedent," which could threaten other "promising emerging technologies" such as food irradiation. *See* MARCHANT ET AL., *supra* note 35, at 5, 67. Talk about getting things entirely backwards (or at the very least missing an opportunity to use the experience with food irradiation disclosure as a concrete lesson too often overlooked in the debate about GMO labeling).

II. FOOD IRRADIATION AND MANDATORY DISCLOSURE

The use of radiation to treat food has a relatively long history.[42] The technology goes back fully a century, though its earliest applications involved efforts at vitamin fortification.[43] Irradiation also facilitated a primitive form of genetic engineering by inducing random mutations in seeds that plant breeders then would grow in search of desirable traits.[44] Thousands of modern crops can trace their genesis to the use of this technique.[45] Nowadays, irradiation serves primarily as a method for reducing pathogenic microorganisms and other types of contamination in various classes of food.[46]

When it created a licensing process for "food additives" more than 50 years ago,[47] Congress specifically included irradiation within the definition.[48] It took less than two years before the FDA approved the

42. *See* Edward Samuel Josephson, *An Historical Review of Food Irradiation*, 5 J. FOOD SAFETY 161 (1983).

43. *See* Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d 941, 942–43 (9th Cir. 1944) (reviewing patents claiming a process for supplementing food with vitamin D by irradiating it with ultraviolet light); Frank L. Gunderson, *Improvement in Nutritive Value of Foods*, 7 FOOD DRUG COSM. L.J. 128, 132 (1952).

44. *See* Noah, *Managing Biotechnology's [R]evolution*, *supra* note 2, ¶ 2 ("[B]efore rDNA techniques became available, plant breeders might use mutagenesis, inducing random mutations with chemicals or radiation and then hoping to discover some desirable characteristics in the progeny."); Doughton, *supra* note 23 ("[S]eeds [may be] soaked in a mutagenic chemical to scramble the DNA and produce plants with a wide variety of traits. Breeders also blast seeds with gamma rays to achieve the same effect. . . . Compared to genetic engineering, which inserts one or two genes, so-called mutation breeding is like taking a sledgehammer to a plant's DNA, . . . [and] it's completely unregulated.").

45. *See* Doughton, *supra* note 23 ("One of the most popular varieties of red grapefruit and more than 2,000 other types of vegetables, fruits and grains—including many that are grown organically—were created through radiation mutagenesis.").

46. *See* 72 Fed. Reg. 16,291, 16,295 (Apr. 4, 2007) ("Food is most commonly irradiated to control food-borne pathogens."); Michael T. Osterholm & Andrew P. Norgan, *The Role of Irradiation in Food Safety*, 350 NEW ENG. J. MED. 1898, 1898–99 (2004) (describing the different methods of irradiating food); *see also id.* at 1899–900 (canvassing the arguments for and against the use of this technology); *id.* at 1898 ("The irradiation of food has the potential to decrease the incidence of foodborne disease dramatically. It is widely supported by international and national medical, scientific, and public health organizations . . . ."). *See generally* FOOD IRRADIATION RESEARCH AND TECHNOLOGY (Xuetong Fan & Christopher H. Sommers eds., 2d ed. 2013).

47. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (codified as amended in scattered sections of 21 U.S.C.). *See generally* Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329 (1998).

48. *See* G.H. Pauli & L.M. Tarantino, *FDA Regulatory Aspects of Food Irradiation*, 58 J. FOOD PROTECTION 209, 209 (1995). The definition in the statute provides as follows:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food

first food additive petitions generally authorizing use of certain sources of irradiation.[49] Three years later, the agency issued the first regulations allowing irradiation for particular food uses: preservation of canned bacon,[50] followed by the control of insects in wheat and wheat products.[51]

The first requirements for disclosures in labeling appeared in 1966. In tandem with its approval of the use of low-dose electron beam radiation to control insects in wheat and wheat flour,[52] the FDA mandated that retail packages of these foods include the following language: "Treated with ionizing radiation."[53] The same language also had to appear on the packages of these foods when processed using previously authorized low-dose gamma radiation,[54] while the labels of

> (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and *including any source of radiation intended for any such use*) . . . .

21 U.S.C. § 321(s) (2012) (emphasis added); *see also id.* § 342(a)(7) (providing that a food violates the prohibition against adulteration "if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title").

49. *See* 25 Fed. Reg. 6469 (July 9, 1960), *amended*, 26 Fed. Reg. 3640, 3641 (Apr. 28, 1961) (codified as amended at 21 C.F.R. § 121.3001 (1966)). Five years later, the agency authorized the use of ultraviolet (UV) radiation to control microorganisms on the surface of foods. *See* 30 Fed. Reg. 8572 (July 7, 1965) (codified at 21 C.F.R. § 121.3006 (1966)). In 1967, it tacked a brief new section onto the end of subpart 121(G), initially authorizing the use of microwave radiation only for fish protein concentrate, *see* 32 Fed. Reg. 1173, 1175 (Feb. 2, 1967), which it soon amended to allow for general use in heating foods, *see* 33 Fed. Reg. 4173 (Mar. 6, 1968) (codified at 21 C.F.R. § 121.3008 (1969)).

50. *See* 28 Fed. Reg. 1465 (Feb. 15, 1963), *amended*, 29 Fed. Reg. 4672 (Apr. 1, 1964) (codified as amended at 21 C.F.R. § 121.3002 (1966)); 28 Fed. Reg. 9526 (Aug. 30, 1963) (codified as amended at 21 C.F.R. § 121.3004 (1966)); *see also* 29 Fed. Reg. 18,056 (Dec. 19, 1964) (codified as amended at 21 C.F.R. § 121.3005 (1966)) (approving X-ray irradiation of canned bacon).

51. *See* 28 Fed. Reg. 9208 (Aug. 21, 1963), *amended*, 29 Fed. Reg. 9329 (July 8, 1964) (adding the inhibition of sprouts in white potatoes) (codified as amended at 21 C.F.R. § 121.3003 (1966)); *see also Regulations Permitting the Use of Radiation*, 18 FOOD DRUG COSM. L.J. 536 (1963). Almost two decades later, however, the agency explained that "there has been no commercial application of these approved uses." 46 Fed. Reg. 18,992, 18,992 (Mar. 27, 1981). In any event, the FDA subsumed these approved uses in wheat and potatoes when it authorized low-dose irradiation of fresh produce to inhibit maturation and of all foods to control insects. *See* 51 Fed. Reg. 13,376, 13,399 (Apr. 18, 1986) (codified at 21 C.F.R. § 179.26(b)(2)&(3) (2013)).

52. *See* 31 Fed. Reg. 9491, 9491–92 (July 13, 1966) (codified at 21 C.F.R. § 121.3007 (1967)).

53. 21 C.F.R. § 121.3007(d)(1) (1967).

54. *Id.* § 121.3003(c)(1). In both cases, wholesale items required use of the following language: "Treated with ionizing radiation—do not irradiate again." *Id.* §§ 121.3003(c)(2), 121.3007(d)(2). As explained in the preamble to the final rule, "doses exceeding those permitted might impair the baking qualities of wheat and cause undesirable physical changes in potatoes. No data have been set forth to show that an excessive radiation dose accumulated over several exposures would not have the same

canned bacon treated with high-dose gamma ray, X-ray, or electron beam radiation had to disclose that it was "Processed by ionizing radiation."[55] It is not entirely clear what prompted the agency to pursue this issue.[56] The notice of proposed rulemaking simply had announced (without offering any further elaboration) that the Commissioner "has concluded that food treated by radiation should have such fact declared on its label."[57]

The brief preamble to the 1966 regulation, issued less than three months after the close of the public comment period, noted that the FDA had received half a dozen negative comments on its proposal.[58] The agency accepted one minor suggested revision, but, on the strength of the preliminary results from a consumer survey conducted by Atomic Energy Commission (AEC), the FDA rejected other ideas for softening the language of the disclosure statements: it doubted that the reference to "radiation" would cause undue alarm, and it concluded that suggestions to replace "ionizing radiation" with "ionizing energy" (and prefacing the disclosures with "pasteurized by" or "sterilized by") would only promote consumer confusion.[59] Six months later, in the course of rejecting formal objections and hearing requests filed in response to the final rule, the FDA reiterated its position that the terms "pasteurized" and "sterilized" as commonly understood could not be applied to irradiated foods, but it did propose to allow for some flexibility in the disclosure statements.[60] After receiving no further comments, the agency authorized alternative language specifying the type of radiation used: instead of "Treated with [or processed by] ionizing radiation," sellers could choose to state

deleterious effects as those reported from single doses of the same magnitude." 31 Fed. Reg. at 9491.

55. 21 C.F.R. §§ 121.3002(d), 121.3004(e), 121.3005(d).

