ADMINISTRATIVE GUIDANCE AND GENETICALLY MODIFIED FOOD

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One of the most controversial issues in administrative law, the use of guidance, is exemplified by the regulation of one of the most controversial areas in modern society: genetically modified (GM) food. The appropriate use of guidance versus notice and comment rulemaking is a much-debated issue in administrative law. While agency officials generally assert that they are using guidance to express an agency's thoughts about how to comply with a specific statutory provision or agency rule, the practical consequence is that the regulated party will hesitate to disobey, even if it believes that the guidance goes beyond the requirements of the statute or rule. The Food and Drug Administration's (FDA) regulation of GM food through a guidance document provides a prime example of this effect: the document recommends a premarket review process that the FDA describes as voluntary for firms attempting to bring a new product to market. The reality is that regulated parties feel compelled to comply. This is a controversial and questionable result because many types of genetic modifications are well understood and pose no safety issues; the scientific consensus is that GM foods currently available are as safe as non-GM foods. This situation raises the central issue addressed by this Article: how to determine whether an agency is appropriately using guidance, or whether the agency should be required to use notice and comment rulemaking. After discussing why the current theoretical approaches—interpretation and bindingness—are inadequate to solve this problem, this Article proposes a new theoretical framework in which to answer this question of public controversy to determine when informal rulemaking with notice and comment is advantageous and even required by the Administrative Procedures Act (APA). This new theoretical framework is then applied to the controversial issue of GM food.

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INTRODUCTION

One of the most extensively debated issues in administrative law is whether administrative agencies are appropriately complying with the Administrative Procedures Act (APA) in their use of guidance documents. The Food and Drug Administration (FDA) is primarily responsible for the safety and labeling of all food sold in the marketplace for human consumption. Currently, the FDA uses a guidance document to carry out this function for genetically modified (GM) foods.[1] In other words, one of the most controversial techniques in administrative law is being used to govern one of the most controversial practices in modern technology.[2]

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1. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter FDA 1992 Guidance Document].

2. Regarding the controversy surrounding GM food, see, e.g., CARY FUNK & BRIAN KENNEDY, THE NEW FOOD FIGHTS: U.S. PUBLIC DIVIDES OVER FOOD SCIENCE (2016), http://assets.pewresearch.org/wp-content/uploads/sites/14/2016/12/23173602/PS_2016.12.01_Food-Science_FINAL.pdf; MCKAY JENKINS, FOOD FIGHT: GMOS AND THE FUTURE OF THE AMERICAN DIET 17–19 (2017); BILL LAMBRECHT, DINNER AT THE NEW GENE CAFÉ: HOW GENETIC ENGINEERING IS CHANGING WHAT WE EAT, HOW WE LIVE, AND THE GLOBAL POLITICS OF FOOD 179–311 (2001); MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE

This Article reconsiders the current framework in order to shed light on both the substance and procedure of GM regulation.[3] In particular, this Article uses the controversial nature of the subject matter that the FDA has chosen to regulate by guidance as an opportunity to reconsider the guidance technique in general. At the same time, this Article explores the effect of the FDA's decision to regulate by guidance and asks how the GM technology itself and public attitudes about GM use have been affected by reliance on this controversial regulatory method.[4]

It is not surprising that the FDA decided to regulate GM food by guidance. Guidance provides a way to regulate controversial subjects without exposing an agency to the full force of public backlash.[5] The subject of GM food elicits strong reactions from the general public.[6] Because most scientists regard the public reaction to GM food as irrational,[7] there are some good arguments for the strategy that the FDA has adopted. But an agency's use of guidance to fly under the radar of public controversy is one of the main reasons why the use of guidance has itself been controversial.

This Article argues that the present situation represents one controversy too many. Administrative guidance has been controversial particularly because it enables an agency to promulgate rules without resorting to the notice and comment

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INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOOD 34–38 (2009); DAVID VOGEL, THE POLITICS OF PRECAUTION: REGULATING HEALTH, SAFETY, AND ENVIRONMENTAL RISKS IN EUROPE AND THE UNITED STATES 73–91 (2012).

