LACK OF INTEREST IN CONSUMER INTERESTS: FDA'S NARROW PERSPECTIVE ON FOOD LABELING AND LABEL STATEMENTS UNDERMINES A CENTURY OF AGENCY LEADERSHIP

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INTRODUCTION

The idea that federal administrative agencies are disconnected from the public is not new. Given the confines of the Administrative Procedure Act (APA)[1] and agency discretion to create the procedures that an agency uses to develop substantive policies and regulations, federal courts offer the public little recourse for more public participation and recognition of diverse views.[2] Courts cannot declare an "unwise" policy illegal, but they may remand the decision to the agency to provide further justification.[3] As noted by Professor Sax in 1970, "The very fact that sensitive courts perceive a need to reorient administrative conduct in this fashion suggests how insulated such agencies may be from the relevant constituencies."[4]

This insulation from the public is impacting the Food and Drug Administration's (FDA) food labeling and other food policies. This isolation and lack of public confidence in the agency may lead to troubling results. More than eighty percent of Americans feel confident that the food available at most grocery stores is safe to eat, but only fifteen

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[1] 5 U.S.C. § 500 *et seq*. (2011).

[2] *See*, *e.g*., Vermont Yankee Nuclear Power Corp. v. Nat. Resources Def. Council, 435 U.S. 519 (1978) (courts cannot impose procedural requirements on agencies beyond those set in statute); NLRB v. Bell Aerospace Co., 416 U.S. 267, 291-94 (1974) (agencies can make policy through adjudication or rulemaking).

[3] Joseph Sax, *The Public Trust Doctrine in Natural Resources Law: Effective Judicial Intervention*, 68 MICH. L. REV. 471, 558 (1970).

[4] *Id.*

percent have a "great deal" of confidence in the federal government to ensure its safety.[5] This lack of faith in the agency, combined with Americans' skepticism towards large corporations,[6] causes consumers to seek out other sources of verification for the integrity of the food they eat. One of these other sources is independent, third-party food labels, which, in addition to informing consumers of the food content within a package, provide information about how the food was grown, raised or caught; what the animals were fed; and, the environmental impacts of the agricultural methods used. Consumers have also turned to the courts to fill the regulatory gaps in the FDA's oversight. Despite the relatively narrow ground that remains between the interaction of state and federal food labeling laws to maintain private food labeling litigation, there are currently hundreds of active food labeling class action suits.[7] State governments have also taken up the task of addressing consumer concerns, particularly with content labeling of genetically engineered plants.

Given these trends, the FDA should change the procedures used to carry out its functions in order to ensure its control and relative national consistency in food labeling. This does not mean altering existing FDA policies to mirror often under or mis-informed popular opinion. Instead, the agency must utilize its knowledge and expertise to formulate good policy. In doing so, the agency must recognize that the public's existing confusion of food labels and label statements undermines public confidence in the FDA, which in turn diminishes the public's acceptance of the agency's directives.[8] Therefore, transparency and public participation will be key to its policy success. One of President Obama's first actions was his statement that he would work together with the head of federal agencies "to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government."[9]

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[5] In a poll dated July 10-13, 2008, an additional 56% of Americans had "a fair amount" of confidence in the federal government to ensure the safety of the U.S. food supply, though 29% had "not much" or "none at all." *Gallup Historical Trends: Nutrition and Food*, GALLUP, http://www.gallup.com/poll/6424/nutrition-food.aspx (last visited Jan. 5, 2016).

[6] *See*, *e.g.*, *Gallup Historical Trends: Confidence in Institutions*, GALLUP, http://www.gallup.com/poll/1597/confidence-institutions.aspx (last visited Jan. 5, 2016) (poll dated June 5-8, 2014, showed 21% of respondents with a "great deal" or "quite a lot" of confidence in "big business").

[7] *See*, *e.g.*, Glenn G. Lammi, *FDA Action Should Take the Juice Out of Some Food Labeling Class Actions*, FORBES (Mar. 4, 2014, 2:08 PM), http://www.forbes.com/sites/wlf/2014/03/04/fda-action-should-take-the-juice-out-of-some-food-labeling-class-actions/ (fifty-two pending labeling suits involving "evaporated cane juice" in Jan. 2014); Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, BLOOMBERG BUSINESSWEEK, (Aug. 22, 2013), http://www.businessweek.com/articles/2013-08-22/californias-food-court-where-lawyers-never-go-hungry (thirty-six food labeling suits filed in the Northern District of California between January 2012 and August 2013).

[8] *See*, *e.g.*, Tom R. Tyler & Hulda Thorisdottir, *A Psychological Perspective on Compensation for Harm: Examining the September 11th Victim Compensation Fund*, 53 DEPAUL L. REV. 355, 363 (2003) ("People are more willing to believe that poor management, or even negligence, has occurred when they lack trust in . . . the authorities with whom they are dealing.").

[9] Transparency and Open Government, 74 Fed. Reg. 4685 (Jan. 21, 2009). Many have questioned the Obama Administration's commitment to this promise. *See*, *e.g.*, Josh Gerstein, *President Obama's Muddy*

Part I of this paper provides background on labeling and other public concerns about food where there has been separation in the public's understanding of FDA policies, the FDA has authority to address the public's desire for information but has chosen not to do so, or both. This divergence has led consumers to seek alternatives to augment the information gap. Some of those alternatives include private labeling, food mislabeling litigation, and state legislation and referenda. The relative strengths and weakness of these alternatives is also discussed. Part II investigates conditions that may have led to FDA policies deviating from public expectations. The FDA has historically been held in high regard by courts and the public, making significant contributions to the protection of Americans' health and welfare. However, something has gone awry, with increasing statutory duties, lack of congressional guidance or fiscal support, and agency conceit likely playing a role. These characteristics may merely be representative of modern federal agencies, but the FDA's isolation is significant due to its consumer protection mandates and frequency with which its policies affect the public. Finally, Part III offers policy and rulemaking changes for the FDA to improve public engagement. Enhanced public participation serves to empower and inform the public while educating the FDA about how its policies could be more relatable to the public.

I. THE FDA AND PUBLIC DETACHMENT: MANY CONSUMER ISSUES AND ATTEMPTS FOR ALTERNATIVE CLARITY

When deciding what to eat, Americans consider the nutritional value, ingredients, environmental sustainability, and, perhaps most of all, the safety of their food.[10] Confidence in the U.S. food supply, however, has been eroding, with less than half of Americans believing the government provides accurate information about food safety.[11] Conflicting information, uncertainty about food production, and not knowing who to trust affects Americans' confidence in food safety,[12] despite a thirty-seven percent *decline* in estimated foodborne illness over the last decade.[13] Public trust in the

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Transparency Record, POLITICO (Mar. 5, 2012, 4:52 AM), http://www.politico.com/news/stories/0312/73606.html; Jennifer LaFleur, *Has Obama Kept His Open-Government Pledge?*, PROPUBLICA (Feb. 11, 2013, 7:00 AM), http://www.propublica.org/article/has-obama-kept-his-open-government-pledge; Paul D. Thacker, *Where the Sun Don't Shine,* SLATE, (Mar. 12, 2013), http://www.slate.com/articles/news_and_politics/politics/2013/03/barack_obama_promised_transparency_the_white_house_is_as_opaque_secretive.html.

[10] *See generally* INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION (IFIC), 2014 FOOD AND HEALTH SURVEY (2014).

[11] *Id.* at 27, 72, 74 (only 14% "strongly agreed" that the FDA is effective at ensuring food safety).

[12] *Id.* at 74 (poll respondents agreed that conflicting information (77%), uncertainty about how food is produced (72%), and not knowing what sources to trust (59%) caused concerns with food safety).

[13] CTR. FOR DISEASE CONTROL (CDC), CDC ESTIMATES OF FOODBORNE ILLNESS IN THE UNITED STATES: DATA AND METHODOLOGICAL DIFFERENCES, 2011 AND 1999, (Jan. 8, 2014) (decrease from 76 million to 47.8 million).

government has been steadily declining since the 1960s[14] and the Food Program is a very visible program, accounting for about one-fifth of the FDA's budget,[15] making it difficult to assign too much liability for these general trends.[16] The FDA was historically a popular agency, maintaining favorable ratings with three-quarters of the country from 1984 through 1997.[17] Since 1997, however, the FDA has experienced a steep decline in popularity, down to fifty-eight percent favorable in 2010 and thirty-seven percent in 2014.[18]

A. Examples of Issues of Public Concern that Fail to Align with FDA Policies

There are likely a number of reasons for the dropping confidence. Also, there are numerous issues of public concern this paper could cover, including Bisphenol A (BPA) in food packaging and containers,[19] artificial food colorings and hyperactivity and behavior changes in some children,[20] milk from cows treated with the synthetic growth hormone recombinant Bovine Somatotropin (rBST),[21] food allergen labels,[22] and

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[14] *See* WILLIAM A. GALSTON & ELAINE C. KAMARCK, THE THIRD WAY MIDDLE CLASS PROGRAM: CHANGE YOU CAN BELIEVE IN NEEDS A GOVERNMENT YOU CAN TRUST 4-5 Tbl. 1 (2008), http://www.uvm.edu/~dguber/POLS293/articles/galston.pdf (tracking decline in trust in government, 1958-2008).

[15] *See generally* U.S. FOOD & DRUG ADMIN. (FDA), OPERATING PLAN FOR FY 2014 1-3 (last updated Mar. 7, 2014),http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM388301.pdf. My calculations are based on FY 2013 & FY 2014 of $4.0 billion and $4.4 billion; the Food Program is about one-third of FDA's discretionary budget authorized by Congress.

[16] *See* David C. Vladeck, *The FDA and Deference Lost: A Self-Inflicted Wound or the Product of A Wounded Agency? A Response to Professor O'Reilly*, 93 CORNELL L. REV. 981, 995 (2008) (politicization of scientific decisions and new drug approval regulatory failures during George W. Bush Administration hurt FDA's reputation).

[17] PEW RESEARCH, THE PEOPLE AND THEIR GOVERNMENT: DISTRUST, DISCONTENT, ANGER AND PARTISAN RANCOR 2, 124 (2010).

[18] *Id.* at 2; *Poll: Evaluating Government Agencies and American Institutions*, CBS NEWS (Oct. 17, 2014, 7:00 AM), https://www.scribd.com/doc/243332819/Oct14d-govt-institutions-CTM (FDA rated seventh of nine agencies in poll; 47% believed FDA doing "excellent" or "good" job).

[19] *Update on Bisphenol A (BPA) for Use in Food Contact Applications,* FDA, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm (last updated Jul. 31, 2014).

[20] *See*, *e.g.*, FDA, BACKGROUND DOCUMENT FOR THE FOOD ADVISORY COMMITTEE: CERTIFIED COLOR ADDITIVES IN FOOD AND POSSIBLE ASSOCIATION WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN (Mar. 30-31, 2011), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM248549.pdf.

[21] *See Bovine Somatotropin (BST)*, FDA, http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055435.htm (last updated Jul. 28, 2014).

[22] *See, e.g.*, *Food Allergens*, FDA, http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm (last updated Oct. 23, 2014).

modification of the recognizable nutrition labels,[23] to name but a few. However, this paper highlights topics that appear to have a strong public position, which may or may not have a scientific consensus, but current FDA policies do not meet consumer expectations, including: (1) food biotechnology, (2) food irradiation, (3) antibiotic use in animal meat production, and (4) sustainability and "natural" food claims.

1. Food Biotechnology (a/k/a Genetically Engineered Foods or GMOs)

Nothing epitomizes the melding of modern science, food, and public perceptions more than biotechnology—also known as genetic engineering (GE), genetically modified organisms (GMOs), and recombinant Deoxyribonucleic Acid (rDNA) technology. Unlike traditional plant breeding, where controlled cross pollination is used to pass the most desired genetic traits to the next generation of plants, biotechnology is a type of genetic modification that involves making intentional, targeted changes in a plant's gene sequence to achieve a specific result through the use of recombinant deoxyribonucleic acid (rDNA) technology.[24] Although the first GE food crops for human consumption—insect resistant corn and cotton—were planted in the U.S. in 1996,[25] the rapid proliferation of GE crops since has been staggering. From 1997 to 2014, biotech soybeans increased from seventeen percent of planted soybean acreage to ninety-four percent, and biotech corn from eight percent to ninety-three percent of corn acreage.[26] By July 2015, the FDA had approved 168 varieties of GE plants for use as food crops.[27]

While there has been no documented negative health effects for people or animals eating GE crops, potential health concerns center around the production of new or increased levels of naturally occurring allergens or toxins in crops, though these can occur with traditional plant breeding as well.[28] In addition, there are environmental concerns with the use of GE crops, including the potential production of toxins that kill or harm non-target insects, birds or other organisms; the unintended spread of herbicide-resistant plants; cross-mating with wild relatives of GE crop producing super

[23] Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11,880 (Mar. 3, 2014) (to be codified at 21 C.F.R. pt. 101).

[24] INST. OF MED. AND NAT'L RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 16-18 (2004).

[25] U.S. DEP'T OF AGRIC. (USDA), ECON. RES. SERV. (ERS), RECENT TRENDS IN GE ADOPTION, http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx (last updated July 9, 2015).

[26] *Id.*

[27] *Biotechnology Consultations on Food from GE Plant Varieties*, FDA, http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon (last updated July 19, 2015).

[28] *See, e.g.*, *Interest, Straight Talk on Genetically Engineered Foods: Answers to Frequently Asked Questions*, CTR. FOR SCI. IN THE PUB. 9 (2015), https://cspinet.org/new/pdf/biotech-faq.pdf.

weeds; and, the development of pesticide resistant invertebrates.[29] Again, these risks "are the same in kind as those . . . organisms modified by other methods."[30]

While many Americans are undoubtedly unaware that they are eating GE foods, public awareness about food biotechnology is increasing.[31] Despite, or because, of this awareness, consumers have become less favorable towards the use of biotechnology in food over the past six years.[32] In 2013, only twenty-one percent of Americans believed GE foods were safe to eat, compared to the thirty-five percent who believed they were dangerous to eat and bad for the environment.[33] One survey in 2014 showed that seventy-two percent of consumers say it is important to avoid GMOs when shopping.[34] Moreover, in various polls between 2001 and 2013, at least eighty-two percent and as many as ninety-six percent of Americans believed foods containing GE plants should be labeled as such.[35]

The FDA's approach to biotechnology does not synch with these public perceptions. FDA's policy focuses on the nutritional characteristics and safety of the food product rather than the use of biotechnology in the crops.[36] The FDA has stated that there is "no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[37] The FDA allows voluntary labeling of food products indicating the presence or absence of GE ingredients, but this guidance provides warnings against the use of language such as "GMO-free" because it may be misleading,[38] thus violating the FDCA.[39] The

[29] *Id.* at 11-14; AMERICAN MED. ASS'N (AMA), REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH, LABELING OF BIOENGINEERED FOODS (RESOLUTIONS 508 AND 509-A-11) (2012), http://factsaboutgmos.org/sites/default/files/AMA%20Report.pdf.