56. In 1950, the FDA had started to demand that foods treated with certain pesticides after harvest disclose the use of these "chemical preservatives," but, one decade later, Congress barred imposition of such a retail labeling requirement. *See* Goldman, *supra* note 35, at 740–45. If the agency viewed the postharvest use of, for instance, fungicides on grain or produce as something that consumers should know about (putting aside the legislative override), then it would make sense to impose a comparable disclosure requirement for irradiation when used for a similar purpose.

57. *See* 31 Fed. Reg. 3402, 3402 (Mar. 4, 1966) (explaining also that "wheat flour" should replace the broader indefinite reference to "wheat products" used previously), *comment period extended*, 31 Fed. Reg. 5453 (Apr. 6, 1966). When it revised this requirement 20 years later, the agency explained that the original rules "were based on misbranding considerations and not on food safety or health risk considerations." 51 Fed. Reg. 13,376, 13,389 (Apr. 18, 1986).

58. *See* 31 Fed. Reg. at 9491.

59. *See id.* (conceding, however, that the AEC survey found that the use of "pasteurized by" in consumer labeling "was more acceptable than 'processed by' because 'pasteurized' is a familiar word with positive connotations").

60. *See* 32 Fed. Reg. 140 (Jan. 7, 1967).

"Treated with [or processed by] gamma [or electron or X-] radiation" as appropriate.[61]

Thus, over the course of a decade, the FDA had crafted a rudimentary set of regulations implementing its command from Congress to review uses of radiation under its new food additive authority. In 1968, however, after announcing that the results of long-term feeding studies in animals had raised safety concerns,[62] the agency withdrew its approval of three forms of high-dose radiation (gamma, electron beam, and X-ray) for the processing of canned bacon.[63] After this initial spurt of regulatory activity by the FDA, the next decade witnessed essentially no further movement on food irradiation.[64]

During the 1980s, the subject again drew sustained attention from the FDA. First, the agency gradually expanded the list of permitted uses in foods.[65] In 1983, it approved gamma radiation to control microbial contamination of more than three dozen spices and seasonings.[66] Less than a year later, the FDA amended the rule to allow for the use of

61. *See* 32 Fed. Reg. 3442, 3443 (Mar. 2, 1967) (codified at 21 C.F.R. §§ 121.3002–.3007 (1968)).

62. *See* 33 Fed. Reg. 12,055, 12,055 (Aug. 24, 1968) ("conclud[ing] that further research on the wholesomeness of this product is necessary to establish the conditions of safe use for irradiation of bacon"). *But cf.* 51 Fed. Reg. 13,376, 13,384 (Apr. 18, 1986) ("Although previous reviewers asserted that the irradiated bacon studies may have shown adverse effects, the agency, after extensive reexamination of the study, now concludes that the claimed adverse effects cannot be substantiated . . . .").

63. *See* 33 Fed. Reg. 15,416 (Oct. 17, 1968) (revoking 21 C.F.R. §§ 121.3002, .3004, .3005); *see also* 49 Fed. Reg. 5714, 5715 (Feb. 14, 1984) ("Other [food additive] petitions [for irradiation] were submitted [during the 1960s], but they could not be accepted because of poor experimental design and many unresolved questions.").

64. Perhaps the most notable action that the FDA took during this time involved the renumbering of its food additive (and other) regulations, which converted subpart 121(G) into part 179. *See* 42 Fed. Reg. 14,302, 14,635 (Mar. 15, 1977) (codified at 21 C.F.R. pt. 179 (1977)). New subpart 179(C), which specified the types of food packaging that one could use when irradiating foods, previously had appeared separately from subpart 121(G). *See* 21 C.F.R. § 121.2543 (1976). The food additive regulations governing animal feed and pet food incorporate by reference the rules allowing for the irradiation of human food. *See* 42 Fed. Reg. 44,227, 44,228 (Sept. 2, 1977) (codified at 21 C.F.R. § 570.12 (1985)), *amended*, 51 Fed. Reg. 5992, 5993 (Feb. 19, 1986) (codified as amended at 21 C.F.R. pt. 579 (2013)).

65. For the latest list, see 21 C.F.R. § 179.26(b) (2013). In the footnotes that follow, I omit as redundant any parenthetical references to this particular subsection (or its predecessors) for final rules that were codified there.

66. *See* 48 Fed. Reg. 30,613, 30,614 (July 5, 1983). The agency announced the filing of this food additive petition almost three years earlier. *See* 45 Fed. Reg. 69,044 (Oct. 17, 1980). In response to the final rule, the FDA received five sets of comments but concluded that none of them constituted objections or hearing requests, raising instead collateral issues that the agency had under consideration at the time as part of a broader rulemaking effort to address the general subject. *See* 50 Fed. Reg. 15,417 (Apr. 18, 1985).

gamma radiation to control insects in these same spices and seasonings,[67] and the next year it added another dozen spices and herbs to the list.[68] In 1985, the agency allowed irradiation of pork for purposes of combating the parasitic disease trichinosis.[69]

Second, the FDA undertook an omnibus rulemaking to address some of the broader issues related to the irradiation of food.[70] Among other things, the notice of proposed rulemaking (NPRM) suggested eliminating the retail labeling requirements.[71] After receiving more than 2,000 adverse public comments on just this aspect of the NPRM,[72] however, the agency issued a final rule in 1986 that opted instead for fairly minor revisions to the disclosure requirements that it had first imposed 20 years earlier.[73]

67. *See* 49 Fed. Reg. 24,988, 24,989 (June 19, 1984).

68. *See* 50 Fed. Reg. 15,415, 15,416 (Apr. 18, 1985) (also allowing blends that include minor amounts of table salt), *amended*, 51 Fed. Reg. 13,376, 13,399 (Apr. 18, 1986) (renumbering, replacing the list with more general classes, and increasing the allowable dose); *see also* 50 Fed. Reg. 24,190, 24,191 (June 10, 1985) (adding enzyme preparations). A few years later, the agency amended the description of aromatic vegetable substances eligible for irradiation. *See* 53 Fed. Reg. 53,176, 53,209 (Dec. 30, 1988); *see also* 54 Fed. Reg. 32,335 (Aug. 7, 1989) (responding to objections).

69. *See* 50 Fed. Reg. 29,658, 29,659 (July 22, 1985); *see also* 53 Fed. Reg. 53,176, 53,187–88 (Dec. 30, 1988) (explaining, in the course of responding to objections and requests for a hearing, why the 1968 revocation of the approval for irradiation of canned bacon had no bearing on the approval of much lower doses for pork). The USDA had to issue a parallel regulation in order to authorize this use. *See* 51 Fed. Reg. 1769, 1770 (Jan. 15, 1986) (codified at 9 C.F.R. § 318.7(c)(4) (1999)); *see also* John W. McCutcheon, *Labeling: USDA's Process and Policy*, 43 FOOD DRUG COSM. L.J. 385, 388 (1988) (summarizing that agency's informal labeling policy on irradiated pork).

70. *See* 46 Fed. Reg. 18,992, 18,993 (Mar. 27, 1981) (issuing an advance notice of proposed rulemaking, asking among other things (and with little elaboration) "[w]hether there is need for [continued] labeling of irradiated foods"); *see also* Sanford A. Miller, *The FDA in the 1980s: The Center for Food Safety and Applied Nutrition*, 45 FOOD DRUG COSM. L.J. 69, 72 (1990) ("Inflamed by antinuclear groups, the public confused the use of ionizing radiation for the preservation of food with nuclear power plants and weapons systems. It was clear to the agency that any action it took in this area would be challenged.").

71. *See* 49 Fed. Reg. 5714, 5720 (Feb. 14, 1984) ("No retail labeling requirement is being proposed because any changes in food are of no safety concern at the proposed doses and because the agency is not persuaded that special labeling is necessary."); *id.* at 5718–19 (elaborating, but also inviting comments on the possibility of retaining such a requirement); *id.* at 5719 ("FDA agrees with the view that some consumers might erroneously associate the food irradiation process and the words 'ionizing radiation' with the idea of radioactivity . . . ."); *see also id.* (explaining that it would retain the wholesale labeling requirement in order to ensure that processors would not apply a second dose and possibly exceed the maximum allowed).

72. *See* 51 Fed. Reg. 13,376, 13,377 (Apr. 18, 1986) ("The agency received over 5,000 comments on the proposal."); *id.* at 13,388 ("Half the comments specifically addressed the retail labeling issue, and over 80 percent of those comments urged that retail labeling be 'required to prevent consumer deception.'").