3. *See* John P. Holdron et al., *Improving Transparency and Ensuring Continued Safety in Biotechnology*, WHITE HOUSE (July 5, 2015, 2:57 PM), https://obamawhitehouse.archives.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology.

4. *Id.* The time is particularly relevant given that the U.S. government is halfway through a five-year study to reevaluate the regulatory process for GM food.

5. *See, e.g.*, Richard A. Epstein, *The Role of Guidances in Modern Administrative Procedure: The Case for De Novo Review*, 8 J. LEGAL ANALYSIS 47, 48 (2016) (the use of guidance allows agencies to expand their power and avoid legal constraints on their actions); James T. Hamilton & Christopher H. Schroeder, *Strategic Regulators and the Choice of Rulemaking Procedures: The Selection of Formal vs. Informal Rules in Regulating Hazardous Waste*, 57 LAW & CONTEMP. PROBS. 111, 130–34 (1994) (agencies can use guidance to circumvent oversight by both courts and elected officials); Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 407–08 (2007) (guidance does not expose an agency to the same level of judicial or political scrutiny as adoption of a rule); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166 (2000) (guidance avoids the scrutiny to which rulemaking is subject). Mendelson notes: "The prospect of 'compliance for less' is almost certainly among the reasons that agencies use guidance documents rather than go through the effort of notice-and-comment rulemaking." Mendelson, *supra*, at 408.

6. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS, at xiii (2016) [hereinafter NAS REPORT], http://nap.edu/23395 ("In carrying out this study, the committee members and I were well aware of the controversial nature of genetic engineering in the United States and globally.").

7. In effect, science denial from the left parallels the rejection of evolution and anthropogenic climate change from the right. *See infra* note 59 and accompanying text.

rulemaking procedure established by the APA.[8] Agencies justify the issuance of guidance by various means, but the most prominent is that it falls within an exception established by the APA for interpretive rules.[9] The existing criteria for determining whether a rule is truly interpretive are whether it truly interprets the language of the controlling statute and whether it has binding legal force.[10] This Article suggests that an additional criterion for determining the legal validity of guidance—one that might possibly replace the existing tests—is whether the subject matter of the rule is sufficiently controversial to elicit broad input from both interested parties and the general public. In that case, the standard and well-accepted method of notice and comment rulemaking should be used instead.

The marketing of GM food products certainly satisfies this public controversy criterion. This Article further argues that providing a forum for public debate through the notice and comment procedure, rather than attempting to circumvent or foreclose that debate through the use of guidance, would have beneficial effects for the GM food controversy itself. First, it would educate the public about the scientific findings regarding GM food and possibly decrease the resistance to its use. Members of the public may have concerns about GM food simply because of its extensive regulation; in other words, such regulation leads to the perception that GM food must be dangerous.[11] Second, it would allow a broader range of voices from within the GM industry to be heard, thereby enabling small, innovative firms to compete more effectively with the large, somewhat stodgy agricultural giants that currently dominate the field.[12] This is not to say that there is no place in modern government for expert decision-making that is insulated from public input, but rather that the choice between that approach and others that involve public debate should be based on principled considerations, not on the convenience of an agency or its comfortable relationship with the leading firms in the field that it regulates.

Part I of this Article briefly discusses the scientific basis of GM techniques and public understanding of those techniques. Part II describes the current legal regulation of GM food, particularly the FDA's use of a guidance document to regulate GM food products. Part III then discusses the use of guidance in administrative law in general, including the existing criteria of interpretation and legal bindingness, and the proposed criterion of public controversy. Finally, Part IV applies the discussion of guidance to the FDA's regulation of GM food. By using a practical example such as the FDA's regulation of GM food to illustrate the

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8. 5 U.S.C. § 553 (2012).

9. *Id.* § 553 (b)(A). *See infra* notes 157–161 and accompanying text.

10. *See infra* Section I.B.