[30] AMA, *supra* note 29, at 8.

[31] *See, e.g.*, INT'L FOOD INFO. COUNCIL, CONSUMER PERCEPTIONS OF FOOD TECHNOLOGY SURVEY 1, 15 (May 2014),http://www.foodinsight.org/sites/default/files/FINAL%20Full%20Report_IFIC%202014%20Food%20Tech%20Survey.pdf.

[32] *Id.* at 18.

[33] Emily Swanson, *GMO Poll Finds Huge Majority Say Foods Should Be Labeled*, HUFFINGTON POST (Jun. 11, 2013, 5:50 PM), http://www.huffingtonpost.com/2013/03/04/gmo-poll_n_2807595.html.

[34] CONSUMER REP., FOOD SAFETY AND SUSTAINABILITY CTR., REPORT ON GMOS IN CORN AND SOY 1 (Oct. 2014), http://www.greenerchoices.org/pdf/CR_FSASC_GMO_Final_Report_10062014.pdf.

[35] *Id.* (92% in favor of GE labeling); CTR. FOR FOOD SAFETY, *U.S. Polls on GE Food Labeling*, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling# (last visited Jan. 5, 2016) (7 polls on the topic between June 19, 2001 and July 27, 2013, showing 93%-96% in support of labeling).

[36] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984-85 (May 29, 1992).

[37] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4,839 (Jan. 18, 2001).

[38] *Id.*

American Medical Association (AMA) supports this policy, stating "there is no scientific justification for special labeling of gene bioengineered foods and that voluntary labeling is without value unless it is accompanied by focused consumer education."[40]

Statements analogous to the following are common: "There is broad scientific consensus that genetically engineered crops currently on the market are safe to eat. After fourteen years of cultivation and a cumulative total of two billion acres planted, no adverse health or environmental effects have resulted from commercialization of genetically engineered crops."[41] However, "it is worth mentioning that most of the studies demonstrating that GM foods are as nutritional and safe as those obtained by conventional breeding, have been performed by biotechnology companies or associates, which are also responsible for commercializing these GM plants," and "the number of studies specifically focused on safety assessment of GM plants is limited."[42] Moreover, this 2010 review of GMO scientific literature noted that independent studies have increased since 2006 and there is now "equilibrium" between the numbers of peer-reviewed studies concluding GM foods are safe as those raising "serious concerns."[43]

In addition, environmental effects have been documented, most obviously as related to secondary effects of increased GMO crops. Though it may have initially displaced the use of more toxic herbicides, "[g]lyphosate has been the most heavily used pesticide in the United States since 2001, due in part to the popularity of [herbicide tolerant GE (HT)] crops and the steady decline in its price following the expiration of glyphosate's patent."[44] Between 1997 and 2012, application of glyphosate to U.S. corn and soybean crops increased ten-fold, from approximately 16.3 million to more than 173 million pounds.[45] Prior to 1998, there were no known weed plants resistant to glyphosate in the United States, but there are now 137 populations of fourteen different weed species in

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[39] 21 U.S.C. 343(a)(1) (2010) (food shall be deemed misbranded if "its labeling is false or misleading in any particular.").

[40] AMA, *supra* note 29, at 8.

[41] Louis Z.G. Touyz, *Genetically Modified Foods, Cancer, and Diet: Myths and Reality*, 20 CURRENT ONCOLOGY e59, e60 (2013) (quoting *Pamela Ronald, Genetically Engineered Crops—What, How and Why*, SCI. AM. GUEST BLOG (Aug. 11, 2011), http://blogs.scientificamerican.com/guest-blog/2011/08/11/genetically-engineered-crops/).

[42] José L. Domingo and Jordi Giné Bordonaba*, A Literature Review on the Safety Assessment of Genetically Modified Plants,* 37 ENVT. INT'L 734, 741 (May 2011).

[43] *Id.*

[44] JORGE FERNANDEZ-CORNEJO ET AL., GENETICALLY ENGINEERED CROPS IN THE UNITED STATES 31 (Feb. 2014), http://www.ers.usda.gov/media/1282246/err162.pdf

[45] *Nat. Agric. Stat. Serv.: Quick Stats Database*, USDA, http://quickstats.nass.usda.gov ("Select Commodity" input: "Survey", "Environmental", "Corn & Soybean", "Application", "Measured in Lb (Glyphosate)"; then "Select Location" input: "Regional : Multi-State"; then "Select Time" inputs: 1997-2012; then "Get Data").

thirty-three states resistant to glyphosate.[46] "HT adoption likely reduced herbicide use initially, but herbicide resistance among weed populations may have induced farmers to raise application rates in recent years, thus offsetting some of the economic and environmental advantages of HT corn adoption regarding herbicide use."[47] More toxic herbicides are needed to eradicate glyphosate-resistant weeds. The application of herbicides containing 2,4-D to corn and soybean crops declined nearly fifty percent between 1998 and 2002, but more than tripled since, up to 9 million pounds in 2012.[48] The U.S. Department of Agriculture (USDA) approved Dow's petition for unregulated use of 2,4-D-resistant corn and soybeans in September 2014.[49]

2. Irradiated Foods

Irradiated foods, or the application of ionizing radiation—in the form of gamma ray, x-rays, or electron beams—to food is another issue of consumer interest.[50] Irradiation is used to eliminate foodborne illness-causing pathogens, control insects, extend shelf-life, inhibit sprouting, and delay ripening, and the FDA has approved many types of food for treatment by irradiation, including meat, shell eggs, sprout seeds, and fresh fruits and vegetables.[51] Potential health risks observed in animals fed food treated with high levels of irradiation include cancer, premature death, reproductive problems, mutations, and stunted growth.[52] In addition, one study measuring concentrations of sixty-five chemical compounds in irradiated meat identified fifty-five chemicals, including known carcinogens, unique to all food, unique to beef, or that grew in concentration due to irradiation.[53] The FDA acknowledges that irradiation can also diminish the nutritional value of food by reducing some vitamin levels—just not the important vitamins or very

[46] Ian Heap, *The Int'l Survey of Herbicide Resistant Weeds: Weeds Resistant to the Herbicide Glyphosate*, WEED SCI., http://www.weedscience.org/summary/ResistbyActive.aspx (last visited Nov. 16, 2015).

[47] JORGE FERNANDEZ-CORNEJO ET AL., *supra* note 44, at 31.

[48] USDA, *supra* note 45 ("Select Commodity" input: "Survey", "Environmental", "Corn & Soybean", "Application", "Measured in Lb (2,4-D)"; then "Select Location" input: "Regional: Multi-State"; then "Select Time" inputs: 1997-2012; then "Get Data").

[49] *See* USDA, ANIMAL & PLANT HEALTH INSPECTION SERV. (APHIS), RECORD OF DECISION, DOW AGROSCIENCES PETITIONS (09-233-01P, 09-349-01P) FOR DETERMINATION OF NONREGULATED STATUS FOR 2,4-D RESISTANT CORN AND SOYBEAN VARIETIES (Sept. 18, 2014).

[50] FDA, FOOD IRRADIATION: WHAT YOU NEED TO KNOW 1 (2011) http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM262295.pdf.

[51] *Id.* at 1-2.

[52] *See* PUB. CITIZEN, TOP 10 PROBLEMS WITH IRRADIATED FOOD 1 (2003).

[53] PUB. CITIZEN, A BROKEN RECORD: HOW THE FDA LEGALIZED—AND CONTINUES TO LEGALIZE—FOOD IRRADIATION WITHOUT TESTING IT FOR SAFETY 11 (Oct. 2000) (citing FED. OF AMER. SOC'YS FOR EXPERIMENTAL BIOL., EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF (1979)).

significant reductions.[54] In addition, some people notice "a slight but distinct off-taste and smell" in irradiated beef and chicken.[55] Although the FDA first approved irradiated food in 1986 and permitted the irradiation of raw meat in 1997,[56] by 2007 more than two-thirds of consumers were concerned about the sale of irradiated foods.[57] However, "[i]f consumers are first educated about what irradiation is and why it is done, approximately 80% will buy the product."[58]

Upon initial approval of irradiated food in 1986, and in response to public comments, the FDA required that irradiated foods be labeled as such.[59] Food processors did not use irradiation very extensively because of high equipment costs, required labeling, and consumer dislike for the technology.[60] In an effort to spur the use of irradiation, the 2002 Farm Bill directed the U.S. Department of Agriculture (USDA) to "not prohibit the use of approved food safety technologies on foods purchased for the National School Lunch Program." [61] The USDA announced the availability of irradiated ground beef to schools in 2004, the unintended consequence of which was the revival of public concern about irradiated food.[62] In 2006, the multi-state outbreak of *E. coli* O157:H7 infections from fresh spinach resulted in the hospitalization of 200 people and at least three deaths.[63] In policy, the FDA responded by proposing to remove the

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[54] Irradiation in the Production, Processing, and Handling of Food, 70 Fed. Reg. 48,057, 48,059 (Aug. 16, 2005) (to be codified at 21 C.F.R. pt. 179) ("[F]ew vitamins are severely affected, with the exception of thiamine and vitamin E. However, these losses are small (on the order of 10 to 20 percent or less)").

[55] *Consumer Reports Conducts Test to Bring the Truth about Irradiated Meat*, CONSUMER'S UNION (Jul. 8, 2003), http://consumersunion.org/news/consumer-reports-conducts-test-to-bring-the-truth-about-irradiated-meat/.

[56] Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (April 18, 1986) (to be codified at 21 C.F.R. pt. 179).

[57] CONSUMER REP., FOOD LABELING POLL 11 (2007).

[58] *Irradiation of Food: FAQs*, CDC, http://www.cdc.gov/nczved/divisions/dfbmd/diseases/irradiation_food/ (last updated Nov.19, 2009).

[59] *See* Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376 (codified at 21 C.F.R. § 179.26(c)).

[60] *FDA Affirms Irradiation for Lettuce & Spinach*, UNITEDAG NEWS, Spring 2014, at 5, http://www.unitedag.org/wp-content/uploads/2014/04/UnitedAg_Newsletter_Spring-2014_PEQN-414.pdf.

[61] News Release, USDA, USDA Releases Specifications for the Purchase of Irradiated Ground Beef in the National School Lunch Program: Provides Education Recommendations for Local School Districts (May 29, 2003),http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2003/05/0172.html.

[62] *See, e.g.*, Bootie Cosgrove-Mather, *Irradiated Meat on School Lunch Menu*, CBS NEWS (Apr. 21, 2003, 1:07 PM), http://www.cbsnews.com/news/irradiated-meat-on-school-lunch-menu/.

[63] *Update on Multi-State Outbreak of E. coli O157:H7 Infections From Fresh Spinach, October 6, 2006,* CDC, http://www.cdc.gov/ecoli/2006/september/updates/100606.htm (last modified Oct 6, 2006).

labeling requirement for irradiated food in 2007,[64] which has still not been finalized, and then approving as safe the "use of ionizing radiation for control of food-borne pathogens, and extension of shelf-life, in iceberg lettuce and spinach up to a maximum dose of [4.0 kiloGray (kGy)]."[65] The FDA denied requests for hearings on the 2008 lettuce and spinach rule in 2014.[66] No one in the food industry has been able to identify any processors using the technology on lettuce and spinach.[67]

3. Use of Antibiotics in Meat Production

One use of technology in food production where there is consensus among the public, medical professionals, and government agencies, including the FDA, is the overuse of antibiotics, or antimicrobial drugs, in livestock and meat production. According to FDA estimates, antibiotics sold for use in meat-producing animals totaled 14.62 million kilograms (kg),[68] compared to around 3.29 million kg sold for human use in 2012.[69] Thus, more than eighty percent of the antibiotics sold in the U.S. are used in meat production to promote growth, as well as to prevent, control, and treat disease. Overuse of antibiotics leads to antibiotic resistant, or antimicrobial resistant (AMR), bacteria, which seriously infect more than 2 million and kill 23,000 people annually in the U.S.[70] According to the World Health Organization (WHO), AMR is "so serious that it threatens the achievements of modern medicine."[71] The President's Council of Advisors on Science and Technology found "that without rapid and coordinated action, the Nation risks losing the tremendous public health progress made over the last century from the discovery and development of antibiotic drugs."[72]

An overwhelming majority—eighty-six percent—of Americans believe customers should be able to buy meat and poultry raised without antibiotics at their local

[64] Irradiation in the Production, Processing, and Handling of Food, 72 Fed. Reg.16,291 (Apr. 4, 2007) (to be codified at 21 C.F.R. pt. 179).

[65] Irradiation in the Production, Processing, and Handling of Food, 73 Fed. Reg. 49,593-94 (Aug. 22, 2008) (codified at 21 C.F.R. § 179.26(b)(12)).

[66] Irradiation in the Production, Processing, and Handling of Food, 79 Fed. Reg. 10,353 (Feb. 25, 2014) (to be codified at 21 C.F.R. pt. 179) ("denial of request for a stay of effective date and for a hearing").

[67] *FDA Affirms Irradiation for Lettuce & Spinach, supra* note 60.

[68] FDA, 2012 SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS 14 (2014).

[69] FDA, CTR. FOR DRUG EVAL. & RES., DRUG USE REVIEW 2 (Apr. 5, 2012) (estimates from 2011, but amount of antibiotics sold for human use has remained stable for decades).

[70] CDC, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES 11 (2013).

[71] WHO, ANTIMICROBIAL RESISTANCE: GLOBAL REPORT ON SURVEILLANCE I, IX (2014).