73. *See id.* at 13,399 (codified as amended at 21 C.F.R. § 179.26(c) (2013)); *see also* 53 Fed. Reg. 53,176, 53,177–203 (Dec. 30, 1988) (responding to objections and requests

In justifying its decision, the agency twice pointed out that "the large number of consumer comments requesting retail labeling attest to the significance placed on such information by consumers,"[74] but it prefaced the second reference to this point with an important caveat: "Whether information is material under . . . the [statute] depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer."[75] In light of this proviso, the FDA concluded that, without labeling, consumers would have no way of knowing that an irradiated whole food had undergone any sort of processing.[76] In contrast, and notwithstanding presumably comparable consumer demand for this information, multi-ingredient food products obviously have undergone some form of processing and would, therefore, require no disclosure if one or more of those ingredients had been irradiated.[77]

Retail labels of irradiated food would have to include the simple disclosure statement "Treated with radiation" or "Treated by irradiation."[78] The FDA invited sellers to elaborate on the purposes of

for a hearing related to the agency's conclusions concerning safety and effects on nutritional quality); *id.* at 53,203–05 (same, with regard to labeling); 52 Fed. Reg. 5450, 5453 (Feb. 23, 1987) (declining requests for a stay of the effective date). For foods not sold prepackaged, the disclosures must appear in another form at the point of sale. *See* 21 C.F.R. § 179.26(c)(2); *see also* 51 Fed. Reg. at 13,391 (elaborating). Persons who ship irradiated foods to another company for further preparation or processing must state "Treated with radiation [or "by irradiation"]—do not irradiate again." 21 C.F.R. § 179.26(c)(3).

74. 51 Fed. Reg. at 13,388 (repeating this statement just five paragraphs later, though substituting "labeling" for "information"); *see also id.* at 13,390 ("[I]rradiation causes certain changes in foods and . . . even small changes that pose no safety hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers.").

75. *Id.* at 13,388. The FDA also emphasized "that the labeling requirement is not based on any concern about the safety of the [allowed] uses of radiation." *Id.*; *see also id.* at 13,389–90 (discounting any safety rationale for disclosure).

76. *See id.* at 13,388 ("Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed."); *id.* at 13,390 ("[T]he absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed."). Although perhaps a fair point with regard to fresh produce (e.g., bananas), the agency also required that unmistakably processed (e.g., canned, frozen, and multiple-ingredient) products include the same labeling if irradiated in their finished form but not in the event that an ingredient in such a food previously had undergone irradiation.

77. *See id.* at 13,389 ("[T]he irradiation of one ingredient in a multiple-ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities.").

78. *See* 21 C.F.R. § 179.26(c)(1); *see also* 51 Fed. Reg. at 13,389 (explaining that "the original labeling terminology required by existing [rules] may be overly technical

such treatment.[79] In addition, labels would have to include the internationally recognized "radura" symbol,[80] which portrays a stylized plant inside a circle with several gaps in its top half:

These requirements only apply "to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated."[81] One decade later, Congress ordered that the

and that the type of radiation being used is not necessarily meaningful to consumers"); *id.* at 13,390 (rejecting the proposed alternative terminology "ionizing energy" or "picowave treatment").

79. *See* 51 Fed. Reg. at 13,387 ("In addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or expand upon the kind of treatment used."); *id.* at 13,389 ("Recognizing that labeling itself is a valuable source of consumer education, FDA encourages optional statements to be included on the retail label that expand upon the kind of treatment used or the purpose of the treatment."); *see also id.* at 13,388 ("The agency recognizes that, because this is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort . . . [such as] 'this treatment does not induce radioactivity.'").

80. *See* 21 C.F.R. § 179.26(c)(1); *see also* 51 Fed. Reg. at 13,390–91 (responding to comments from the EPA expressing concern that the symbol resembled the agency's official logo and might suggest that it had endorsed a food). The text-based part of the retail labeling requirement was set to expire after two years, *see id.* at 13,391, but, after concluding that consumers had not yet become sufficiently familiar with the radura symbol, the FDA subsequently extended the sunset date by two additional years, *see* 53 Fed. Reg. 12,756, 12,757 (Apr. 18, 1988), before removing it altogether and making the requirement permanent, *see* 55 Fed. Reg. 14,413, 14,415 (Apr. 18, 1990).

81. 21 C.F.R. § 179.26(c)(2); *see also* 51 Fed. Reg. at 13,389 ("[T]he retail labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated."). The USDA's subsequently adopted regulations governing irradiated meat and poultry generally track the FDA's labeling requirements, except with regard to irradiated ingredients. *See* 9 C.F.R. § 424.22(c)(4)(iii) (2013) ("The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling."); *see also* Council Directive 1999/2, art. 6, § 1, 1999 O.J. (L66) 16, 18 (EC) (EU requires labeling either whole foods or any listed ingredients as "irradiated" or "treated with ionising radiation").

irradiation disclosure should not be more prominent than the statement of ingredients.[82]

During the 1990s, the FDA focused on the irradiation of various types of foods derived from animals: poultry,[83] red meats,[84] and eggs.[85] Evidently impatient with the pace of the agency's review of the pending food additive petition on red meats, Congress had ordered it to take final action.[86] Even after the FDA gave its stamp of approval to combat the threat of foodborne illness from meat, however, retailers remained hesitant because they feared consumer resistance.[87]

82. *See* Food and Drug Administration Modernization Act (FDAMA) of 1997, Pub. L. No. 105-115, § 306, 111 Stat. 2296, 2353 (codified at 21 U.S.C. § 343-3 (2012)); *see also* 63 Fed. Reg. 43,875, 43,876 (Aug. 17, 1998) (revising the regulation accordingly). In tandem with this legislation, Congress informally directed the FDA to solicit comments on the possibility of further revising or altogether revoking this requirement. *See* H.R. REP. No. 105-399, at 98–99 (1997) (Conf. Rep.), *reprinted in* 1997 U.S.C.C.A.N. 2880, 2888–89 ("The conferees intend for any required disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety."). The agency issued an advance notice of proposed rulemaking for this purpose. *See* 64 Fed. Reg. 7834 (Feb. 17, 1999); *see also* 72 Fed. Reg. 16,291, 16,292 (Apr. 4, 2007) (explaining that the FDA had received more than 5,500 comments in response, most of which opposed making any revisions); *cf.* 66 Fed. Reg. 17,183, 17,183 (Mar. 29, 2001) (proposing to undertake a focus group study into whether "the current labeling requirement is an obstacle to consumer acceptance of irradiated foods" in order to meet a commitment made to Congress for a decision by March 2002).

83. *See* 55 Fed. Reg. 18,538, 18,544 (May 2, 1990), *amended*, 77 Fed. Reg. 71,316, 71,321 (Nov. 30, 2012); *see also* 62 Fed. Reg. 64,102 (Dec. 3, 1997) (responding to objections and denying hearing requests on the original rule).

84. *See* 62 Fed. Reg. 64,107, 64,121 (Dec. 3, 1997); *see also* 64 Fed. Reg. 72,150, 72,165–66 (Dec. 23, 1999) (codified as amended at 9 C.F.R. § 424.22(c) (2013)) (announcing the USDA's concurrence); *id*. at 72,155–60 (discussing labeling issues); *cf.* 77 Fed. Reg. 71,312, 71,316 (Nov. 30, 2012) (authorizing irradiation of processed meat products). A couple of years earlier, the FDA had issued a regulation allowing for high-dose irradiation to sterilize frozen prepackaged meats for use in NASA's space flight program. *See* 60 Fed. Reg. 12,669, 12,670 (Mar. 8, 1995).

85. *See* 65 Fed. Reg. 45,280, 45,281–82 (July 21, 2000) (approved for control of *Salmonella* in fresh shell eggs); *see also* 76 Fed. Reg. 20,509 (Apr. 13, 2011) (responding to objections and denying hearing requests). *See generally* Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59 FOOD & DRUG L.J. 441 (2004) (discussing growing concerns in the 1990s about *Salmonella enteriditis* in eggs and various regulatory responses).

86. *See* FDAMA, § 307, 111 Stat. at 2353 (giving the FDA 60 days to reach a decision). The FDA soon thereafter established a process for expediting its review of petitions for technologies intended to reduce the levels of pathogens in foods. *See* 64 Fed. Reg. 517 (Jan. 5, 1999) (announcing the availability of a guidance document that set forth this prioritization mechanism).