11. *See* Peter M. Wiedemann & Holger Schutz, *The Precautionary Principle and Risk Perception: Experimental Studies in the EMF Area*, 113 ENVTL. HEALTH PERSP. 402, 402–05 (2005).

12. *See, e.g.*, *Biotechnology Consultations on Food from GE Plant Varieties*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon (last visited Dec. 4, 2017) (showing 73 submissions from Monsanto and 2 from Okanagan Specialty Fruits, suggesting large agricultural giants dominate the field).

controversy criterion, this Article provides an analysis that can be extrapolated to the proper use of guidance in other regulated areas.

I. THE SCIENCE OF GENETICALLY MODIFIED FOOD

A. Biotechnology and the Food Supply

People have been systematically altering the genetic composition of the food they eat for thousands of years.[13] Many of the plant and animal products that appear in even the earliest historical records resulted from centuries, if not millennia, of selective breeding and vary greatly from anything that could be found in nature.[14] Take one notable example: corn, or maize—now the world's leading source of human and domesticated-animal nutrition—cannot propagate without human intervention.[15] It was so extensively modified that the original plant from which it was developed, a form of grass called teosinte, was not identified until recent times.[16]

These selective-breeding techniques have achieved both superficial and substantive advantages. A superficial advantage might be a better-looking fruit or vegetable. A substantive advantage might be increased resistance to a particular pest or inhibition of a particular stress pathway. Historically, these breeding techniques combined two or more genes of interest (known as stacking) from wild relatives into the domesticated crop to confer such traits.[17] By the 20th century, scientists were able to employ a variety of techniques—such as hybridization, chemical mutagenesis, or irradiation—to alter the genetic profile of a particular crop and

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13. NAS REPORT, *supra* note 6, at 65 ("People have been domesticating plants for at least 10,000 years.").

14. ROBERT W. ALLARD, PRINCIPLES OF PLANT BREEDING 24–68 (2d ed. 1999); NINA FEDEROFF & NANCY MARIE BROWN, MENDEL IN THE KITCHEN: A SCIENTIST'S VIEW OF GENETICALLY MODIFIED FOOD 23–26 (2004); SUE HUBBELL, SHRINKING THE CAT: GENETIC ENGINEERING BEFORE WE KNEW ABOUT GENES 121–54 (2001); ROGER J. WOOD & VITEZSLAV OREL, GENETIC PREHISTORY IN SELECTIVE BREEDING: A PRELUDE TO MENDEL (2001) (development of domestic sheep in Europe through selective breeding); John Doebley, *Mapping the Genes that Made Maize*, 8 TRENDS GENETICS 302 (1992); Hugh H. Iltis, *From Teosinte to Maize: The Catastrophic Sexual Transformation*, 222 SCIENCE 886 (1983).

15. *See, e.g.*, NAS REPORT, *supra* note 6, at 66.

16. *See* FEDEROFF & BROWN, *supra* note 14, at 32–41; HUBBELL, *supra* note 14, at 11–12; PAUL C. MANGELSDORF, CORN: ITS ORIGIN, EVOLUTION AND IMPROVEMENT 21–26 (1974); CORN: HISTORY, TECHNOLOGY, AND PRODUCTION 7–15 (C. Wayne Smith et al. eds., 2004).

17. Natalie Weber et al., *Crop Genome Plasticity and Its Relevance to Food and Feed Safety of Genetically Engineered Breeding Stacks*, 160 PLANT PHYSIOLOGY 1842, 1842 (2012); *see also Pocket K No. 42: Stacked Traits in Biotech Crops*, INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APP., http://isaaa.org/resources/publications/pocketk/42/default.asp (last visited Dec. 6, 2017) ("Gene stacking refers to the process of combining two or more genes of interest into a single plant. . . . Compared to mono-trait crop varieties, stacks offer broader agronomic enhancements that allow farmers to meet their needs under complex farming conditions.").