[72] PRES. COUNCIL ADV. SCI. & TECH., REPORT TO THE PRESIDENT ON COMBATING ANTIBIOTIC RESISTANCE, I, V (2014).

supermarket, but only fifty-seven percent of shoppers reported that they even had that option.[73] While there are many concerns with the use of antibiotics in animal feed, the public is most worried about the creation of AMRs. In the medical profession, ninety-three percent of doctors are concerned with non-therapeutic antibiotic use, and eighty-five percent of physicians reported seeing at least one patient with an AMR infection a year.[74]

The FDA, CDC, and USDA all recognize the link between AMR and antibiotic use in animal feed.[75] In December 2013, the FDA finalized nonbinding guidance for industry to voluntarily limit the use of "medically important antimicrobial drugs" only when necessary for animal health and under the supervision of a veterinarian[76] and requested pharmaceutical companies to voluntarily modify the use of these antibiotics.[77] These antibiotics, important in human medical therapy, represent sixty-one percent of the antibiotics used in food-producing animals.[78] The policy "considers uses that are associated with the treatment, control, or *prevention* of specific diseases, including administration through feed or water, to be uses that are necessary for assuring the health of food-producing animals."[79] This includes administering antibiotics to animals not exhibiting clinical signs of disease but where disease is likely to occur if the drug is not used, which is often the case due to the overcrowded, unsanitary, and stressful conditions in commercial animal feeding operations.[80]

4. Local, Sustainable and "Natural" Food Claims

Consumer demand for more natural, environmentally friendly, socially-responsible, and locally produced food has proliferated. When purchasing food, crucial parts of the decision include supporting locals, protecting the environment from chemicals, reducing pesticide exposure, promoting animal welfare, reducing antibiotic use,

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[73] CONSUMER REP. NAT. RES. CTR., SURVEY RESEARCH REPORT: ANTIBIOTICS IN ANIMAL FEED 3 (2012).

[74] CONSUMER'S UNION *ET AL.*, PRESCRIPTION FOR CHANGE: ANTIBIOTICS USE IN HUMANS & ANIMALS AMIDST GROWING CONCERNS OF DOCTORS 2 (Oct. 2014).

[75] *See*, *e.g.*, CDC, *supra* note 70, at 37; *Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture Hearing Before the Subcomm. on Health*, 111th Cong. 42 (testimony of John Clifford, Dep. Admin., Vet. Serv., U.S. Dep't of Agric., 2010).

[76] CTR. FOR VETERINARY MED. (CVM), FDA, GFI #209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS (Apr. 2012).

[77] CVM, FDA, GFI #213, NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT USE CONDITIONS WITH GFI #209 (Dec. 2013).

[78] FDA, 2012 SUMMARY REPORT, *supra* note 68, at 16.

[79] FDA, GFI #209, *supra* note 76, at 21 (emphasis added).

[80] *See*, *e.g.*, CONSUMER'S UNION *ET AL.*, *supra* note 74, at 6.

avoiding GMOs, and avoiding artificial ingredients.[81] A significant percentage of Americans act on these concerns, looking for labels indicating whether the food product is *locally produced*, *natural*, contains *no artificial growth hormones*, is *pesticide-free*, *organic*, contains *no artificial ingredients*, *non-GMO*, contains *no antibiotics*, and is *certified humane*.[82] These preferences are growing, demonstrated by the increase in certified organic food sales from $4 billion to $35 billion in the last decade.[83]

Consumer perception of what these labels do and should mean does not align with the FDA's existing policies, with food labeled *natural* the most confusing. For packaged foods labeled as *natural*, about two-thirds of consumers believe this currently means no artificial materials during processing, no pesticides, no artificial ingredients, and no GMOs, and more than eighty-five percent believe the *natural* label *should* mean these things.[84] A similar percentage of consumers have the same expectation for meat and poultry labeled *natural*.[85] When a majority of consumers see the *raised without antibiotics* label, they believe it means *no* antibiotics were used, not just non-therapeutic applications, and many think the label means no drugs were used at all.[86]

The FDA, however, has declined to provide a standard definition of the term "natural," despite decades-long recognition that the meaning and use of the term are of "considerable interest to consumers and industry" and "are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning."[87] Thus, the FDA has maintained its policy regarding the use of "natural" as meaning "that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food."[88] The FDA reaffirmed

[81] CONSUMER REP. NAT'L RES. CTR., FOOD LABELS SURVEY 2, 5, 17 (2014) ("crucial" consists of responses of "very important" or "important", which 72%-92% of respondents included the following: supporting locals, protecting the environment from chemicals, reducing pesticide exposure, promoting animal welfare, reducing antibiotic use, avoiding GMOs, and avoiding artificial ingredients).

[82] *Id.* at 4, 17 (categories reported, in decreasing order from top of list, by 44%-66% of respondents).

[83] USDA, AGRIC. RESOURCES AND ENVIRONMENTAL INDICATORS, 2012 37-38 (Craig Osteen et al. eds., 2012)

[84] CONSUMER REP. NAT'L RES. CTR., FOOD LABELS SURVEY, *supra* note 81, at 9, 19-20.

[85] *Id.* at 7, 9, 17-20.

[86] *Id.* at 8, 12, 18.

[87] Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, 105) (noting the FTC attempted a definition in 1974).

[88] Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101) (Final Rule not adopting a definition of "natural").

this position as recently as January 2014, though it did not foreclose the possibility of promulgating a formal definition.[89]

B. Consumers Alternatives for More Food Certainty

In most cases, people seek certainty.[90] This desire for certainty is so strong that experiments show many people prefer clear choices, even when confident they are risky, over choices that may be safer but are ambiguous.[91] FDA policies parse terminology to assure ambiguity, to maintain the non-binding nature of its guidance.[92] When asked by federal courts to weigh in on the issue of whether high-fructose corn syrup (HFCS) qualifies as a "natural" ingredient, the FDA's response included that "[c]onsumers currently receive some protection in the absence of a definition of 'natural' because the [FDCA] and FDA's implementing regulations require that all ingredients used in a food be declared on the food's label. Thus, the label provides consumers with information to decide whether to purchase the food."[93] The FDA's Everything Added to Food in the United States (EAFUS) has an inventory of 3,968 substances, including 1,167 which are reportedly used but for which the FDA has not started an initial review.[94] (The European Union has 332 approved food additives.)[95] If the FDA cannot stay abreast of what is in our food, it is likely that consumers lack the knowledge needed to make healthy, let alone sustainable or socially-conscious, food choices. When the FDA's rules and policies fail to bring clarity to the issues, consumers will seek certainty from other

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[89] *See* Letter from Leslie Kux, Asst. Comm'r for Policy, FDA, to Hon. Yvonne Gonzalez Rogers, Hon. Jeffrey S. White, and Hon. Kevin McNulty, U.S. District Courts (Jan. 6, 2014), *as filed in* Cox v. Gumma Corp., No. 4:12-cv-6502-YGR, ECF No. 70 (N.D. Cal. filed Jan. 7, 2014).

[90] *See, e.g.*, Ming Hsu, *et al.*, *Neural Systems Responding to Degrees of Uncertainty in Human Decision-Making*, 310 SCI. MAG. 1680-83 (2005) ("level of ambiguity in choices correlates positively with activation in the amygdala [emotions and motivation] and orbitofrontal cortex, and negatively with a striatal system [potential rewards].").

[91] Jane Qiu, *Neuroeconomics: Decisions, Decisions*, 7 NAT. REVIEWS NEUROSCIENCE 88 (Feb. 2006). Study provides author with satisfactory explanation for his choices to eat fast food when traveling.

[92] *See* Discussion *supra* Part II.B.0.

[93] Letter from Michael M. Landa, Act. Dir., Ctr. Food Safety & Applied Nutrition, FDA, to Hon. Jerome B. Simandle, U.S. Dist. Ct., D.N.J. (Sept. 16, 2010), *as filed in* Coyle v. Hornell Brewing Co., Civil No. 08-2797 (JBS-JS), 2011 WL 2147218, at *1 (D.N.J. May 26, 2011).

[94] *Everything Added to Food in the United States (EAFUS)*, FDA, http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafuslisting (last updated Apr. 23, 2013) (list represents "only five of 196 fields in FDA/CFSAN's PAFA database"). 1,167 substances are author's calculations from spreadsheet created EAFUS database, DocTypes labeled "EAF." EAFUS is "only a partial" list of lawful food additives, a GRAS determination can be made without FDA knowledge. *Everything Added to Food in the United States (EAFUS)*,FDA,http://www.fda.gov/food/ingredientspackaginglabeling/%20foodadditivesingredients/ucm115326.htm (last updated Nov. 26, 2014).

[95] *Current EU Approved Additives and their E Numbers*, FOOD STANDARDS AGENCY (UK), http://www.food.gov.uk/science/additives/enumberlist?v (last updated Dec. 30, 2014).

sources. Areas consumers have turned to for this assurance include third-party labels, courts, and state governments.

1. Third Party "Eco-Labels"

The information gap between the FDA's labeling policies and consumers' desire for more information has resulted in the propagation of various "eco-labels" which expound a variety of environmental virtues of the food and its production processes. In broad terms, the goal of eco-labels is the "communication of verifiable and accurate information that is not misleading on environmental aspects of products and services, to encourage the demand for and supply of those products and services that cause less stress on the environment, thereby stimulating the potential for market-driven continuous environmental improvement."[96] In the U.S., the broader eco-label nomenclature includes any generalized *green*, sustainable, or environmentally-friendly claim, using language such as *100% vegetarian ingredients*, *antibiotic free*, or *free-range*. [97] None of these have government-set standards, thus manufacturers use such phrases at their discretion. These types of labels provide little value to the consumer and are often mere "greenwashing."[98] To add to the mix, "individual retailers have come up with their own rules for suppliers, which are slightly different."[99]

To provide some standardized meaning to many of these eco-labels, the International Organization for Standardization (ISO) has identified three basic types of Voluntary Environmental Performance Labeling, which have varying degrees of dependability, with third-party verification generally more reliable and self-declarations the most susceptible to greenwashing. [100] Federal Trade Commission (FTC) rules, known as "Green Guides," provide a measure for controlling self-declarations by regulating the truthfulness and verification of environmental marketing claims.[101]

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[96] *What is Ecolabelling?,* GLOB. ECOLABELLING NETWORK, http://www.globalecolabelling.net/what_is_ecolabelling/index.htm (last visited Jan. 5, 2016) (quoting International Organization for Standardization (ISO)); *see also* Jason Czarnezki, *The Future of Food Eco-Labeling: Organic, Carbon Footprint, and Environmental Life-Cycle Analysis*, 30 STAN. ENVTL. L.J. 3 (2011).

[97] *See generally*, *Eco-Labels Center,* CONSUMER REP., GREENER CHOICES FOOD SAFETY & SUSTAINABILITY CTR., http://www.greenerchoices.org/eco-labels/ (last visited Jan. 5, 2016).

[98] Greenwashing: "expressions of environmentalist concerns especially as a cover for products, policies, or activities." MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/greenwashing. *See also* Devika Kewalramani & Richard J. Sobelsohn, *Are You Being Greenwashed?*, 84 N.Y. ST. B.J. 10 (2012) ("deceptive use of 'green marketing' to promote a misleading perception" of environmentally friendliness).

[99] Elaine Watson, *Industry Should Develop Working Definition of 'Natural' if FDA Won't, Expert,* FOOD NAVIGATOR-USA (Oct. 25, 2011, 3:14 PM), http://www.foodnavigator-usa.com/Markets/Industry-should-develop-working-definition-of-natural-if-FDA-won-t-expert (quoting Karen Duesler, Pres., Food Consulting Company).

[100] ISO 14021:1999 (Type I labels), ISO 14024:1999 (Type I labels), ISO 14025:2006 (Type III labels). GLOB. ECOLABELLING NET., *supra* note 96.

[101] Guides for the Use of Environmental Marketing Claims ("Green Guides"), 16 C.F.R. § 260.1-260.17 (2015).

Consumer Reports maintains that "the best eco-labels are seals or logos indicating that an independent organization has verified that a product meets a set of meaningful and consistent standards."[102]

The number of food product eco-labels continues to grow as do the number of products displaying them. Industry consulting and food advocacy organizations estimate hundreds of third party eco-labe1 logos, seals, and stamps on food products in the United States,[103] and Consumer Reports has evaluated the reliability of 151 food eco-labels.[104] While not specific to food products, one survey found that for "single-standard" eco-labels, "there was virtually no market penetration until 2004, at which point the cumulative number of products certified grew rapidly, expanding from 510 in 2005 to 13,650 in 2008."[105]

While the proliferation is expected to continue, further market saturation by new eco-labels does not necessarily benefit the public. The growth of consumer interests in the methods of food production may have propelled the rise of eco-labels in the food industry, but there is concern about the impacts of such proliferation. Without significant research, it is difficult for consumers to distinguish between the various eco-labels and the plethora of labels causes additional confusion.[106] The unregulated proliferation of eco-labels tends to weaken the overall effectiveness of eco-labels.[107] "[T]he addition of qualifying language can reduce the flow of information to consumers," by creating "'information overload,' in which the consumers block out all information, and their decision making becomes worse rather than better."[108]

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[102] *What Makes a Good Eco-Label?*, CONSUMER REP., GREENER CHOICES FOOD SAFETY & SUSTAINABILITY CTR., http://www.greenerchoices.org/eco-labels/eco-good.cfm (last visited Jan. 5, 2016).

[103] *See, e.g.*, *Proliferation of Food Eco-Labels to Continue*, ORGANIC MONITOR (Jan. 8, 2013), http://www.organicmonitor.com/r0801.htm (more than 200 food labels internationally); *All Ecolabels in United States*, ECOLABEL INDEX, http://www.ecolabelindex.com/ecolabels/?st=country,us (last visited Jan. 5, 2016) (tracking 458 ecolabels in 197 countries, 25 industries, and 201 in the U.S. for all sectors); Lea Stewart, *Eco Labels 101: Green Certifications Explained!*, INHABITAT (Apr. 6, 2010), http://inhabitat.com/demystifying-eco-labels/ (more than 400 eco certification systems); Joshua Saunders, *Are There Too Many Eco-Labels and Green Ratings?*, GREENBIZ (Sept. 23, 2010, 4:00 AM), http://www.greenbiz.com/blog/2010/09/23/are-there-too-many-eco-labels-and-green-ratings (more than 300 eco-labels for various products).