87. *See* Marian Burros, *Irradiated Beef: In Markets, Quietly*, N.Y. TIMES, Feb. 28, 2001, at F1. The minimal price differential would not by itself explain the absence of consumer demand. *See* Osterholm & Norgan, *supra* note 46, at 1899 ("The cost to the consumer of irradiating food in large volumes is estimated to be less than five cents a pound for meat or poultry."); *see also* Christine M. Bruhn & Olivia Bennett Wood,

After these high profile approvals, the first decade of the new century witnessed the addition of only a handful of miscellaneous uses of irradiation: alfalfa and other seeds used for producing sprouts,[88] oysters and other molluscan shellfish,[89] and certain leafy green vegetables.[90] More notable developments took place at the USDA during this period. In 2002, its Animal and Plant Health Inspection Service authorized the use of irradiation as a phytosanitary measure for imported fruits and vegetables (for instance, to eradicate fruit flies that such produce might harbor).[91] One year later, a different branch of the Department

Position of the American Dietetic Association: Food Irradiation, 100 J. AM. DIET. ASS'N 246, 251 (2000) (noting that the irradiation of fruits and vegetables would cost two to three cents per pound, and adding that "[p]roduce has been marketed without a price premium as a result of decreased losses and increased shelf life").

88. *See* 65 Fed. Reg. 64,605, 64,607 (Oct. 30, 2000); *id.* at 64,606–07 (adding "that sprouts grown from seeds that have been irradiated need not be labeled as treated by irradiation where the sprouts themselves have not been irradiated"); *see also* 77 Fed. Reg. 27,586 (May 11, 2012) (responding to objections and denying hearing requests); *id.* at 27,590 (abiding by its decision not to require separate labeling of sprouts). *See generally* Janet C. Mohle-Boetani et al., Escherichia coli *O157 and* Salmonella *Infections Associated with Sprouts in California, 1996–1998*, 135 ANNALS INTERNAL MED. 239 (2001); *C.D.C. Issues Warning About Raw Sprouts*, N.Y. TIMES, Jan. 15, 2002, at F8 ("[S]prouts have in the past decade gained a risky reputation as scientists and health officials linked them to food-borne illnesses."). Note that this use differs from high-dose irradiation of seeds to promote mutagenesis for purposes of plant breeding. *See supra* notes 44–45 and accompanying text.

89. *See* 70 Fed. Reg. 48,057, 48,073 (Aug. 16, 2005); *see also* 76 Fed. Reg. 15,841 (Mar. 22, 2011) (responding to objections and denying hearing requests). *See generally* Greg Winter, *Doubts Cast on U.S. Effort for the Safety of Shellfish*, N.Y. TIMES, July 19, 2001, at C7 (reporting that "more than 100,000 Americans become ill from eating contaminated clams, mussels, oysters and scallops every year" and that almost 20 die annually from *Vibrio* infections). More recently, the FDA approved the use of irradiation to control foodborne pathogens in crustaceans such as crabs and shrimp. *See* 79 Fed. Reg. 20,771, 20,779 (Apr. 14, 2014).

90. *See* 73 Fed. Reg. 49,593, 49,603 (Aug. 22, 2008) (fresh iceberg lettuce and spinach). Again this action came in the wake of a particular food safety scare, though consumer resistance made its widespread adoption unlikely. *See* Andrew Martin, *Spinach and Peanuts, with a Dash of Radiation*, N.Y. TIMES, Feb. 2, 2009, at A10. *See generally* Sara M. Benson, *Guidance for Improving the Federal Response to Foodborne Illness Outbreaks Associated with Fresh Produce*, 65 FOOD & DRUG L.J. 503 (2010). The seemingly random list of approved uses indicates nothing more than choices made by petitioners; it does not reflect negative judgments by the FDA about unlisted uses. *Cf.* 72 Fed. Reg. 16,291, 16,295 (Apr. 4, 2007) (discussing a study that found the "firmness of cut romaine lettuce irradiated at 0.35 kGy decreased by 10 percent" while the firmness of iceberg lettuce irradiated at 2 kGy did not change). In fact, the agency has granted blanket approval to low-dose irradiation of all foods to control pests and of all fresh foods (e.g., fruits and vegetables) to inhibit maturation. *See* 51 Fed. Reg. 13,376, 13,399 (Apr. 18, 1986). It requires, however, that interested persons file food additive petitions for higher doses and/or to combat foodborne pathogens. *See id.* at 13,393–94.

91. *See* 67 Fed. Reg. 65,016, 65,027–29 (Oct. 23, 2002), *superseded*, 70 Fed. Reg. 33,264, 33,317–23 (June 7, 2005), *superseded*, 75 Fed. Reg. 4228, 4231–36, 4246–49 (Jan. 26, 2010) (codified as further amended at 7 C.F.R. § 305.9 (2013)); *see also*

announced that the National School Lunch Program would begin offering irradiated ground beef.[92] Instead of reassuring parents about food safety in the aftermath of highly publicized scares involving meat products,[93] this policy change encountered substantial resistance,[94] prompting Congress to demand that USDA ensure clear disclosure and voluntary participation.[95]

In 2002, Congress invited the FDA to consider revising its labeling requirements for irradiated foods.[96] Five years later, the agency

Kimberly Kindy, *Irradiation's Food-Safety Message Lost in the Glow*, WASH. POST, Apr. 28, 2014, at A1 ("The only large expansion of irradiated food in recent years . . . is with imported fruits and vegetables. In 2007, 10 million pounds . . . were being irradiated, typically to kill invasive insects that could harm domestic crops. Now . . . it's closer to 40 million pounds."). This explains why Hawaiian papayas are one of the rare foods that undergo both irradiation and genetic modification. *See* Carol Ness, *Irradiated Food Gets Thumbs-up from USDA: Tropical Fruits Likely First in Line to Zapped*, S.F. CHRON., Oct. 22, 2002, at A1 ("Irradiated papayas . . . from Hawaii have been sold on the mainland for the past two years . . . ."); Andrew Pollack, *Unease in Hawaii's Cornfields*, N.Y. TIMES, Oct. 8, 2013, at B1 ("[M]ost of the island's papayas are genetically engineered to resist a virus that almost wiped out the crop in the 1990s.").

92. *See* Michael A. Fletcher, *Ban on Irradiated Ground Beef Lifted in School Lunch Program*, WASH. POST, May 30, 2003, at A11; *see also* Marian Burros, *Irradiated Beef: A Question in Lunchrooms*, N.Y. TIMES, Jan. 29, 2003, at F3. Congress had directed the agency to do this. *See* Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 4201(b)(3), 116 Stat. 134, 328–29.

93. *See* Patricia Callahan, *Supermarkets Test Appetite for Irradiated Meat*, WALL ST. J., Nov. 7, 2002, at B1 ("Supermarkets are betting that a rash of illnesses and deaths from meat contaminated with strains of E. coli and listeria bacteria will make [irradiated meat] more palatable to consumers."); *see also* Hana Simon, Comment, *Food Safety Enforcement Enhancement Act of 1997: Putting Public Health Before the Meat Industry's Bottom Line*, 50 ADMIN. L. REV. 679, 680–81 (1998) (referencing a pair of notable incidents from the 1990s). Schools have had their share of foodborne illness outbreaks. *See, e.g.*, Almquist v. Finley Sch. Dist. No. 53, 57 P.3d 1191, 1193–94 (Wash. Ct. App. 2002) (affirming judgment for a dozen children infected with *E. coli* 0157:H7 traced to tacos served at an elementary school cafeteria in 1998); *see also* Xuetong Fan, *Irradiated Ground Beef for the National School Lunch Program*, *in* FOOD IRRADIATION RESEARCH AND TECHNOLOGY, *supra* note 46, at 373, 374–76 (discussing GAO report on this issue).

94. *See* Donald W. Thayer, *Irradiation of Food—Helping to Ensure Food Safety*, 350 NEW ENG. J. MED. 1811, 1811 (2004) ("The recent approval of irradiated hamburgers for school lunch programs in the United States has been met with unfounded claims by groups opposed to food irradiation that children are being used as experimental animals. Unfortunately, this campaign has influenced some school boards to deny their students the increased safety of irradiated foods."); Marian Burros, *Schools Seem in No Hurry to Buy Irradiated Beef*, N.Y. TIMES, Oct. 8, 2003, at F1; Cindy Skrzycki, *Fallout over Irradiated Food in School Lunches*, WASH. POST, Apr. 29, 2003, at E1.

95. *See* Child Nutrition and WIC Reauthorization Act of 2004, Pub. L. No. 108-265, § 118, 118 Stat. 729, 752–53 (codified at 42 U.S.C. § 1762a(h) (2012)).

96. *See* Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 10809, 116 Stat. 134, 531 (calling for rulemaking "to revise, as appropriate, the current regulation governing the labeling of foods that have been treated to reduce pest infestation or pathogens by treatment by irradiation"); *see also* Cindy Skrzycki, *Zapping a New Label on Irradiation?*, WASH. POST, Nov. 5, 2002, at E1 ("[T]he industry indicated

responding by publishing a notice of proposed rulemaking that would roll back some of its disclosure rules.[97] The FDA prefaced these suggested changes by recognizing that consumers may have misunderstood existing disclosures and, as a result, missed out on the safety benefits of this technology.[98] The agency did not, however, manage to finalize this rulemaking effort before the transition from the Bush to the Obama Administration,[99] so these proposals seem to have stalled for the time being.

Nonetheless, just as the never-finalized (and nonbinding) 2001 draft guidance on voluntary GMO labeling offers the most current official position of the FDA on that subject, the still-pending 2007 NPRM on irradiation labeling deserves attention as a signal about possible future

that it would like to call irradiated food almost anything but irradiated. It felt that the word, along with the radura, looked more like a warning than an assurance of safety to consumers."). Five years earlier, Congress had used a committee report to encourage such reconsideration. *See supra* note 82.

97. *See* 72 Fed. Reg. 16,291, 16,305–06 (Apr. 4, 2007); *id.* at 16,296 ("[W]e tentatively believe that it may no longer be necessary to require that all irradiated food be labeled as such."); *see also infra* notes 100–05 and accompanying text (elaborating).

98. *See* 72 Fed. Reg. at 16,294 ("FDA has approved irradiation for a number of foods, . . . [but] only a small fraction of these foods are actually irradiated."). In preparing its preliminary regulatory impact analysis, the FDA assumed that no more than 5% of firms would choose to irradiate, "based on the generally observed very low rate of adoption of irradiation technology in food processing to date." *Id.* at 16,298; *see also id.* at 16,301 ("[I]t is possible that some manufacturers not currently using irradiation as a safety tool (because of the current labeling requirement) may opt to start using irradiation in order to enhance the safety of their products, if there is no material change in the product."). Contrast the agency's seemingly cavalier attitude on this score when issuing the current labeling rule more than 20 years earlier. *See* 51 Fed. Reg. 13,376, 13,389 (Apr. 18, 1986) ("[A]ny confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs, and the presence of a retail label statement should not deter the development of this technology."); *id.* at 13,395 ("FDA has no proper role as a promoter of a specific food additive or food process. The agency believes that the primary responsibility for such educational activities remains with industry in this instance."); *id.* at 13,396 ("The agency believes that the marketplace will determine whether irradiation of food is economically feasible.").

99. The outpouring of comments—presumably most of which expressed opposition—may well have dissuaded the agency. *Cf.* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-309R, FEDERAL OVERSIGHT OF FOOD IRRADIATION 5 (2010), *available at* http://www.gao.gov/assets/100/96545.pdf [hereinafter GAO 2010 REPORT] ("As of December 2009, FDA officials stated they had completed a summary of the more than 32,000 public comments on its proposed [labeling] changes . . . [and are] actively working to develop a final rule, but given FDA's competing priorities and limited resources, officials do not know when it will be completed."). In announcing a public hearing about the possibility of labeling transgenic salmon in the event of approval, the FDA did cite this still-pending proposal as authority for the proposition that it "cannot require labeling based on differences in the production process if the resulting products are not materially different due solely to the production process." 75 Fed. Reg. 52,602, 52,602 (Aug. 26, 2010); *see also* Andrew Pollack, *F.D.A. Hearing Focuses on the Labeling of Genetically Engineered Salmon*, N.Y. TIMES, Sept. 22, 2010, at B3.

directions. First, the proposal sought to limit the occasions when labels would have to reveal the fact that foods had undergone irradiation: only in those instances where the process caused a material change in the characteristics of a food would disclosure requirements attach.[100] Much like the agency's previously discussed policy for when it will demand labeling of GM foods, this approach turns on a case-by-case rather than blanket assessment of the need for disclosure.[101] Second, the proposal would have truncated the existing statement as simply "irradiated" (or some derivative term) to accompany the radura logo,[102] though this would now have to include a description of the nature of any resulting material changes.[103] Third, the proposal allowed for substitution with the term "pasteurized" upon the filing of a notification with the agency that demonstrated the irradiation process reached the requisite level of pathogen destruction,[104] and it provided for the possible substitution of

100. *See* 72 Fed. Reg. at 16,305 (proposed amendment to 21 C.F.R. § 179.26(c)(1)); *id.* at 16,295 ("FDA tentatively believes that when the irradiation causes a material change in the characteristics of the food, the consumer *needs to know* about this change, and not just the fact that the food has been irradiated." (emphasis added)); *id.* at 16,294 ("[I]n the absence of a material change, under the proposal, the fact that the food has been irradiated is not considered a material fact and, therefore, no logo or label statement would be needed."); *id.* ("FDA is proposing to require that only those irradiated foods in which irradiation causes a material change in a food's characteristics (e.g., organoleptic, nutritional, or functional properties) . . . bear the radura logo.").

101. *See id.* at 16,294 ("[A] blanket statement on when labeling would be required due to irradiation causing material changes cannot be made in advance for all products. Rather, the need for labeling must be determined on a case-by-case basis by appropriate testing of the food irradiated under specific conditions . . . ."); *id.* at 16,295 ("In recent years, FDA policies on the labeling of foods have focused on the results of the processing of the food rather than the processing itself. . . . [A]lthough foods that have been irradiated have been processed, the irradiation does not always result in a material change . . . ."). The agency offered an extended discussion to illustrate how irradiation to extend the shelf-life of some foods (e.g., delayed ripening in bananas) might qualify as material (e.g., for consumers interested in baking banana bread) but not for other foods (e.g., spices). *See id.* at 16,294. In any event, the FDA's earlier assumption that irradiation routinely introduced organoleptic (e.g., taste, smell, or texture) changes in food seemed to have become untenable. *See* Osterholm & Norgan, *supra* note 46, at 1900 ("Recent improvements in food irradiation techniques are expected to reduce or eliminate the effect of the process on sensory quality."); *see also id.* (explaining that irradiation does not produce toxins in—or reduce the nutritional quality of—foods).

102. *See* 72 Fed. Reg. at 16,305 (proposed amendment to 21 C.F.R. § 179.26(c)(1)).

103. *See id.*; *see also id.* at 16,295 ("The disclosure statement would describe the material change in the properties of the food and give consumers additional information that would enable them to make better informed decisions about whether to purchase an irradiated food."). Previously the FDA had simply invited sellers to include such elaboration. *See supra* note 79.

104. *See* 72 Fed. Reg. at 16,306 (proposed amendment to 21 C.F.R. § 179.26(c)(2)(ii)); *see also id.* at 16,292 ("Some comments suggested alternate wording, such as 'cold pasteurization,' or 'electronic pasteurization,' while other comments contended that these terms serve only to obscure information and confuse consumers."). A seller proposing to use this alternative language would have to notify the agency ahead

some other term upon agency approval of a petition making such a request.[105] Even if the NPRM is never finalized, companies apparently already can ask for variances of this sort.[106]

Suggestions for use of the term "pasteurization" (in tandem with or in lieu of irradiation), which the FDA originally had rejected in the mid-1960s,[107] point up an important historical parallel. When heat pasteurization of milk was first introduced more than a century ago, consumers did not warmly embrace it at first, but this processing technique became an undoubted public health success story (in no small part, of course, because over time many jurisdictions banned unpasteurized milk).[108] In contrast, no one has suggested that irradiation

of time (giving it 120 days to object) and supply data supporting the claim that irradiation would eliminate the most serious microorganisms. *See id.* at 16,294, 16,296. This standard reflects the statutory parameters for use of the term "pasteurized" added by Congress in 2002. *See* 21 U.S.C. § 343(h)(3) (2012).

105. *See* 72 Fed. Reg. at 16,305–06 (proposed amendment to 21 C.F.R. § 179.26(c)(2)(i)); *see also id.* at 16,296 (specifying what to submit).

106. In its preliminary response to the 2002 directive from Congress, the FDA had announced the availability of a guidance document describing the petition process that companies could use if they wanted to request alternative labeling of irradiated foods pending the completion of planned rulemaking on the question. *See* 67 Fed. Reg. 62,487 (Oct. 7, 2002); *see also* 51 Fed. Reg. 13,376, 13,389 (Apr. 18, 1986) ("[A] manufacturer who finds that the terms 'treated with radiation' or 'treated by irradiation' are misinterpreted by a significant number of consumers may petition FDA for approval of alternative language, e.g., 'freshness preserved by irradiation.'"). As of 2007, evidently no one had tried. *See* 72 Fed. Reg. at 16,293 ("To date, FDA has not received any petitions requesting the use of alternative labeling for irradiated foods."). It remains to be seen whether any companies will do so after the NPRM's endorsement of flexibility.

107. *See supra* notes 59–60 and accompanying text.