[104] *Label Index Results*, CONSUMER REP., GREENER CHOICES FOOD SAFETY & SUSTAINABILITY CTR., http://www.greenerchoices.org/eco-labels/labelIndex.cfm (last visited Jan. 5, 2016) (includes verification organizations for USDA "organic" label).

[105] DUKE UNIV., NICHOLAS INST. FOR ENV'L POL'Y SOLUTIONS, AN OVERVIEW OF ECOLABELS AND SUSTAINABILITY CERTIFICATIONS IN THE GLOBAL MARKETPLACE 14 (Jay. Golden ed., Oct. 2010).

[106] *See, e.g.*, U.N. ECON. & SOCIAL COMM'N FOR ASIA AND THE PACIFIC, LOW CARBON GREEN GROWTH ROADMAP FOR ASIA AND THE PACIFIC 145, 150-151 (2012); ORGANIC MONITOR, *supra* note 103.

[107] U.N. ECON. & SOCIAL COMM'N FOR ASIA AND THE PACIFIC, LOW CARBON GREEN GROWTH ROADMAP FOR ASIA AND THE PACIFIC 145, 150-151 (2012); ORGANIC MONITOR, *supra* note 103.

[108] Richard Craswell, *Interpreting Deceptive Advertising*, 65 B.U. L. REV. 657, 690-91 (1985).

New certifications also require additional costs for producers, thus discouraging their adoption of new eco-labels because of multiple certification costs.[109] Although consumers are willing to pay more for socially responsible products,[110] little research has been conducted on either the profitability of third-party certified eco-labels for producers or the environmental benefits of certified products. In 2010, for example, seventy-five percent of surveyed certifying organizations were unaware of the market share of products carrying their labels and less than half had made any efforts to study the market impact of their label and only one-third had plans to do so.[111]

2. Food Label Litigation

In addition to looking for third party verification, consumers have increasingly been turning to the courts. Since 2009, hundreds of tort suits have been filed across the country, many which involve the meaning of the term "natural."[112] In January 2014, there were reportedly fifty class action suits that included products containing evaporated cane juice (ECJ)[113] (a/k/a sugar cane syrup). The Northern District of California in particular "has seen a flood of such cases, in which plaintiffs have challenged, with varying degrees of success, marketing claims on everything," with the court "recognizing that the Northern District of California is known as the 'Food Court.'"[114] This trend is likely to continue, especially if the FDA remains silent.[115]

The products subject to "natural" class action suits have fallen into four general categories: alleged mislabeling for containing HFCS, GMOs, artificial preservatives, and other unnatural ingredients or chemicals added during processing.[116] A common harm

[109] ORGANIC MONITOR, *supra* note 103.

[110] *See*, *e.g.*, CONSUMER REP., ANTIBIOTICS IN ANIMAL FEED, *supra* note 73, at 3; CONSUMER REP. NAT'L RES. CTR., FOOD LABELS SURVEY, *supra* note 81, at 6.

[111] DUKE UNIV., *supra* note 105, at 6.

[112] While an inexact approximation, a basic Westlaw search of the terms "food label natural" returned 431 cases, 239 of which were dated 2009 or later, more than double the number of cases reported than the previous 115 years since the Supreme Court took on the "oleomargarine" controversy in Plumley v. Commonwealth of Mass., 155 U.S. 461 (1894).

[113] Glenn G. Lammi, *FDA Action Should Take The Juice Out Of Some Food Labeling Class Actions*, FORBES (Mar. 4, 2014, 2:08 PM), http://www.forbes.com/sites/wlf/2014/03/04/fda-action-should-take-the-juice-out-of-some-food-labeling-class-actions/.

[114] Jones v. ConAgra Foods, No. C12-01633CRB, 2014 WL 2702726 at *1 & n. 1 (N.D. Cal., June 13, 2014) (citing Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT U. L. REV. 329, 333 (2014)).

[115] *See*, *e.g.*, R. Trent Taylor, *United States: 2014 Food Industry Outlook—Food Labeling Litigation*, MONDAQ (Jan. 13, 2014), http://www.mondaq.com/unitedstates/x/285746/food+drugs+law/2014+Food+Industry+Outlook+Food+Labeling+Litigation.

[116] *See*, Nicole E. Negowetti, *A National "Natural" Standard for Food Labeling*, 65 ME. L. REV. 581, 596 (2013) (citing Dawn Goulet, *Confusion in Court Over "All Natural" Claims*, AM. BAR ASS'N (Apr. 30, 2012),

alleged in these cases is the price premium that can be attributed to "natural", "all natural", or "100% natural" label statements.[117] Defendants in these cases have raised preemption and FDA's primary jurisdiction as common arguments. In cases where the FDA has not taken a clear position, such as HFCS and GMO "natural" claims, courts have held that nonbinding FDA opinions do not preempt state law claims.[118] The primary jurisdiction issue has been more of a hurdle for plaintiffs when the FDA has asserted authority. In March 2014, the FDA reopened the comment period on its Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice.[119] As a result, many of the ECJ cases were either dismissed or stayed.[120]

Beyond financial incentives of plaintiffs and their attorneys, the broader societal role of these class action suits is to deter misleading corporate behavior in labeling through large damage awards.[121] In addition to consumer class action suits, the June 2014 Supreme Court decision in *POM Wonderful LLC v. Coca-Cola Co.* opens the door for competitors to file Lanham Act[122] claims to food and drink labels.[123] Consumers cannot

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http://apps.americanbar.org/litigation/committees/classactions/articles/spring2012-0412-all-natural-labels-mean-marketing.html).

[117] *See*, *e.g.*, Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1368 (S.D. Fla. 2014); Brazil v. Dole Packaged Foods, No. 12-CV-01831-LHK, ECF 142, 26 (N.D. Cal. Order May 30, 2014); Jones v. ConAgra Foods., No. CV-12-01633-CRB, 2014 WL 2702726, at *21 (N.D. Cal. Order June 13, 2014) (denying class certification due to plaintiffs' inability to demonstrate "the entire price difference is attributable to the challenged statement."); Wilson, v. Frito-Law North America, No. 3:12-CV-01586-SC, ECF 47, 2013 WL 3734032 (N.D. Cal. May 1, 2013); Brown v. Hain Celestial Grp., 913 F. Supp. 2d 881, 885 (N.D. Cal. 2012).

[118] *See*, *e.g.*, Lilly v. ConAgra Foods, Inc., 743 F.3d 662, 663 (9th Cir. 2014); Holk v. Snapple Beverage Corp., 575 F.3d 329, 342 (3d Cir. 2009); Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274 (S.D.N.Y. 2014); Garcia v. Kashi Co., No. 12-21678-CIV, 2014 WL 4392163 (S.D. Fla. Sept. 5, 2014); Gedalia v. Whole Foods Mkt. Servs., Inc., No. 4:13-CV-3517, 2014 WL 5315030, at *4 (S.D. Tex. Sept. 30, 2014); In re Frito–Lay North Amer., Inc. All Natural Litig., No. 12-MD-2413(RRM)(RLM), 2013 WL 4647512, at *10 (E.D.N.Y. 2013); Stewart v. Smart Balance, Inc., No. CIV.A. 11-6174 JLL, 2012 WL 4168584, at *7 (D.N.J. June 26, 2012); Porrazzo v. Bumble Bee Foods, LLC, 822 F. Supp. 2d 406, 411-13 (S.D.N.Y. 2011); Von Koenig v. Snapple Beverage Corp., 713 F. Supp. 2d 1066, 1076 (E.D. Cal. 2010).

[119] Draft Guidance for Industry on Ingredients Declared as Evaporated Cane Juice; Reopening of Comment Period; Requests for Comments, Data, Information, 79 Fed. Reg. 12,507 (Mar. 5, 2014).

[120] *See*, *e.g.*, Reese v. Odwalla, Inc., No. 13-CV-947 YGR, 2014 WL 1244940, at *4 (N.D. Cal. Order Mar. 25, 2014) (stayed until Aug. 1, 2014 on primacy grounds); Gitson v. Trader Joe's Co., No. 13-CV-01333-VC, 2014 WL 3933921, at *2 (N.D. Cal. Order Aug. 8, 2014) (case stayed until Nov. 4, 2014); Figy v. Lifeway Foods, No. 13-CV-04828-TEH, 2014 WL 1779251, at *5 (N.D. Cal. Order May 5, 2014) (case stayed until Nov. 3, 2014); Gitson v. Clover Stornetta Farms, No. C-13-01517(EDL), 2014 WL 2638203, at *9 (N.D. Cal. Order June 9, 2014) (case stayed for 6 months); Ibarrola v Kind, Case No. 13 C 50377 (N.D. Ill., Order July 14, 2014) (dismissed on other grounds).

[121] *See generally* Richard Craswell, *Deterrence and Damages: The Multiplier Principle and Its Alternatives*, 97 MICH. L. REV. 2185 (1999).

[122] 15 U.S.C. § 1125 (2010).

[123] *See generally*, POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014)

use *POM Wonderful* as precedent because "[t]he Lanham Act creates a *cause of action for unfair competition* through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers."[124]

While private litigation may ultimately benefit consumers, changes to labeling requirements will occur without the FDA's participation, much less control. In addition, conflicting court opinions could result in certain "natural" label statements being permitted in some jurisdictions and not others. In the long-term, private suits, no matter the outcome, may undermine "Congress' grant of authority to the FDA to 'establish a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead consumers.'"[125]

3. Labeling Federalism

States have a long history with food safety and labeling regulation, predating the existence of the FDA. Prior to the Pure Food and Drug Act of 1906,[126] states controlled domestically produced and distributed foods, control that varied significantly between states.[127] In fact, food laws date back to the colonies, mainly to serve the needs of trade, but also providing for inspections of exports and local production to insure consumer protection as well as fair competition.[128] After Congress passed the Food Drug and Cosmetic Act of 1938 (FDCA), state food labeling laws have been found to violate the Supremacy Clause when the legislation conflicts with federal law or "an obstacle to the achievement of the purposes of the FDCA,"[129] but the FDCA does not contain an express preemption clause.[130] The Nutrition Labeling and Education Act of 1990 (NLEA),[131] amending the FDCA, "prevent[s] State and local governments from adopting

[124] *Id.* at 2234 (emphasis added).

[125] Reese v. Odwalla, No. 13-CV-947, 2014 WL 1244940 at *2 (N.D.Cal. Mar. 25, 2014) (citing 21 U.S.C. § 341 (2010)).

[126] Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938).

[127] John P. Swann, *FDA's Origins*, FDA (Jun. 23, 2014), http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm.

[128] Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA (Mar. 11, 2014), http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

[129] Comm. for Accurate Labeling & Mktg. v. Brownback, 665 F. Supp. 880, 885 (D. Kan. 1987) (citing Grocery Mfrs. of Am., Inc. v. Gerace, 581 F. Supp. 658, 668 (S.D.N.Y. 1984)).

[130] Wyeth v. Levine, 555 U.S. 555, 574 (2009) (discussing lack of pre-emption clause applicable to the entire FDCA, but the 1976 FDCA amendments included an express pre-emption clause applicable only to medical devices).

[131] Pub. L. No. 101–535, 104 Stat. 2353 (1990).

inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods."[132] Nonetheless,

> NLEA plainly states that the Act "shall not be construed to preempt any provision of state law, unless such provision is expressly preempted under [21 U.S.C. § 343-1 of the Federal Food, Drug, and Cosmetic Act." Furthermore, NLEA declares that its express preemption provision "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food," thereby preserving state warning laws.[133]

"Therefore, the preemption provisions in [NLEA] explicitly permit the States to adopt requirements for warning about the ingredients or components of food,"[134] leaving the door open for states to require labeling for issues of consumer interests not preempted. Estimates show more than 240 state laws or regulations imposing requirements on food that are not identical to federal standards,[135] but labeling requirements for products containing GMOs has been the most prominent issue of recent state action. In 2014, legislatures in twenty-five states considered sixty-seven bills that would require GMO labeling.[136]

Connecticut became the first state to enact a GMO labeling bill in June 2013,[137] but it will not go into effect until four additional northeastern states with an aggregate population of 20 million enact mandatory laws consistent with Connecticut's requirements.[138] In January 2014, Maine enacted a similar law, without the governor's

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[132] H.R. Rep. No. 101-538 at 8 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. *See also* 21 U.S.C. § 343-1 (2010) (prohibiting state requirement "that is not identical to the requirement" of most labeling provisions of the FDCA).

[133] Holk v. Snapple Beverage Corp., 575 F.3d 329, 338 (3d Cir. 2009) (citations omitted).

[134] 136 Cong. Rec. H5836-01 (statement of Rep. Waxman, July 30, 1990), 1990 WL 107635.

[135] CONG. BUDGET OFFICE, COST ESTIMATE: H.R. 4167—NATIONAL UNIFORMITY FOR FOOD ACT OF 2005 3 (2006).

[136] James E. McWilliams, *The Price of Your Right to Know: Calculating the Hidden Cost of Genetically Modified Food Labels*, SLATE (May 20, 2014, 7:17 AM), http://www.slate.com/articles/health_and_science/science/2014/05/gmo_food_labels_would_label_laws_in_vermont_maine_connecticut_increase_food.html. *See also State Labeling Initiatives*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/state-labeling-initiatives (last visited Jan. 5, 2016).

[137] CONN. GEN. ASSEMB., *SUBSTITUTE FOR RAISED H.B. NO. 6527, SESSION YEAR 2013*, http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=6527&which_year=2013&SUBMIT1.x=0&SUBMIT1.y=0 (last visited Jan. 5, 2016).