108. *See* Ronald F. Eustice & Christine M. Bruhn, *Consumer Acceptance and Marketing of Irradiated Foods*, *in* FOOD IRRADIATION RESEARCH AND TECHNOLOGY, *supra* note 46, at 173, 178 ("Pasteurization took nearly 70 years to be fully accepted in the United States, and the arguments against it were almost identical to those used today against food irradiation. . . . [T]he campaign against pasteurization . . . significantly delayed its introduction, with the effect that thousands of people suffered . . . or died."); James H. Steele, *History, Trends, and Extent of Pasteurization*, 217 J. AM. VETERINARY MED. ASS'N 175, 176 (2000) ("Pasteurization was not always readily accepted by consumers . . . . With so many unfavorable beliefs about the pasteurization of milk, one is astounded that the process was ever successfully introduced."); Jane Zhang et al., *Cloned Livestock Poised to Receive FDA Clearance*, WALL ST. J., Jan. 4, 2008, at B1 ("Consumers . . . have a long history of turning up their noses at technological innovations in food. It took years for consumers to accept pasteurized milk as safe."). Even today, however, some consumers want their milk raw, and fringe groups vociferously object to governmental interference with these unwise dietary choices. *See* Kimberly Kindy, *A Growing Thirst for Raw Milk*, WASH. POST, Apr. 5, 2014, at A1; Jessica Leving, *New Culture War: Raw Milk Fans vs. FDA, CDC*, USA TODAY, Oct. 16, 2009, at 3A; Kim Painter, *Raw-Milk Illnesses Often Go Unreported, Study Suggests*, USA TODAY, Dec. 12, 2013, at 3D ("Public health officials long have warned about the health risks. A previous CDC study found that raw milk was 150 times more likely than pasteurized milk to cause illness outbreaks."). *See generally* Damian C. Adams et al., *Déjà Moo: Is the Return to Public Sale of Raw Milk Udder Nonsense?*, 13 DRAKE J.

of certain foods become mandatory. More recently, after a widely publicized outbreak of foodborne illness associated with apple juice,[109] the FDA encouraged heat pasteurization of fruit juices by demanding that unpasteurized products carry an alarming "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."[110] Perhaps it should require a similar sort of statement in the labeling of any unirradiated foods that it has made eligible for irradiation to combat microbial contamination.[111]

Twenty years ago, the director of the U.S. Public Health Service lamented that "[t]he technology of food irradiation has languished too long already."[112] In a 2000 report, the General Accounting Office (GAO) found that only a tiny fraction (< 0.002 percent) of produce and poultry got irradiated.[113] One year later, a researcher from the Centers

AGRIC. L. 305, 306–19 (2008); Donna M. Byrne, *Raw Milk in Context*, 26 J. ENVTL. L. & LITIG. 109 (2011).

109. *See* Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 689–94 (1998) (detailing a serious *E. coli* 0157:H7 outbreak linked to Odwalla apple cider). Under FDA rules, the labels of foods that underwent thermal processing could not use the term "fresh," which counterproductively had discouraged the pasteurization of juices. *See id.* at 710–11.

110. 63 Fed. Reg. 37,030, 37,055–56 (July 8, 1998) (codified at 21 C.F.R. § 101.17(g)(2) (2013)). The FDA also subsequently amended its irradiation regulations to approve the use of UV treatment for juice products. *See* 65 Fed. Reg. 71,056, 71,057–58 (Nov. 29, 2000) (codified at 21 C.F.R. § 179.39(b) (2013)).

111. One commentator invoked the FDA's warning requirement for unpasteurized juice in the course of suggesting that conventional and organic corn products disclose the increased risk of contamination with a potentially hazardous mycotoxin that GM corn can avoid. *See* Drew L. Kershen, *Health and Food Safety: The Benefits of Bt-Corn*, 61 FOOD & DRUG L.J. 197, 223–24 (2006) ("[C]onsumers need to know that non-Bt-corns have an increased risk of fumonisin contamination . . . . [P]articularly with regard to corn grown organically, consumers may not associate fumonisin contamination with organic corn and may have a perception (incorrect) that organic corn is purer and healthier.").

112. Philip R. Lee, *Irradiation to Prevent Foodborne Illness*, 272 JAMA 261, 261 (1994); *see also* Randall Lutter, *Food Irradiation—The Neglected Solution to Food-Borne Illness*, 286 SCIENCE 2275, 2276 (1999); Michael R. Taylor, *Preparing America's Food Safety System for the Twenty-First Century: Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13, 26 (1997) ("Public understanding of the technology and confidence in its safety also can have profound effects, as evidenced by the failure of food irradiation to take hold despite its food safety benefits.").

113. *See* U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-00-217, FOOD IRRADIATION: AVAILABLE RESEARCH INDICATES THAT BENEFITS OUTWEIGH RISKS 11 tbl.1 (2000), *available at* http://www.gao.gov/assets/240/230554.pdf; *see also* Bruhn & Wood, *supra* note 87, at 251 ("Despite repeated endorsements and regulatory approval, irradiated foods are not widely available in the United States."). Similarly, the EU has done little to authorize particular uses of food irradiation, and, while some of its member states allow it on a limited basis, the process is rarely used anywhere in Europe. *See* Ignacio Carreño & Paolo R. Vergano, *Food Irradiation: The EU Regulatory Framework, Risk Assessment*

for Disease Control and Prevention (CDC) estimated that irradiating half of all "poultry, ground beef, pork, and processed meats . . . could prevent nearly 900,000 cases of infection, 8,500 hospitalizations, over 6,000 catastrophic illnesses, and 350 deaths each year."[114] Aside from the widespread use of irradiation for spices, which largely escape the labeling requirement as ingredients in processed foods,[115] the situation has not improved markedly in the interim.[116] The FDA's decision to

and International Trade Considerations, 2012 EUR. J. RISK REG. 373, 378–81; *see also id.* at 385–86 ("Irradiation has not been widely adopted in the EU due to an asserted negative public perception, the concerns expressed by some consumer groups, and the reluctance of many food producers."); Spencer Henson, *Demand-Side Constraints on the Introduction of New Food Technologies: The Case of Food Irradiation*, 20 FOOD POL'Y 111, 125 (1995) ("[D]espite considerable efforts to promote food irradiation over more than two decades, the majority of consumers remain ambivalent towards the process and consequently the market for irradiated products is undeveloped."); *supra* note 81 (noting EU labeling requirements).

114. Robert V. Tauxe, *Food Safety and Irradiation: Protecting the Public from Foodborne Infections*, 7 EMERGING INFECTIOUS DISEASES 516, 519 (2001); *see also* Osterholm & Norgan, *supra* note 46, at 1899 (adding that, because "many cases of foodborne illness are likely to be unreported and undetected, the actual reduction would probably be even greater"). *See generally* Gardiner Harris, *Food Safety Has Reached a Plateau, U.S. Finds*, N.Y. TIMES, Apr. 10, 2009, at A12 ("Roughly 76 million people in the United States suffer foodborne illnesses each year, 300,000 are hospitalized, and 5,000 die, according to C.D.C. estimates."); Betsy McKay, *Salmonella Cases Fall but Other Ills Don't*, WALL ST. J., Apr. 18, 2014, at A2 ("[T]he overall rate of foodborne illness is holding stubbornly steady despite new measures intended to curb it . . . .").

115. *See* Thayer, *supra* note 94, at 1811 ("Most spices are contaminated with 1 million or more bacteria per gram, so many commercial facilities irradiate spices. Unfortunately, irradiated foods are in limited supply in the United States, although our astronauts have been eating steaks sterilized with 45 kGy of gamma radiation since 1960."); Elena Conis, *Will Irradiation Be Back on the Table?; Some Experts Say the Process Could Be a Solution to Deadly Food-Borne Illnesses*, L.A. TIMES, June 19, 2011, at A22 ("The top use in the U.S. is to treat spices used by the food industry; 175 million pounds of spices—a third of the spices used in commercial production—are irradiated . . . ."). Untreated spices continue to pose a risk of salmonella transmission. *See* Gardiner Harris, *Farmers Change over Spices' Link to Food Ills*, N.Y. TIMES, Aug. 28, 2013, at A1 ("In a study of more than 20,000 food shipments, the [FDA] found that nearly 7 percent of spice lots were contaminated with salmonella, twice the average of all other imported foods.").

116. *See* 72 Fed. Reg. 16,291, 16,294, 16,297 (Apr. 4, 2007) (citing estimates from the 2000 GAO report, and noting that "spices, shell eggs, fruits and vegetables account for virtually all the food irradiation done in the United States"); GAO 2010 REPORT, *supra* note 99, at 3 ("Although no comprehensive information exists on the amount of food that is currently irradiated in the United States, several industry experts estimate that the amount of food irradiated has been relatively steady or slowly increasing since 2000."); Eustice & Bruhn, *supra* note 108, at 176 (citing estimates that "approximately 15–18 million pounds of irradiated ground beef and poultry were marketed in the United States in 2011" and that "30–35 million pounds of irradiated" produce are sold annually); Dennis G. Maki, *Don't Eat the Spinach—Controlling Foodborne Infectious Disease*, 355 NEW ENG. J. MED. 1952, 1955 (2006) ("Unfortunately, . . . because of intense opposition from antinuclear activists and other interest groups . . . irradiation of food as a public health measure has not yet achieved widespread acceptance."); *see also id.* (explaining

mandate routine disclosure surely deserves a share of the blame for this unfortunate state of affairs.[117]

III. CHARTING A SENSIBLE MIDDLE COURSE?

As the FDA has belatedly recognized, it should never have mandated routine disclosure for irradiated foods nearly half a century ago, but the agency seems unable to reverse course at this juncture. The lesson, however, may well help to explain its subsequent unwillingness to require similar labeling for genetically modified foods. Notwithstanding the agency's consistently expressed policy on GMOs, proponents of consumers' purported "right to know" continue to press their case. As an intermediate option, avenues other than labeling might satisfy demands for disclosure without posing the same danger of reflexive rejection of GM and irradiated foods at the point of purchase.[118]

that "the World Health Organization, CDC, FDA, USDA, American Medical Association, and European Commission Scientific Committee on Food" have endorsed irradiation); Dennis G. Maki, *Coming to Grips with Foodborne Infection—Peanut Butter, Peppers, and Nationwide Salmonella Outbreaks*, 360 NEW ENG. J. MED. 949, 953 (2009) ("[R]outine irradiation of the final commercial product in the case of poultry and hamburger, processed foods containing eggs or milk, and selected leafy and other vegetables eaten raw could greatly reduce the incidence of bacterial foodborne disease.").

117. *See* GAO 2010 REPORT, *supra* note 99, at 2 ("Some industry officials believe that the labeling requirements for irradiated food products suggest to consumers that these foods are less than safe and thus deter the purchase of such products."); *id.* at 5–6 (explaining that revocation of the FDA's requirement for routine disclosure would lead to greater use of irradiation in food); Osterholm & Norgan, *supra* note 46, at 1898 (noting reasons for the "[s]low acceptance of irradiation," including that "the term 'irradiation' is sometimes confusing or alarming to consumers because of its apparent, but nonexistent, association with radioactivity," and that "an anti-irradiation campaign has been conducted by certain groups because of their beliefs about food, nuclear power, and agricultural economics"); Brenda Lawson, Comment, *Foodborne Illness: The Cause and Effect of* E. Coli *0157:H7 Contamination of Our Food Supply*, 4 J. MED. & L. 71, 89–90 (1999); Conis, *supra* note 115, at A22 ("[B]ecause manufacturers have been reluctant to proclaim the treatment to consumers, irradiation hasn't been widely used."). *But cf.* Bruhn & Wood, *supra* note 87, at 251 (summarizing evidence of consumer willingness to purchase irradiated food when provided with fuller information about its safety and benefits).

118. *See* Emily Robertson, Note, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 177, 184 (2003) (recommending, instead of labeling that might unfairly stigmatize GM foods, the creation of a database accessible to interested consumers that provides disclosures concerning the presence of GMOs in listed food products); *cf.* Andrew Pollack, *Seeking Support, Biotech Food Companies Pledge Transparency*, N.Y. TIMES, July 29, 2013, at B3 (reporting that an industry group just launched www.GMOAnswers.com, which provides fairly generic information designed to reassure). The advent of social media as a tool for amplifying objections and organizing protests may, however, make even this strategy somewhat foolhardy. *See* Monica Eng, *Activists Taking Beefs Online: "Pink Slime" Battle Shows the Power of Social Media Drives*, CHI. TRIB., Mar. 29, 2012, at A1; Stephanie Strom, *Social Media as a Megaphone to Push Food Makers to Change*, N.Y. TIMES, Dec. 31, 2013, at B1.

Ultimately, it makes more sense to approach the labeling issue from the other side by allowing absence claims such as "GM free."[119] Wholly apart from practical problems of verifying their accuracy,[120] however, unadorned absence claims of this sort have the potential to mislead consumers unless appropriately qualified.[121] Perhaps the use of broader claims such as "organic" would signal to interested consumers that genetic engineering and irradiation have played no role in the production of a particular food,[122] though it would not help those buyers who favor

119. *See* MARCHANT ET AL., *supra* note 35, at 62–65; Beales, *supra* note 35, at 111–13, 117; Burk, *supra* note 30, at 315; Goldman, *supra* note 35, at 758–59; *id.* at 723 ("[T]o respond to national and international pressure to label GM foods, but at the same time promote the development and use of this beneficial technology, a voluntary labeling program could be instituted."); Matthew Franken, Comment, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 175–80 (2000); Galant, *supra* note 35, at 161–62. Along similar lines, the FDA recently issued a rule governing voluntary "gluten-free" claims in food labeling, which expressly preempted state laws on that issue. *See* 78 Fed. Reg. 47,154 (Aug. 5, 2013) (to be codified at 21 C.F.R. § 101.91).

120. *See* Patricia Callahan, *Some Ingredients Are Genetically Modified Despite Labels' Claims*, WALL ST. J., Apr. 5, 2001, at A1; William Neuman, *Biotech-Free, Mostly*, N.Y. TIMES, Aug. 29, 2009, at B1; Stephanie Strom, *Seeking Food Ingredients That Aren't Gene-Altered*, N.Y. TIMES, May 27, 2013, at B1; *see also* Stephanie Strom, *U.S. Approves a Label for Meat from Animals Fed a Diet Free of Gene-Modified Products*, N.Y. TIMES, June 21, 2013, at B8 (reporting that the USDA for the first time authorized such an absence claim). The producer of an iconic breakfast cereal made primarily from oats—a crop that has not been genetically modified to date—recently altered the source of a few of its other components so that the company can claim "not made with genetically modified ingredients" on the product's label. *See* Annie Gasparro, *Some Cheerios Won't Have GMOs*, WALL ST. J., Jan. 3, 2014, at B1 ("General Mills Inc. has started producing Cheerios free of genetically modified content, making the 73-year-old breakfast cereal one of the highest-profile brands to change in the face of growing complaints over such ingredients from activist groups and some consumers. . . . [T]he company notes that they could contain trace amounts due to contamination in shipping or manufacturing.").

121. *See* 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001) ("[T]hese terms would be misleading if they imply that the food is superior because the food is not bioengineered."); *see also* 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994) ("[E]ven such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. . . . Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows."); *cf.* Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 635–50 (6th Cir. 2010) (invalidating on First Amendment grounds one state's prohibition on "rBST-free" labeling, but affirming in part a disclaimer requirement); Andrew Martin, *Fighting on a Battlefield the Size of a Milk Label*, N.Y. TIMES, Mar. 9, 2008, at BU7 (discussing the continued debate over rBST and the increased use of absence labeling claims).

122. *See* 66 Fed. Reg. at 4842 (noting, in connection with the FDA's draft guidance, that "organic products available today would be able to bear a voluntary labeling statement that the food was not developed using bioengineering"); A. Bryan Endres, *An Awkward Adolescence in the Organics Industry: Coming to Terms with Big Organics and Other Legal Challenges for the Industry's Next Ten Years*, 12 DRAKE J. AGRIC. L. 17, 41–42 (2007) ("At least some of the increased demand for organic products in the past

one of these technologies while fearing the other. After initially proposing to allow genetic engineering and irradiation for "organic" foods,[123] the final USDA regulations clearly exclude both practices,[124] even the use of irradiated ingredients in processed foods (or more distant inputs such as irradiated or GM animal feeds) that the FDA's retail disclosure requirements exempt. The FDA has not yet issued regulations to restrict the use of the term "natural," though it too could exclude both of these technologies from foods so labeled even if that might prompt some consumers to forego the benefits of "unnatural" production processes.[125]

If some left-wing activists and outspoken celebrities want to protest modernity in agriculture, let them and their followers pay a premium.[126]

decade is in response to consumer avoidance of foods produced through genetic engineering."); Michelle T. Friedland, *You Call* That *Organic?—The USDA's Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 403–04, 408–09 (2005); *cf. id.* at 396–403, 411–13, 423–27, 438–39 (explaining that this represents something of a misconception insofar as unintentional contamination (e.g., pollen drift from GE crops) would not prevent "organic" certification under the USDA's rules); Dan Glickman & Kathleen Merrigan, Op-Ed., *GMO-Free, at Last*, L.A. TIMES, Dec. 19, 2013, at A27 (conceding as much). In the EU, GMOs accidentally present in food would not require disclosure so long as they accounted for less than 1% of the finished product. *See supra* note 26.