[138] Conn. Pub. Act No. 13-183 § 3 (2013).

signature,[139] that is contingent on five other states enacting laws substantially similar to its own.[140] Vermont became the first state that actually requires GMO labeling for food products beginning July 1, 2016, when Governor Peter Shumlin signed Act 120 into law on May 8, 2014.[141] Food industry groups filed a lawsuit challenging Act 120 a month later,[142] alleging violations of the 1st, 5th, and 14th Amendments, as well as the Commerce and Supremacy Clauses.[143]

In the FDCA and its subsequent amendments, Congress has maintained that states play an important role in food regulation. Most recently, Congress included three "no preemption" clauses in the Food Safety Modernization Act of 2011 (FSMA),[144] providing that compliance with the provisions "shall not relieve any person from liability at common law or under State statutory law."[145] Further, legislation to explicitly preempt state labeling laws in the National Uniformity for Food Act was introduced in every congressional session between 1998 and 2006, but never enacted.[146] Because of the public's current lack of faith in the FDA, such explicit legislation will be politically challenging to pass in the foreseeable future. While existing state food laws are likely to remain, how far new laws are able to push up against the consistency requirements while imposing "no greater burden"[147] than federal requirements, may depend on the FDA's diligence. When speaking to other state attorneys general in 2014, the Attorney General for Hawaii, where Hawaii County passed an ordinance banning the planting of

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[139] ME. LEG., *LEGISLATIVE INFORMATION: HP 490*, http://www.mainelegislature.org/legis/bills/display_ps.asp?paper=HP0490&PID=undefined&snum=126 (last visited Jan. 5, 2016).

[140] Me. Rev. Stat. ch. 565 § 2595(2) (statute self-repealing if the conditions not met by Jan. 1, 2023).

[141] *Gov. Peter Shumlin Signs First-in-the-Nation Genetically Engineered Foods Labeling Law*, STATE OF VT. (May 8, 2014), http://governor.vermont.gov/newsroom-gmo-bill-signing-release; *Current Status of a Specific Bill or Resolution 2013-2014 Legislative Session: Bill H. 112*, VT. GEN. ASSEM., http://legislature.vermont.gov/bill/status/2014/H.112 (last visited Jan. 5, 2016).

[142] Nancy Remsen, *Trade Groups Sue VT Over GMO Labeling Law*, BURLINGTON FREE PRESS (June 13, 2014), http://www.burlingtonfreepress.com/story/news/politics/2014/06/12/gma-sues-vt-gmo-law/10389209/.

[143] Grocery Manufactures Ass'n v. Sorrell, No. 5:14-CV-117 ECF 1 at 4 (D.Vt. Complaint filed June 12, 2014).

[144] FDA Food Safety Modernization Act, Pub. L. No. 111-353, §§ 103, 105, 112, 124 Stat. 3885, 3894, 3904, 3918 (Jan. 4, 2011) (codified at 21 U.S.C. § 350g(l)(6) (2010); 21 U.S.C. § 350h(f)(5) (2010); 25 U.S.C. § 2205(b)(3) (2010)).

[145] *Id.*

[146] DONNA V. PORTER, CONG. RES. SERV., FOOD SAFETY: NATIONAL UNIFORMITY FOR FOOD ACT 3-7 (2007), http://nationalaglawcenter.org/wp-content/uploads/assets/crs/RL33559.pdf. The National Uniformity for Food Act of 2005 passed in the House, but never came to a vote in the Senate. *Id. See* National Uniformity for Food Act of 2005, H.R. 4167, 109th Cong. (as passed by House of Representatives, Mar. 8, 2006).

[147] *See*, *e.g.*, Lilly v. ConAgra Foods, Inc., 743 F.3d 662, 663 (9th Cir. 2014).

most GMO crops, said: "This is a national movement . . . . Don't think that it's not coming to you."[148]

II. FROM ENFORCER TO REGULATOR: FDA'S METAMORPHOSIS FROM A PROGRESSIVE ERA AGENCY UNDER A NEW DEAL ERA STATUTE PROVIDES THE FRAMEWORK FOR PUBLIC DETACHMENT

With a lack of alternatives and the existing label regulatory framework, these alternatives to FDA oversight that consumers have pursued all have legitimate and positive roles. A commonality with third party eco-labels, private litigation, and state labeling efforts is the potential to lead to disjointed food labeling across the country. Given the geographic variances in food preferences across the country,[149] a totally uniform labeling system may not be desirable. However, if labeling requirements do differ from state-to-state, requiring different packaging and verification, the food production industry's additional costs could be substantial and would largely be passed on to consumers.[150]

Perhaps these alternatives are merely enhancements to the FDA's limited statutory guidance, or maybe they are symptoms of the FDA's failure to evolve its current policies, within the existing legal framework, to reflect consumer interests in the twenty-first century. If the latter, there are numerous causes that may have led to this divergence between the agency and the public's interests it is supposed to protect. The sources of the separation of the FDA from consumers are likely cumulative, many of which would be beyond the agency's control. However, other than simple regulatory capture, the FDA's history provides a window for identifying themes in its operations.

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[148] Pamela Prah, *Many States Weigh GMO Labels*, PEW CHARITABLE TRS. (Mar. 13, 2014) http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2014/03/13/many-states-weigh-gmo-labels.

[149] *See, e.g.*, *Across the Country in 50 State Dishes*, COOKING CHANNEL, http://www.cookingchanneltv.com/recipes/50-state-foods.html (last visited Jan. 5, 2016); Alvin Ward, *The Signature Food of Each State*, MENTAL FLOSS (Sept. 22, 2014, 2:04 PM), http://mentalfloss.com/article/59015/signature-food-each-state; Gus Wezerek & Mark Wilson, *The Weirdest Eating Patterns of Each U.S. State*, FAST CO. (Sept. 2, 2014, 8:00 AM), http://www.fastcodesign.com/3029454/food-week/the-weirdest-eating-patterns-of-each-us-state; Adam Lapetina, *The Unofficial Comfort Foods of Every State in America*, THRILLIST (June 29, 2014), http://www.thrillist.com/eat/nation/comfort-foods-of-every-state-in-america-thrillist.

[150] Studies of the annual per capita costs of state GMO labeling have ranged from $2.30 (label costs only in Oregon) to $12 to $389 (aggregate label, production, and regulatory costs in New York). *See* Letter from Dr. Andrew Dyke & Robert Whelan, ECONorthwest, to Consumers Union (Sept. 12, 2014), https://consumersunion.org/wp-content/uploads/2014/09/GMO_labeling_cost_findings_Exe_Summ.pdf; WILLIAM LESSER, DYSON SCHOOL, CORNELL UNIV., COSTS OF LABELING GENETICALLY MODIFIED FOODS PRODUCTS IN N.Y. STATE (2014), https://web.archive.org/web/20150219024718/http://dyson.cornell.edu/people/profiles/docs/LabelingNY.pdf.

A. BROAD CONGRESSIONAL MANDATES WITHOUT SPECIFIC STATUTORY GUIDANCE: FDA INFLATED ITS AUTHORITY TO PROTECT CONSUMERS

Congress enacted the Pure Food and Drug Act of 1906, creating the agency that would later be renamed the FDA,[151] during the height of the Progressive Era when the first modern administrative agencies were created.[152] The 1906 Act authorized the agency to regulate "adulterated" and "misbranded" food and drugs, providing the agency enforcement powers of seizure, examination, and disposal of offending products and the accused with the right to administrative hearings.[153] Although the 1906 Act granted authority to issue rules, the enumerated purposes were limited to "collection and examination of specimens of foods and drugs manufactured or offered for sale" in interstate commerce.[154] Moreover, the 1906 Act did not confer legislative rulemaking authority for such things as standards of identity or poison residue tolerances in food.[155]

Born during the era of the New Deal and unlike the 1906 Act it repealed, the FDCA of 1938 provided a variety of rulemaking authority with detailed procedural safeguards, most of which are found in section 701.[156] Section 701(a) provides general authority to promulgate regulations for the "efficient enforcement" of the FDCA, but does not contain specific procedural requirements.[157] Further, based on legislative history and conventions at the time, "nothing in the Act indicated that a regulation issued under the authority of section 701(a) would subject the violator to any sanction, penalty, or other legal consequence. This silence suggests Congress's intent to withhold legislative rulemaking powers under that section."[158] In contrast, sections 701(e), (f), and (g) set forth detailed procedures for promulgating regulations, including public trial-like hearings and judicial review for seven specified categories of actions, including misbranded or adulterated food, tolerances for poisonous or deleterious substances in food, and standards of identity.[159]

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[151] Swann, *supra* note 127.

[152] *See* CASS R. SUNSTEIN, AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE 18-21 (1990).

[153] Pure Food and Drug Act of 1906, Pub. L. No. 59-384 §§ 3, 4, 7, 8, 10, 11, 34 Stat. 768, 769-72 (repealed 1938).

[154] *Id.* § 3, 34 Stat. at 768-69.

[155] Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 513 (2002) (citing Wesley E. Forte, *The GMP Regulations and the Proper Scope of FDA Rulemaking Authority*, 56 GEO. L.J. 688, 691 (1968)).

[156] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371 (2010).

[157] Id. § 371(a)

[158] Merrill & Watts, *supra* note 158, at 515.

[159] 21 U.S.C. § 371(e)-(g).

These procedural rulemaking safeguards were a reflection of the FDCA's New Deal Era origins. The FDA was required to hold a "public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections" for all topics enumerated in section 701(e).[160] Further, the statute requires that the FDA's final rules "shall be based only on substantial evidence of record at such hearing."[161] The House Report accompanying the FDCA added:

> [I]f the order of the Secretary is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert *viva voce* the Government's evidence. . . . [I]t is essential to such a hearing that all the evidence on which the administrative officer acts be disclosed at the hearing . . . .[162]

Like other statutes granting rulemaking authority at the time, the FDCA's legislative history demonstrates that "Congress believed it was very important that a trial-type hearing be held before a regulation became effective."[163]

B. HISTORY OF "BURDENSOME" RULEMAKING AND EFFORTS TO STREAMLINE

1. Formal Rulemaking by Adjudicatory Hearings

The FDA operated under the structure of evidentiary rulemaking hearings for nearly two decades. It worked well for creating "standards of identity" under section 401, which the FDA applied using a "recipe" approach through the 1940s and into the early 1950s.[164] However, "[i]n the late 1940's and early 1950's, it became apparent that the excessive formality of the rule-making procedures of the [FDCA] impeded the issuance of non-controversial regulations."[165] The first FDA hearings on a standard of identity for white bread began in 1941, but the standard excluding bread "softeners" (polyoxyethylene monostearates) from the identity was not published until 1950.[166] The

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[160] *Id.* § 371(e)(3).

[161] *Id.*

[162] Wesley E. Forte, *Fair Hearing in Administrative Rule-Making: A Recent Experience Under the Federal Food, Drug, and Fair Packaging and Labeling Acts*, 1968 DUKE L.J. 1, 5 (1968) (quoting H.R. REP. NO. 2139 (1938)).

[163] *Id.* at 4.

[164] Suzanne White Junod, FDA, *The Rise and Fall of Federal Food Standards in the United States: The Case of the Peanut Butter and Jelly Sandwich* (Apr. 9, 1999), *reprinted in* LISA HEINZERLING, U.S. FOOD LAW: CASES AND MATERIALS 97 (2014).

[165] Forte, *supra* note 162, at 11.

[166] Junod, *supra* note 164, at 100-01.

standard for peanut butter was another decades-long process, with the evidentiary hearing alone taking twenty weeks in 1961.[167] Congress addressed the delay issue in 1954 with the Hale Amendment, which streamlined the rulemaking process by requiring adjudicatory rulemaking hearings only when requested by the public, at first only for standards of identity but later extended to all rulemaking on the subjects articulated in § 701(e).[168]

By the late 1960s, the FDA made two important changes that would have lasting effects on its procedures and interaction with the public. First, despite the FDCA requiring the FDA to hold public evidentiary hearings on rulemaking "[a]s soon as practicable after" receiving a request,[169] the FDA started not holding public hearings even when such requests were made. The first instance occurred during the drafting of regulation under the Fair Packaging and Labeling Act of 1966 (FPLA), which provided less than eight months for the FDA to finalize regulations.[170] The FDA received some 300 comments on its proposed rules published on March 17, 1967,[171] and re-published the proposal after making changes based on the received comments on July 21, 1967.[172] Despite receiving additional comments on the revised rule, including requests for a hearing, the FDA "considered the objections, made a few minor amendments, and denied all requests for a public hearing."[173]

A second important change occurred when the FDA began using the general rulemaking authority under FDCA section 701(a) to promulgate legislative rules. For thirty years, the FDA had:

> [S]et policy through case-by-case adjudication, interpretive rulemaking, and legislative rulemaking under its specific rulemaking grants. . . . [H]owever, the FDA—primarily in an effort to free itself from the formal procedural constraints that attached to the FDCA's specific rulemaking grants under section 701(e)— began to assert that section 701(a)

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[167] *Id.* at 102.

[168] Act of Apr. 15, 1954, ch. 143, sec. 1-3, §§ 401, 701(e), 68 Stat. 54, 54-55 (amending Federal Food, Drug, and Cosmetic Act §§ 401, 701(e)); Act of Aug. 1, 1956, ch. 861, sec. 2, §§ 401, 701(e), 70 Stat. 919, 919 (amending Federal Food, Drug, and Cosmetic Act §§ 401, 701(e)); *see also* Forte, *supra* note 162, at 11-13.

[169] 21 U.S.C. § 371(e)(3) (2010).

[170] Fair Packaging and Labeling Act of 1966, Pub. L. No. 89-755, § 13, 80 Stat. 1296, 1302 (codified as amended at 15 U.S.C. §§ 1451-1461 (2010)).

[171] Labels of Foods, Drugs, Devices and Cosmetics, 32 Fed. Reg. 4172 (Mar. 17, 1967) (to be codified at 21 C.F.R. pt. 1).

[172] Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act, 32 Fed. Reg. 10,729, 10,729 (July 21, 1967).

[173] Forte, *supra* note 162, at 3 (questioning the legality of the denial given explicit statutory language).

> authorized it to issue legislative rules using only informal notice-and-comment rulemaking procedures.[174]

This shift was pushed by the FDA's Chief Counsel Peter Barton Hutt and marked the beginning of FDA's transition "from a law enforcement agency which brought deterrent actions against violators, into a more paper-bound generator of rules and regulations."[175] The FDA was a leader amongst federal agencies in making extensive use of this less-than-certain general rulemaking authority.[176] The FDA's expanded legislative rulemaking authority was recognized by the 1973 Supreme Court in decisions known as the *Hynson* Quartet,[177] although the legitimacy of using section 701(a) for legislative regulations was not raised by the parties in any of those cases.

2. Shift to Informal Notice-and-Comment Rulemaking

By the mid-1970s, however, rather than merely procedural or interpretive rules explicitly conferred by statute, appellate courts began allowing the FDA to use this general rulemaking authority for substantive regulations with the force of law.[178] Soon thereafter, the FDA began to utilize section 553 of the APA's informal, "notice-and-comment" rulemaking procedures for the promulgation of rules.[179] Notice-and-comment rulemaking is less burdensome than rulemaking by adjudication due to the time and effort required for evidentiary hearings. While parties affected by the FDA's

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[174] Merrill & Watts, *supra* note 155, at 558 (citing 1 JAMES T. O'REILLY, FOOD AND DRUG ADMIN. § 4:02 (1979)).

[175] *Id.* at 588 & n.488 (quoting 1 JAMES T. O'REILLY, FOOD AND DRUG ADMIN. § 4:02 (1979)).

[176] Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 903 (2008). *See also* Eric R. Claeys, *The Food and Drug Administration and the Command-and-Control Model of Regulation*, 49 ST. LOUIS U. L.J. 105, 117-20 (2004).

[177] The four Supreme Court decisions in cases involving the FDA issued on June 18, 1973—USV Pharm. Corp. v. Weinberger, 412 U.S. 655 (1973); Weinberger v. Bentex Pharm., Inc., 412 U.S. 645 (1973); CIBA Corp. v. Weinberger, 412 U.S. 640 (1973); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973)—are collectively known as the Hynson Quartet. Thomas W. Merrill, *Step Zero After City of Arlington*, 83 FORDHAM L. REV. 753, 781 n.178 (2014). *See also* James O'Reilly, *Jurisdiction to Decide an Agency's Own Jurisdiction: The Forgotten Tale of the Hynson Quartet*, 58 ADMIN. L. REV. 829, 830 (2006); Merrill & Watts, *supra* note 155, at 559-62.

[178] Nat'l Ass'n of Pharm. Mfrs. v. Food & Drug Admin., 637 F.2d 877, 879 (2d Cir. 1981) (Friendly, J., reading the language of § 701(a), "from the Act of 1938, with the eyes of 1980" to find the general rulemaking authority could be used for legislative rules); Nat'l Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 696 (2d Cir. 1975) ("Whatever doubts might have been entertained regarding the FDA's power under s 701(a) to promulgate binding regulations were dispelled by the Supreme Court's recent decisions in [the Hynson Quartet].").

[179] 5 U.S.C. § 553 (2011); Noah, *supra* note 176, at 904.

notice-and-comment rules could still challenge final agency decisions in court,[180] the APA's "arbitrary and capricious" standard of judicial review is also more deferential than the "substantial evidence" requirement for adjudicatory rules.[181]

However, courts have continued to add judicial requirements to section 553 through "hard look" review of agency action and ensuring such things as responding to significant public comments, providing a "reasoned explanation," and that final rules are a "logical outgrowth" of the proposal.[182] This hard look judicial review of agency action under the APA's arbitrary and capricious standard has been "one of, if not the major, impediment to regulatory flexibility."[183]

Prior to a regulation even reaching the point of potential judicial scrutiny, however, the FDA and other agencies must comply with additional requirements that have been imposed by Congress and the White House. Congress has added laws requiring additional agency obligations during rulemaking, including the need to assess the rule's effects on state, local, and tribal governments;[184] "identify and consider a reasonable number of regulatory alternatives and . . . select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule;"[185] analyze and minimize the impacts on small business and information collection;[186] analyze potential environmental impacts;[187] and still provide Congress the opportunity to review and override the regulation before it is implemented.[188] The White House also requires agencies to conduct cost-benefit analyses and submit them for centralized review by the

[180] *See* Abbott Labs. v. Gardner, 387 U.S. 136, 148 (1967) *abrogated on other grounds by* Califano v. Sanders, 430 U.S. 99 (1977) ("[N]othing in the [FDCA] itself precludes" pre-enforcement review by the courts).

[181] 5 U.S.C. § 706(2)(A), (E) (2011).

[182] *See*, *e.g.*, Chamber of Commerce of U.S. v. Sec. & Exch. Comm'n, 412 F.3d 133, 144 (D.C. Cir. 2005) (requiring consideration of policy alternative raised in comments); United Steelworkers of Am., AFL-CIO-CLC v. Marshall, 647 F.2d 1189, 1221 (D.C. Cir. 1980) ("[L]ogical outgrowth"); ARCO Oil & Gas Co. v. Fed. Energy Reg. Comm'n, 932 F.2d 1501, 1504 (D.C. Cir. 1991) ("[C]onclusory statements cannot substitute for . . . reasoned explanation . . . ."); Greater Bos. Television Corp. v. FCC, 444 F.2d 841, 851 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971) ("[H]ard look" review).

[183] Mark Seidenfeld, *Why Agencies Act: A Reassessment of the Ossification Critique of Judicial Review*, 70 OHIO ST. L.J. 251, 251-52 (2009).

[184] Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1531-1538. (1995).

[185] *Id.* § 1535.

[186] Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 601 *et seq.* (2011); Paperwork Reduction Act of 1995, 44 U.S.C. § 3501 *et seq.* (2010).

[187] National Environmental Policy Act of 1969, 42 U.S.C. § 4332(2)(C) (2011).

[188] Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 801 *et seq.* (2011).

Office of Management and Budget (OMB), with additional requirements for "significant regulatory actions."[189]

Combined, these additional judicial, congressional, and executive requirements have resulted in what has been commonly referred to as the "ossification" of the rulemaking process.[190] While courts afford federal agencies a significant amount of deference,[191] the FDA historically received special deference due to its origins as a prosecuting agency using its scientific expertise to protect consumers from adulteration and fraud, serving as "gatekeeper" with the responsibility of protecting the public.[192] The FDA was able to use this deference to expand the reach of its jurisdiction beyond the plain language of the FDCA,[193] but notice-and-comment rulemaking still proved to be too cumbersome. "[S]ome of the comparative advantages of rulemaking have eroded in recent years," wrote a current Supreme Court justice in 1981, predicting that "the procedural advantages of rulemaking for the agency itself are headed for extinction."[194] Though certainly not alone amongst federal agencies, the FDA looked for other procedural short cuts.

3. End-Around Notice-and-Comment Rulemaking

In 1993, recommendations for streamlining government in Vice President Gore's National Performance Review included "direct final" rulemaking for "rules that the agency believes are so noncontroversial that no one would file adverse or negative comments on the proposal."[195] The Administrative Conference of the United States

[189] Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), *supplemented by* Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011) ("Significant regulatory action[s]" include those that "[h]ave an annual effect on the economy of $100 million or more.").

[190] Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1385-86 (1992).

[191] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837 (1984) (providing the modern approach of judicial deference to agency's statutory interpretations).

[192] *See* James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and A Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 949 (2008). *See also*, *e.g.*, United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914) (interpreting the term "may" in the 1906 Act's adulteration prohibition broadly to mean "may possibly" injure); United States v. Dotterweich, 320 U.S. 277, 281 (1943) (reading FDCA to "dispense[] with the conventional requirement for criminal conduct," imposing strict liability and piercing the corporate veil to hold drug company president criminally liable for corporate activity); Smith v. California, 361 U.S. 147, 152 (1959) ("[T]he public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors . . . .").

[193] *See* O'Reilly, *supra* note 192, at 949; *see also* Noah, *supra* note 176, at 917; *cf.* Gary Lawson, *Dirty Dancing—The FDA Stumbles with the Chevron Two-Step: A Response to Professor Noah*, 93 CORNELL L. REV. 927, 929 (2008) (FDA is not the only agency cutting procedural corners; the IRS has "thoroughly outdone the FDA—and quite possibly everyone else.").

[194] Antonin Scalia, *Back to Basics: Making Law Without Making Rules*, REG., July-Aug. 1981, at 25, 26.

[195] OFFICE OF THE VICE PRES., IMPROVING REGULATORY SYSTEMS: ACCOMPANYING REPORT OF THE NATIONAL PERFORMANCE REVIEW § REG05 (1993) [hereinafter NPR REPORT].

endorsed the same process in 1995.[196] Under this process, the first publication in the Federal Register is the final rule. "However, if an adverse comment is filed, the rule is withdrawn, and the agency may publish the rule as a proposed rule under normal notice and comment procedures."[197] Although the Environmental Protection Agency (EPA) had been using this process for a decade, the Vice President's report recognized that direct final rules "arguably" may not comply with the APA.[198] Nonetheless, the EPA only rarely had withdrawn a direct final rule, and the failure of direct final rules to comply with the APA has not been challenged in court.[199]

The FDA published notification of its Direct Final Rulemaking Procedures in the Federal Register—without public comment and referring to its website for the substantive procedural requirements—in 1997.[200] NPR endorsed the process used by the EPA in which the agency was "required to withdraw the direct final rule, republish it as a proposed rule, and go through the usual notice-and-comment procedures" if the agency was merely "*notified* that adverse comments *would* be filed" within 30 days of publication.[201] FDA's procedures, on the other hand, provided that the FDA would "consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process."[202] Between 1995 and 1999, federal agencies had issued more than 1,000 direct final rules with about six percent being withdrawn because of significant adverse comments.[203] The FDA issued thirty-eight direct final rules between 1997 and 2007, "[f]ifteen of these—or forty percent—received significant adverse comments that resulted in withdrawal of the direct final rule in part or in whole."[204] This is not the "rare outcome" predicted when direct final rules were first promoted, suggesting that the FDA either attempted to enact controversial rules through this streamlined process or the agency grossly underestimated or misunderstood what the public might find controversial.[205] Either way, the FDA may not have gained much efficiency from this streamlining effort.

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[196] *See generally* Special Committee to Review the Government in the Sunshine Act, 60 Fed. Reg. 43,108 (Aug. 18, 1995).

[197] *Id.* at 43,110.

[198] NPR REPORT, *supra* note 195, § REG05 & n.16. Others have also questioned the legality of this process. *See*, *e.g.*, Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401, 417 (1999).

[199] Noah, *supra* note 198, at 402.

[200] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466 (Nov. 21, 1997).

[201] NPR REPORT, *supra* note 195, § REG05 (emphasis added).

[202] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,466.

[203] Noah, *supra* note 198, at 411.

[204] Michael Kolber, *Rulemaking Without Rules: An Empirical Study of Direct Final Rulemaking*, 72 ALB. L. REV. 79, 82 (2009).

[205] *Id.* at 82-83 ("[E]xamination of the direct final rules that are being withdrawn suggests both factors are at play.").

Another alternative for avoiding informal rulemaking impediments has been to simply avoid setting policy through rules and instead issue agency guidance or interpretations, a strategy for which the FDA has been notorious.[206] The APA's definition of a "rule" includes "statement[s] of general or particular applicability and future effect,"[207] but "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" are exempted from section 553.[208] Instead, guidance documents are governed by APA section 552, which requires either publication of some types of guidance in the Federal Register, or simply making available for public inspection for others.[209] Guidance documents "are in some respects the product of agency process, but that meet none of the procedural specifications of the preceding three classes."[210]

The FDA has been issuing guidance documents since at least the 1970s,[211] and as of 1996 the FDA acknowledged that "[w]ell over a thousand such documents exist."[212] The first Food Guidance Document, however, was not issued until 1993, and only three others were issued by 1997.[213] Congress endorsed FDA's guidance documents in the Food and Drug Administration Modernization Act of 1997,[214] allowing the agency to make many specifications by issuing "guidance" and certain determinations by "regulation or guidance."[215] In addition, the 1997 amendment required the FDA

[206] *See*, *e.g.*, Claeys, *supra* note 176, at 120 ("To a degree unusual for most agencies, the FDA still sets policy by generating guidelines and interpretive rules."); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1779 n.79 (1996) ("FDA frequently issues what it calls 'guidance documents' . . . ."); Noah, *supra* note 176, at 904 ("As informal rulemaking became more difficult, the FDA shifted from promulgating binding rules to issuing nonbinding guidelines.").

[207] 5 U.S.C. § 551(4) (2011).

[208] *Id.* § 553(b)(A).

[209] *Id.* § 552(a)(1)–(2).

[210] Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468 (1992) (including guidance documents among "other materials of lesser dignity" for setting agency policy).

[211] The oldest example the author could find is CVM, FDA GFI #6, SUBMITTING NADA'S FOR GENERIC DRUGS REVIEWED BY NAS/NR (1971).

[212] Guidance Documents; The Food and Drug Administration's Development and Use; Request for Comments, 61 Fed. Reg. 9181, 9182 (Mar. 7, 1996).

[213] *Guidance for Industry: Guidelines For Determining Metric Equivalents Of Household Measures*, FDA (Oct. 1993), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm063102.htm; *See also* FDA, *Food Guidance Documents* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm (Last Updated Nov. 20, 2015).

[214] Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, 111 Stat. 2296.

[215] *See id.* (codified as amended in scattered sections of 21 U.S.C.).

development of regulations for issuing informal agency statements.[216] Since then, the frequency of the FDA's reliance on Food Guidance Documents has increased significantly, with the agency issuing 185 such document issuances by the end of 2015, two-thirds of which have come since 2006.[217] The FDA has also adopted significantly less regulations through notice-and-comment compared to twenty and thirty years ago.[218]

Food Guidance Documents address many issues of important public policy, including voluntary GMO labeling, action levels for poisonous or deleterious substances in human food and animal feed, pre-petition consultations for food additives and color additives, and the definitions for "high potency" and "antioxidant" for use in nutrient content labeling claims, to name a few.[219] These 185 Guidance Documents, moreover, do not include the numerous policy guidance which effect food products but fall under other FDA programs, such as antibiotic use in feed animals.[220] Moreover, many guidance documents have been issued as drafts but never finalized, including the voluntary GMO labeling guidance issued in 2001.[221]

As originally intended by the APA, "interpretative rules are statements as to what the administrative officer thinks the . . . regulation means."[222] Interpretive rules "clarify and explain" existing rules or laws, and courts have held that they "have neither force of law nor a substantial impact on those regulated."[223] FDA's Good Guidance Practices reflects this and guidance documents routinely include a disclaimer.[224]

At least some courts, however, have been "convinced that FDA has bound itself" given the substantive significance of some guidance documents.[225] FDA routinely acts as though the guidance documents are binding on the public in enforcement letters,

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[216] 21 U.S.C. § 371(h) (2010).