123. *See* 62 Fed. Reg. 65,850, 65,875, 65,884 (Dec. 16, 1997). *See generally* Organic Foods Production Act of 1990, Pub. L. No. 101-624, § 2101, 104 Stat. 3359, 3935 (codified as amended at 7 U.S.C. §§ 6501–6522 (2012)); Donald T. Hornstein, *The Road Also Taken: Lessons from Organic Agriculture for Market- and Risk-Based Regulation*, 56 DUKE L.J. 1541, 1549–54 (2007).

124. *See* 65 Fed. Reg. 80,548, 80,637 (Dec. 21, 2000) (codified as amended at 7 C.F.R. §§ 205.2 (definition of "Excluded methods"), 205.105(e)&(f), 205.301(f) (2013)); *see also* 65 Fed. Reg. 13,512, 13,512–14 (Mar. 13, 2000) (explaining that it had received an avalanche of negative feedback on this question: "in the largest public response to a proposed rule in USDA history," 275,603 persons commented on the original proposal, and essentially all of them opposed the use of either one of these technologies in organic foods); *id.* at 13,534–35, 13,549, 13,587 (elaborating).

125. *See* Nicole E. Negowetti, *A National "Natural" Standard for Food Labeling*, 65 ME. L. REV. 581, 600–01 (2013); *see also id.* at 597–98 (discussing private lawsuits that have challenged companies making "natural" claims for foods containing GMOs); Cha, *supra* note 30, at A3 (same); *cf.* April L. Farris, *The "Natural" Aversion: The FDA's Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403, 421 (2010) ("[T]he USDA, in soliciting comments on whether to continue to include processing in its policy definition, is having great difficulty determining whether to discourage the use of safety-increasing processes by precluding them from being applied to 'natural' products."); Erik Benny, Note, *"Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" That Includes Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1521–26 (2012) (arguing that the agency should permit "natural" claims for GM foods).

126. *See* Andrew Martin & Kim Severson, *Sticker Shock in the Organic Aisles*, N.Y. TIMES, Apr. 18, 2008, at C1 ("Organic food is typically 20 percent to 100 percent more expensive than a conventional counterpart . . . ."); Kim Severson, *An Organic Cash Cow*, N.Y. TIMES, Nov. 9, 2005, at F1; *see also* Beales, *supra* note 35, at 112–13 ("With voluntary labeling, consumers who value the information are the ones who must pay the

For those of us without the intestinal fortitude or spare cash for this kind of "paleo" diet,[127] let us enjoy the fruits of scientific advances and stop spooking unsophisticated consumers and uneasy retailers.[128] Demands for disclosure premised on a "right to know" of things that an expert regulatory agency has judged to be immaterial represent nothing more than efforts to stifle feared technologies by stigmatizing the resulting products in the marketplace.[129] The failure to make broader use of food

costs associated with it; those who do not care are not burdened with the cost of information that is of no value to them."). At the extreme, they could always move to Europe.

127. *See* Karen Ann Cullotta, *Paleo Diet Tries to Mimic Caveman Meals*, CHI. TRIB., Mar. 6, 2013, at C2; Alison George, *Cave-Man Diet Is Flawed, Evolutionary Biologist Says*, WASH. POST, Apr. 23, 2013, at E5; *see also* John R. Block, Op-Ed., *A Reality Check for Organic Food Dreamers*, WALL ST. J., Dec. 24, 2012, at A11 ("Indulging in a romanticized image of the farming industry stands in the way of progress."); Trevor Butterworth, *Fad Food Nation*, WALL ST. J., July 16, 2013, at A13 (reviewing MIKE GIBNEY, SOMETHING TO CHEW ON (2012)). For the record, I say this having spent the last three decades adhering to a strict vegetarian (though not vegan) diet.

128. *Cf.* Drew L. Kershen, *The Risks of Going Non-GMO*, 53 OKLA. L. REV. 631, 636 (2000) ("Food companies face a tremendous dilemma when threatened with consumer boycotts about genetically improved foods."); *id.* at 646 ("In many ways, the risk of scientific ignorance related to irradiation is similar to the risk of scientific ignorance as applied to agricultural biotechnology."); Goldman, *supra* note 35, at 722 (explaining that, by virtue of the need to segregate crops under a mandatory disclosure system, "labeling may amount to a tax on manufacturers, distributors, and retailers who use a new technology, and it may also inhibit future research and development in this promising new area"); Amy Harmon, *A Race to Save the Orange by Altering Its DNA*, N.Y. TIMES, July 28, 2013, at A1 (Eating GMOs "still spooks many people. . . . [H]ostility toward the technology, long ingrained in Europe, has deepened recently among Americans as organic food advocates, environmentalists and others have made opposition to it a pillar of a growing movement for healthier and ethical food choices."); Marc van Montagu, Op-Ed., *The Irrational Fear of GM Food*, WALL ST. J., Oct. 23, 2013, at A15.

129. *See* MARCHANT ET AL., *supra* note 35, at 32–36; *id.* at 33 (calling it "a scarlet letter"); *id.* at 4 ("[C]ontrary to the rhetoric of promoting consumer choice, GM labeling is actually being advocated as part of a strategy to block the availability of GM products as an option consumers may choose."); Kysar, *supra* note 39, at 630 n.452 ("[T]he biotech industry may correctly fear that mandatory labeling would spell the end of GM food products."); Editorial, *Fight the GM Food Scare: Mandatory Labels for Genetically Modified Foods Are a Bad Idea*, SCI. AM., Sept. 2013, at 10, 10 ("Such debates are about so much more than slapping ostensibly simple labels on our food to satisfy a segment of American consumers. Ultimately, we are deciding whether we will continue to develop an immensely beneficial technology or shun it based on unfounded fears."); Harmon & Pollack, *supra* note 29, at A1 ("Rather than label food with what consumers might regard as a skull and crossbones . . . food producers may ultimately switch to ingredients that are not genetically modified, as they did in Europe."); Andrew Pollack, *Labeling Genetically Altered Food Is Thorny Issue*, N.Y. TIMES, Sept. 26, 2000, at Al ("Biotechnology and food industry executives say the critics want labeling because it will scare people away."); *see also* HENRY I. MILLER & GREGORY CONKO, THE FRANKENFOOD MYTH: HOW PROTEST AND POLITICS THREATEN THE BIOTECH REVOLUTION (2004) (debunking the unfounded horror stories spread by activists opposed to GE crops); Bruce Alberts et al., Editorial, *Standing up for GMOs*, 341 SCIENCE 1320, 1320 (2013) ("New technologies often evoke rumors of hazard. These generally fade with time when, as in this case, no

irradiation represents a travesty, one that so far has not really affected genetic engineering in this country, even though the latter techniques do not offer nearly the same promise for improving the safety of foods.[130] As it has done so far with GMOs, the FDA should reserve labeling requirements for genuine hazards. Regulatory choices about mandatory disclosures in labeling—and the entirely predictable responses of the marketplace—explain the very different trajectories of these two innovative food production technologies.

real hazards emerge. But the anti-GMO fever still burns brightly, fanned by electronic gossip and well-organized fear-mongering that profits some individuals and organizations."); Editorial, *Food & Hysteria*, WALL ST. J., Apr. 27, 1994, at A12 (criticizing the propaganda campaigns of anti-irradiation activists); Amy Harmon, *Golden Rice: Lifesaver?*, N.Y. TIMES, Aug. 25, 2013, at SR1 ("On a petition supporting Golden Rice circulated among scientists and signed by several thousand, many vented a simmering frustration with activist organizations like Greenpeace, which they see as playing on misplaced fears of genetic engineering in both the developing and the developed worlds.").

130. GMOs may offer food safety benefits. *See* Kershen, *supra* note 111, at 204–06 (explaining that GM corn suffers from less contamination with a potentially hazardous mycotoxin); McGarity, *supra* note 36, at 415; Andrew Pollack, *Gene Jugglers Take to Fields for Food Allergy Vanishing Act*, N.Y. TIMES, Oct. 15, 2002, at F2; *see also* Andrew Pollack, *Genetically Altered Salmon Set to Move Closer to Dinner Table*, N.Y. TIMES, June 26, 2010, at A1 (reporting that "scientists [are] developing other genetically engineered animals, like cattle resistant to mad cow disease or pigs that could supply healthier bacon"). Researchers also have engineered plants to improve the nutritional content of food, but to this point commercialized GMO crops offer primarily agronomic advantages. *See* Noah, *Managing Biotechnology's [R]evolution*, *supra* note 2, ¶ 36 & nn.129–30; Marc Kaufman, *Extra-Nutritious Bioengineered Foods Still Years Away*, WASH. POST, Nov. 3, 2008, at A12; *see also* David Rotman, *Why We Will Need Genetically Modified Foods*, MIT TECH. REV., Jan.-Feb. 2014, at 24.