[217] FDA, *Food Guidance Documents, supra* note 213 (calculations by author).

[218] Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000).

[219] *Id.*

[220] *See*, *e.g.*, FDA GFI #209, *supra* note 76; FDA GFI #213, *supra* note 77.

[221] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

[222] Gibson Wine Co. v. Snyder, 194 F.2d 329, 331-32 (D.C. Cir. 1952).

[223] Herron v. Heckler, 576 F. Supp. 218, 231 (N.D. Cal. 1983) (citing Gosman v. United States, 573 F.2d 31, 39 (Ct. Cl. 1978)); *see also* Nat. Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 696-97 (2d Cir. 1975).

[224] 21 C.F.R. § 10.115 (2012).

[225] Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 948-49 (D.C. Cir. 1987) ("Our . . . holding is that the current action levels are treated as substantive rules by FDA and, as such, can only be permitted if notice-and-comment procedures are [used].").

however, courts have found that guidance documents may bind the agency but not the regulated parties.[226]

The FDA has many reasons for its preferred use of guidance documents to announce policy, including the relative costs compared to notice-and-comment rulemaking, the flexibility to change policies quickly to stay up to date, and the ability to avoid litigation, congressional oversight, and OMB review.[227] In addition, while the FDA's responsibilities have increased with the numerous amendments to the FDCA and other statutes over the past several decades, the agency's appropriated budget and staffing has remained relatively static.[228]

Some have argued that the FDA has taken the APA's relaxed approach towards guidance documents and adapted it into an "alternative system of regulation."[229] The FDA's intent for pursuing procedural short cuts in rulemaking may have been to avoid the additional obstacles placed on top of APA section 553's informal rulemaking requirements, but the *de facto* result was to further remove the public from the FDA's decision-making processes. "Meanwhile, the lack of procedural discipline can raise the risk of agency action that . . . does not properly engage public preferences."[230] "Although informal guidance documents and technical manuals are a necessary part of a complex administrative regime, they are promulgated without the benefit of comments by an interested public."[231] When APA section 553's informal rulemaking procedures are used, "comments from the lay public make up the vast majority of total comments . . . . [And] agencies react to the notice and comment process by making changes in their proposed rules."[232] Because FDA policymaking has extensively relied on informal guidance, the agency has become less accountable to the public, paving the way for arbitrary decision-making.[233] Moreover, "without broad public input, the agency may

[226] *See*, *e.g.*, Bellarno Int'l Ltd. v. Food & Drug Admin., 678 F. Supp. 410, 416 (E.D.N.Y. 1988) (declaring guidance document unlawful for failing to conduct notice-and-comment rulemaking).

[227] *See*, *e.g.*, Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 408-09, 411 (2007). OMB review of "significant" guidance documents was authorized from Jan. 18, 2007 to Jan. 30, 2009. *Id.* at 411. *See* Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007) (amending Exec. Order No. 12,866); Exec. Order 13,497, 74 Fed. Reg. 6113 (Jan. 30, 2009) (revoking Exec. Order No. 13,422).

[228] *See* U.S. FOOD & DRUG ADMIN., SUBCOMM. ON SCI. AND TECH., FDA SCIENCE AND MISSION AT RISK 9 (2007) (statutes effecting FDA have been enacted at a rate of roughly 6 per year, but appropriations and staffing have remained the static).

[229] Rakoff, *supra* note 218, at 167-68.

[230] Mendelson, *supra* note 227, at 408-09.

[231] McGarity, *supra* note 190, at 1393.

[232] Mariano-Florentino Cuéllar, *Rethinking Regulatory Democracy*, 57 ADMIN. L. REV. 411, 414 (2005).

[233] McGarity, *supra* note 190, at 1442.

not gather the information and consider the arguments that would be a predicate to the development of a sound rule."[234]

III. CHANGES IN FDA PROCEDURES FOR MORE ROBUST POLICIES AND MAINTAINING AUTHORITY ON FOOD LABELS AND LABEL STATEMENTS

During a time in which consumers have become more interested in "food" in general and concerned about food safety, healthfulness, and production methods, the FDA has increasingly implemented food-related policies via means that limit opportunities for public participation, isolating both the public and the agency. The APA's notice-and-comment procedures provide for the exchange of information, and this "'dialogue' between administrative agencies and the public 'is a two-way street.'"[235] "[N]otice-and-comment rulemaking [has been called] the 'most democratic of procedures' because all may participate,"[236] and the public is savvy enough to know when "one of the most fundamental, important, and far-reaching of democratic rights"[237] is curtailed.

The skepticism and distrust accompanying the public's lack of input into FDA policies and the FDA's lack of responsiveness to public concerns needs to change. While some changes may require a paradigm shift in policymaking procedures, the FDA should modify its processes to prevent further attrition of its leadership in the food labeling.

A. EMBRACE DEFERENCE TO FULFILL FDA'S CONSUMER PROTECTION ROLE BY ACKNOWLEDGING THE FOOD PRODUCTION PROCESS

The FDA has received "the highest degree possible" of judicial deference, which the agency has used to assert its jurisdiction in other areas beyond its statutory mandates.[238] In addition, the FDA could utilize the deference afforded to agencies

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[234] M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383, 1396 (2004).

[235] Northside Sanitary Landfill, Inc. v. Thomas, 849 F.2d 1516, 1520 (D.C. Cir. 1988) (quoting Home Box Office, Inc. v. FCC, 567 F.2d 9, 35 (D.C. Cir. 1977)).

[236] MICHAEL HERTZ, FINAL REPORT TO THE ADMIN. CONFERENCE OF THE U.S., USING SOCIAL MEDIA IN RULEMAKING: POSSIBILITIES AND BARRIERS 2 (2013) (quoting KENNETH CULP DAVIS, DISCRETIONARY JUSTICE: A PRELIMINARY INQUIRY 66 (1969)).

[237] Beth Simone Noveck, *The Electronic Revolution in Rulemaking*, 53 EMORY L.J. 433, 517 (2004).

[238] O'Reilly, *supra* note 187, at 950. *See also* Noah, *supra* note 176, at 917 ("The FDA has shown tremendous creativity in construing the reach of its authority . . . . [And] has at times tried to escape the occasionally precise (and, to its mind, inflexible) directives issued by Congress."); Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 807-08 (1993).

under *Chevron*[239] to interpret statutes it implements, and *Auer v. Robbins*[240] to interpret its own regulations to address food issues of material interest to consumers.[241] However, despite being "highly successful in expanding its jurisdiction,"[242] the FDA has taken a more narrow view of the substantive scope of its food regulation authority. The FDA guidance on GMOs, for example, makes it clear that the agency is not concerned with how food is produced, only with the end results of food safety.[243] On the other hand, the FDA has made attempts to broaden its food labeling jurisdiction by, for example, asserting authority over marketing claims under the theory that the websites function as product labels.[244]

In *Alliance for Bio-Integrity v. Shalala*,[245] plaintiffs challenged the FDA's GMO policy, including the agency's interpretation of the term "material" as used in the FDCA's prohibition on misbranding.[246] While plaintiffs argued the *process* of genetic modification and consumer interest were "material," the FDA took a narrower position that "no 'material *change*' . . . has occurred in the rDNA derived foods."[247] Under *Chevron*, the court held that "FDA's exclusion of consumer interest from the factors which determine whether a change is 'material' constitutes a reasonable interpretation of the statute."[248] Further, FDA's conclusion that food produced with rDNA technology did not "present any different or greater safety concern than foods developed by

[239] Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843-44 (1984) (an agency's interpretation of an ambiguous statute will be upheld if reasonable).

[240] Auer v. Robbins, 519 U.S. 452, 461 (1997) (agency interpretation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" (citation omitted)).

[241] *See* Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 883 (D.C. Cir. 2004) ("FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations.") (citation omitted).

[242] Gamerman, *supra* note 238, at 808-09 & n.18 (noting FDA attempts between 1990 and 1992 to claim jurisdiction over a range of issues, such as nonmedical biometrics, police forensics, and ear-piercings) (citations omitted).

[243] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22984-85 (May 29, 1992); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4839 (Jan. 18, 2001).

[244] Sarah Roller & Raqiyyah Pippins, *Marketing Nutrition & Health-Related Benefits of Food & Beverage Products: Enforcement, Litigation & Liability Issues*, 65 FOOD & DRUG L.J. 447, 460-61 (2010).

[245] 116 F. Supp. 2d 166 (D.D.C. 2000).

[246] *Id.* at 178 ("In general, foods shall be deemed misbranded if their labeling 'fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual.'" (quoting 21 U.S.C. § 321(n)).

[247] *Id.* (emphasis added).

[248] *Id.* at 179.

traditional plant breeding" was not "irrational" and "entitled to deference."[249] Had the plaintiffs and FDA taken the opposing party's positions in this case, FDA's interpretation also would have likely been upheld.

The FDA has not always had such a limited view of consumer demands in food regulation. In the early 1970s, FDA's legal advisor wrote, "the fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest."[250] In regulations requiring labeling of irradiated food promulgated in 1986, the FDA took the opposite position it had in *Alliance for Bio-Integrity*. The preamble to that final rule stated:

> The agency is of the opinion that there is adequate statutory authority . . . to require a retail label statement on foods that have been irradiated *even though there is no concern about the safety of such treatment* at the doses provided by this final rule. . . . Whether information is *material* . . . 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. The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers. . . . The agency concludes that requiring a retail label statement that a food has been irradiated is consistent with the agency's statutory authority and current labeling practice.[251]

Although the court in *Alliance for Bio-Integrity* stated that the FDCA does not "authorize labeling requirements solely because of consumer demand,"[252] there are enough differences between GMOs and foods produced through traditional methods that requiring identification labeling would not be "irrational" if FDA so chose. Although mandatory labeling might not be the appropriate position, the FDA's GMO policy never benefitted from the dialogue of traditional notice-and-comment rulemaking. As a result, consumer interests were discounted or not considered, and the agency lost the opportunity to create GMO policy that was articulated in language that could have been more acceptable to the public. The main concern should not be the FDA's substantive policies, but the framework through which those policies are created.

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[249] *Id.* (citation omitted).

[250] Peter Barton Hutt, *Philosophy of Regulation Under the Federal, Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177 (1973), *reprinted in* 50 Food & Drug L.J. 101, 102 (1995).

[251] Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (Apr. 18, 1986) (emphasis added).

[252] *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

B. ENVIRONMENTAL ANALYSES OF POLICIES WOULD BROADEN FDA'S PERSPECTIVE

Another procedural mechanism through which the FDA may be able to broaden its perspective and "[e]ncourage and facilitate public involvement"[253] and concerns without necessarily requiring substantive changes to its policies is the utilization of the National Environmental Policy Act (NEPA).[254] NEPA and the Council on Environmental Quality's (CEQ) implementing regulations require federal agencies to prepare an environmental impact statement (EIS) for "major Federal actions significantly affecting the quality of the human environment."[255] Agencies may prepare a more concise environmental assessment (EA) to determine whether the impacts of its action are "significant" and thus requiring a full EIS.[256]

Although "federal actions" include the "[a]doption of official policy, such as rules, regulations, and interpretations,"[257] the FDA has been unwilling to utilize NEPA's processes in developing its food guidance documents in the past.[258] The FDA's food policymaking would benefit from NEPA's "twin aims" of informed agency decision-making and an informed public.[259] Preparing an EA or EIS on its policy guidance ensures that the FDA, "in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts."[260] An important part of consumer protection is ensuring informed consumers, particularly with regards to dietary choices,[261] and consumers are both uninformed and misinformed about important issues affecting the American food supply.[262]

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[253] 40 C.F.R. § 1500.2(d) (2011).

[254] National Environmental Policy Act, 42 U.S.C. §§ 4321-4370 (2010).

[255] 42 U.S.C. § 4332(2)(C); 40 C.F.R. § 1508.11 (2012).

[256] 40 C.F.R. § 1508.9(a), (a)(1) (2012).

[257] 40 C.F.R. § 1508.18(b), (b)(1) (2010).

[258] *See*, *e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 174 (D.D.C. 2000) (FDA announced that its GMO policy statement "with respect to foods from new plant varieties . . . will [not] constitute agency action under NEPA."); *cf.* Stauber v. Shalala, 895 F. Supp. 1178, 1186 (W.D. Wis. 1995) (FDA approved rbST for dairy cows without preparing an EIS, concluding approval would not have a significant environmental impact based on EA prepared by Monsanto).

[259] *See*, *e.g.*, Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 97 (1983).

[260] Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 349 (1989).

[261] *See*, *e.g.*, 21 U.S.C. § 343(q) (2011) (NLEA allows FDA to change labeling requirements if "information . . . will assist consumers in maintaining healthy dietary practices."); Joseph M. Price & Rachel F. Bond, *Litigation As A Tool in Food Advertising: Consumer Protection Statutes*, 39 LOY. L.A. L. REV. 277 (2006); Forrest Lee Andrews, Comment, *Small Bites: Obesity Lawsuits Prepare to Take on the Fast Food Industry*, 15 ALB. L.J. SCI. & TECH. 153, 171 (2004).

[262] *See supra* Part I.

The FDA has avoided preparing NEPA documents on policy guidance because of their self-declared non-binding nature. As such, NEPA's requirements are not triggered because the guidance does not result in "irreversible and irretrievable commitments of resources."[263] "Moreover, agency decisions that maintain the substantive status quo do not constitute major federal actions under NEPA."[264]

The same intent behind issuing non-binding policy to avoid judicial scrutiny of the rule applies to judicial review of NEPA decisions. The FDA, however, could benefit from informed decisions based on consumer input that NEPA would provide while still arguably avoiding judicial review of potential defects in EAs. CEQ regulations "authorize the use of EAs for a wide array of purposes."[265] "Even if an EA is not required . . . '[a]gencies may prepare an [EA] on any action at any time in order to assist agency planning and decisionmaking.'"[266] The agency could continue to use qualifying statements, such as "FDA does not consider that the activities it may undertake [under this policy] . . . will constitute agency action under NEPA,"[267] in its guidance documents to bolster this. Further, much of the public's confusion surrounding food issues stems from recent technological advances, and a reviewing court must be "at its most deferential" when an agency is "making predictions, within its area of special expertise, at the frontiers of science."[268] In addition, there is case law supporting the idea that plaintiffs do not have standing to challenge agency decisions when NEPA is "voluntarily" invoked due to the lack of redressability.[269]

C. A CITIZEN SUIT PROVISION IN THE FDCA WOULD SUPPLEMENT FDA ENFORCEMENT AND ALLOW AGENCY CONTROL OF LITIGATION

The only thing that may be less timely than arguing for more NEPA may be suggesting that Congress add additional citizen suit enforcement of federal statutes.[270] From the FDA's perspective, however, a federal private right of action could not only supplement the agency's enforcement abilities but also provide the agency more control

[263] 42 U.S.C § 4332(2)(C)(v) (2010).

[264] *See*, *e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 174 (D.D.C. 2000).

[265] Del. Dep't of Nat. Res. & Envtl. Control v. U.S. Army Corps of Eng'rs, 685 F.3d 259, 273 (3d Cir. 2012).

[266] Hale v. Norton, 476 F.3d 694, 700 (9th Cir. 2007) (quoting 40 C.F.R. § 1501.3(b) (2012)).

[267] Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 23,005 (May 29, 1992).

[268] Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1983).

[269] Goat Ranchers of Or. v. Williams, No. CIV. 08-97-ST, 2009 WL 883581, at *3 (D. Or. Mar. 30, 2009) *aff'd*, 379 F. App'x 662 (9th Cir. 2010).

[270] *See*, *e.g.*, current legislation to restrict current citizen suit attorney-fee shifting provisions of the Endangered Species Act. H.R. 4315 (1973). Endangered Species Transparency and Reasonableness Act, H.R. 4315, 113th Cong. (as passed by House of Representatives, July 29, 2014); Endangered Species Litigation Reasonableness Act, H.R. 4318, 113th Cong. (as introduced in House of Representatives, Mar. 27, 2014).

over private food litigation. This would require amending the FDCA to provide such right since the FDCA currently does not.[271] However,

> Citizen suit provisions are included in almost all of our environmental statutes. Citizen resources are an important adjunct to governmental action to assure that these laws are adequately enforced. In a time of limited Government resources, enforcement through court action prompted by citizen suits is a valuable dimension of environmental law.[272]

Congress recognized the importance of augmenting the FDA's enforcement when amending the FDCA with the NLEA in 1990 by allowing states to bring civil enforcement of portions of the FDCA food provisions for the first time.[273] These state enforcements proceedings are brought in federal court to "supplement the FDA's enforcement capabilities."[274] Before commencing a civil suit, a state provides the FDA thirty-day notice of its intent to sue, allowing the FDA opportunity to "commence[] an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding."[275] Moreover, state suits are prohibited if the FDA "is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food."[276]

Such "notice" and "diligent prosecution" limitations are included in federal environmental statute citizen suit provisions[277] and would provide FDA the ability to have some control over private food litigation. Citizen suits cannot be maintained without providing the requisite notice because the notice requirement is jurisdictional.[278] Thus, before private citizens could initiate a suit, FDA would have the

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[271] *See*, *e.g*., Merrell Dow Pharm., Inc. v. Thompson, 478 U.S. 804, 811 (1986) ("Congress did not intend a private federal remedy for violations of the [FDCA]."); Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011) ("[T]he [FDCA] does not create a private right of action.").

[272] 136 CONG. REC. S3162-04 (daily ed. Mar. 26, 1990) (statement of Sen. Durenberger), 1990 WL 45176.

[273] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 4, 104 Stat. 2353, 2362 (codified at 21 U.S.C. § 337(b)(1) (2010)).

[274] H.R. REP. NO. 101-538 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3353, 1990 WL 259223.

[275] 21 U.S.C. § 337(b)(2)(B) (2011).

[276] *Id.* § 337(b)(2)(C).

[277] Most environmental statutes require sixty-day notice to both the relevant agency head and the Attorney General. *See* Toxic Substances Control Act, 15 U.S.C. § 2619(b)(1)(A) (2011); Endangered Species Act, 16 U.S.C. § 1540(g)(2)(i) (2011); Surface Mining Control and Reclamation Act, 30 U.S.C. § 1270(b)(1)(A) (2011); Clean Water Act, 33 U.S.C. § 1365(b)(1)(A) (2011); Resource Conservation and Recovery Act, 42 U.S.C. § 6972(b)(1)(A) (2009); Clean Air Act, 42 U.S.C. §7604(b)(1)(A) (2009).

[278] Hallstrom v. Tillamook Cty., 493 U.S. 20, 33 (1989) (holding when "a party suing under the citizen suit provisions of RCRA fails to meet the notice and 60-day delay requirements . . . the district court must dismiss the action.") (citation omitted).

opportunity to evaluate the claim and bring enforcement actions if it deemed them proper. As the Supreme Court has interpreted notice and diligent prosecution requirements, citizen suits are "meant to supplement rather than to supplant governmental action"[279] and "are proper only 'if the . . . agencies fail to exercise their enforcement responsibility.'"[280] Given budget constraints and expanding statutory responsibilities, FDA might welcome supplemental enforcement. Across all its programs, FDA has increasingly relied on "warning letters" as enforcement strategy.[281]

In the early 1970s, the "the public had lost confidence in the administrative process in general and had turned to litigation to achieve important public goals," thus Congress included citizen suit provisions in the environmental statutes "to restore the public's confidence" by authorizing citizen enforcement of the statutes.[282] Today, citizens can only enforce food claims if the FDA does not regulate the health or nutrition claim at issue or the state provides a private right of action and establishes laws "identical to" those of the claims included in the NLEA or the state petitions and FDA grants an exemption from the requirement of "identicalness."[283]

Despite these narrow exemptions to preemption, hundreds of labeling lawsuits are processing through the courts. An FDCA citizen suit provision may reduce plaintiff attorneys' incentives to file suits without the potential of large damages awards at the end of litigation. While the citizen suit provisions in environmental statutes contain fee-shifting provisions to provide prevailing plaintiffs costs of litigation, including reasonable attorney fees, the provisions either allow only injunctive relief or the assessment of penalties, which are paid to the U.S. Treasury.[284] A citizen suit provision would also remove the possibility of various state courts ruling on labeling claims, thus improving the chances of maintaining consistency in judicial opinions. Thus, as an added benefit, citizen suits might prevent a situation, as described by Judge Posner, where "[m]anufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy."[285]

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[279] Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc., 484 U.S. 49, 60 (1987).

[280] *Id*. (quoting S. REP. No. 92–414, at 64 (1971)).

[281] *See* U.S. FOOD & DRUG ADMIN., FDA ENFORCEMENT STATISTICS SUMMARY FISCAL YEAR 2013, http://www.fda.gov/downloads/ICECI/EnforcementActions/UCM384647.pdf (last visited Jan. 5, 2016).

[282] L. Ward Wagstaff, *Citizen Suits and the Clean Water Act: The Supreme Court Decision in Gwaltney of Smithfield v. Chesapeake Bay Foundation*, 1988 UTAH L. REV. 891, 905-06 (1988) (citing H.R. REP. NO. 92-911, at 132 (1972)).

[283] 21 U.S.C. § 343-1 (2010); Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

[284] *See*, *e.g*., Clean Water Act, 33 U.S.C. § 1365(a)(2), (d) (2011); Clean Air Act, 42 U.S.C. § 7604(d), (g)(1) (2009).

[285] *Turek*, 662 F.3d at 426.

D. FURTHER COMMITMENT TO TRANSPARENCY AND OPEN ACCESS TO FDA'S PROCESSES WOULD REDUCE PUBLIC SKEPTICISM

> Transparency and public participation serve the goals of procedural legitimacy and substantive quality in agency rulemaking. . . . Ultimately, transparency and public-participation reforms have the potential to benefit both administrative agencies and the public at large. Greater participation can yield information that will help agencies better fulfill their statutory mandates, while society will benefit from substantively superior rules as well as a regulatory process with enhanced legitimacy. Improved transparency allows for more effective and useful participation while simultaneously establishing public oversight as a check on agency behavior.[286]

As one scholar wrote two decades ago, "[a]lthough informal rulemaking is still an exceedingly effective tool for eliciting public participation in administrative policymaking, it has not evolved into the flexible and efficient process that its early supporters originally envisioned."[287] Despite the promise of a rulemaking and public participation "revolution" from e-rulemaking a decade, there has been less than hoped for change in how agencies process public information.[288] While section 553 of the APA recognizes a role for the public in agency rulemaking, it contains only minimal requirements and does not encourage agencies to develop their own processes.[289] Thus, agencies such as the FDA have broad authority in determining how to engage with the public. As with NEPA, the most important strategy for public input to have meaningful impact on agency decision-making is engagement early in the process before bureaucratic inertia has become an immovable object. Some have argued early public involvement was made difficult by judicial review of informal rulemaking, transforming the process from "[w]hat was once (perhaps) a means for securing public input into agency decisions . . . [into] primarily a method for compiling a record for judicial review."[290] As this former Administrator and Executive Counsel at EPA acknowledged,

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[286] Cary Coglianese et al., *Transparency and Public Participation in the Federal Rulemaking Process: Recommendations for the New Administration*, 77 GEO. WASH. L. REV. 924, 961-62 (2009).

[287] McGarity, *supra* note 190, at 1385.

[288] *See generally* Nina A. Mendelson, *Rulemaking, Democracy, and Torrents of E-Mail*, 79 GEO. WASH. L. REV. 1343 (2011).

[289] 5 U.S.C. § 553(c) (2011) ("The agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation."); *Id.* § 553(b) (requiring publication of "[g]eneral notice of proposed rule making . . . in the Federal Register.").

[290] E. Donald Elliott, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490, 1492 (1992). "If the agency is to state the detailed basis for its actions in such a way that its actions will survive judicial review, public input through formal notice-and-comment rulemaking must come relatively close to the end of the agency's process, when the proposed rule has 'jelled' into something fairly close to its final form." *Id.* at 1494.

"[b]ecause of the need to create a record, real public participation—the kind of back and forth dialogue in which minds (and rules) are really changed—primarily takes place in various fora well in advance of a notice of proposed rulemaking."[291]

Federal agencies have been experimenting with various forms of early public participation for some time. For example, the FDA has used listening sessions,[292] allowing stakeholders to submit drafts of proposed guidance,[293] focus groups,[294] roundtable discussions,[295] and advisory committees.[296] The FDA has been making efforts at improving transparency.[297] Agencies are also beginning to experiment with social media in early rulemaking as a method of engaging segments of the population that have traditionally been less likely to connect with the agency.[298] These changes show the FDA's willingness to alter the status quo to be open to the public. The more difficult challenge is to be willing to

> [R]eadjust[] the modern system of administrative procedure to allow meaningful collaboration with the public in certain areas—rather than an empty charade wherein the government nominally gathers public input and then promptly ignores it—and eschewing public participation where it is neither desirable nor beneficial—rather than disingenuously acting as if public opinion were relevant to technical issues, such as the viability of climate change science—our government could garner greater trust

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[291] *Id.* at 1495.

[292] *See*, *e.g.*, *Public Listening Session for the Office of Science, Center for Tobacco Products, FDA*, FDA, http://www.fda.gov/TobaccoProducts/NewsEvents/ucm387045.htm (last updated July 20, 2015).

[293] *See*, *e.g.*, FDA, FOOD AND DRUG ADMINISTRATION REPORT ON GOOD GUIDANCE PRACTICES: IMPROVING EFFICIENCY AND TRANSPARENCY 5 (2011), http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM285124.pdf; *see also* 21 C.F.R. § 10.115(f)(2)-(3) (2012).

[294] *See*, *e.g.*, Focus Groups as Used by the Food and Drug Administration, 79 Fed. Reg. 32,555, 32,555 (June 5, 2014) (focus groups provide the FDA with "a more indepth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.").

[295] *See*, *e.g.*, *FDA Announces Nutrition Roundtable Discussion*, U.S. FOOD & DRUG ADMIN. (Nov. 7, 2008), http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm046595.htm.

[296] *Advisory Committees*, FDA, http://www.fda.gov/AdvisoryCommittees/ (last visited Jan. 5, 2016). *See also* McGarity, *supra* note 190, at 1408-09 ("By providing a vehicle for public input into complex science/policy judgments, advisory committees can increase the likelihood that they will be accepted by the regulated industry and the general public.").

[297] *See generally* FDA, FDA TRANSPARENCY INITIATIVE: DRAFT PROPOSALS FOR PUBLIC COMMENT REGARDING DISCLOSURE POLICIES OF THE U.S. FOOD AND DRUG ADMINISTRATION (2010), http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212110.pdf.

[298] HERTZ, *supra* note 236, at 3 ("The Administrative Conference has consistently supported full and effective public participation in rulemaking and the use of new technologies to enhance such participation.").

amongst the electorate while improving the overall quality of its policymaking.[299]

IV. CONCLUSION

Most Americans make choices about what food to eat multiple times every day.[300] Although the food industry—from production and processing through marketing and labeling—has been regulated to provide safety and knowledge to consumers for more than a century,[301] many Americans are uncertain about the meaning of labels and label statements. Multiple factors likely contribute to this lack of consumer confidence and certainty, some of which are either out of the government's control (e.g., marketing claims protected by the First Amendment) or which would require significant new legislation (e.g., consolidating federal food regulation to a single agency). Under existing authority, however, the FDA could greatly improve the role of meaningful public participation in developing clear, binding requirements for food labels. It is perhaps the most practical step the agency can take to make labeling more relatable to the general public, restore confidence in the agency, and maintain its existing control over food regulation throughout the country.

[299] Reeve T. Bull, *Making the Administrative State "Safe for Democracy": A Theoretical and Practical Analysis of Citizen Participation in Agency Decisionmaking*, 65 ADMIN. L. REV. 611, 617 (2013).

[300] "An estimated 85.7 percent of U.S. households were food secure throughout the entire year in 2013." ALISHA COLEMAN-JENSEN ET AL., U.S DEP'T OF AGRIC., HOUSEHOLD FOOD SECURITY IN THE UNITED STATES IN 2013 4 (2014).

[301] LISA HEINZERLING, U.S. FOOD LAW: CASES AND MATERIALS 6, 44 (2014)).