select for desired traits.[18] However, these were all large-scale mutagenic techniques, which means that the seeds may contain hundreds to thousands of completely unknown or uncharacterized mutations.[19] Even with large-scale and unknown mutations, the resulting crops that make it through the commercialization process are safe.[20] Mutations that lead to chromosomal rearrangements, for example, often affect the plant's fertility and thus lead to its disappearance. Those plants that survive can be readily tested for well-known allergens or toxins.[21] According to well-respected scientists, "thus far, there is no evidence that a random genomic change in a crop has ever resulted in a novel safety issue, even when new alleles or genes were created."[22]

The next stage of GM developments was the use of rDNA techniques to alter crops.[23] Beginning in the 1970s, scientists were able to use the momentous discoveries about biological heredity achieved in the preceding century to emulate the biological processes of genetic inheritance in a laboratory setting.[24] Paul Berg's laboratory produced the first rDNA in bacteria in 1972.[25] Shortly thereafter, scientists learned how to synthesize human protein from a transgenic bacterium.[26]

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18. NAS REPORT, *supra* note 6, at 67 ("DNA mutation is relatively rare in nature, but scientists found that they could use chemicals or radiation to induce mutations in DNA at a much greater frequency." (internal citations omitted)).

19. Frank Hartung & Joachim Schiemann, *Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU*, 78 PLANT J. 742, 742 (2014).

20. Gregory Conko et al., *A Risk-Based Approach to the Regulation of Genetically Engineered Organisms*, 34 NATURE BIOTECHNOLOGY 493, 494 (2016).

21. One reason is the commercialization process where deleterious changes will impact fertility as well as the ability to test for well-known allergens and toxins. Weber, et al., *supra* note 17, at 1848–49 (discussing why neither large-scale mutations during breeding nor genetic engineering techniques cause safety issues).

22. *Id.* at 1849.

23. Recombinant DNA (rDNA) is a laboratory technique used to create the coding regions of a gene. *See* NAS REPORT, *supra* note 6, at 68–69; *see also* Conko et al., note 20, at 497.

24. *See* Paul Berg & Janet E. Mertz, *Personal Reflections on the Origins and Emergence of Recombinant DNA Technology,* 184 GENETICS 9, 9 (2010).

> Although the emergence of recombinant DNA technology was transformational in its impact, the tools and procedures that were the keys to its development largely emerged as enhancements and extensions of existing knowledge, *i.e.*, they were evolutionary, not revolutionary, in nature. What was novel was the numerous ways in which many investigators applied these technologies for analyzing and modifying gene structure and the organization of complex genomes.

Id.

25. David A. Jackson, Robert H. Symons & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and Glactose Operon of* Escherichia Coli, 69 PROC. NAT'L ACAD. SCI. 2904, 2904–09 (1972). Other laboratories were also working on similar experiments. *See* Berg & Mertz, *supra* note 24, at 11–14.

26. Berg & Mertz, *supra* note 24, at 12–13 (describing the creation of recombinant DNA in vitro).

These discoveries led to major advances in our ability to control genetic processes, including the ability to create transgenic mice that mimic human diseases and ailments, sequence entire genomes, produce genetically engineered human insulin, clone DNA, and clone animals—e.g., Dolly.[27] At the end of the twentieth century came perhaps one of the greatest scientific achievements in the entire field: the complete sequencing of the human genome.[28]

The modern biotechnology industry is based on these discoveries.[29] Equally essential to the growth of this industry was a legal development—the ability of private parties to patent the techniques used to create rDNA.[30] These patents provide the basis for biotechnology companies and many other types of firms, including large segments of the agriculture firms discussed later in this Article.

As the science of controlling genetic processes advanced, and the legal authority to profit from applications of this science became established, concerns arose about the application of the new technology.[31] Perhaps the greatest concern, expressed by Paul Berg and others, was that the manipulation of *E. coli* (and other bacterium that naturally exist in the human gut) could produce oncogenic or other biohazardous molecules and could end up infecting people—first laboratory personnel and then the general public.[32] In response, an 11-member committee was formed, with Paul Berg as chair, which formally communicated concerns about potential biohazards of genetic modification in a published letter in 1974.[33] In October 1974, the National Institutes of Health (NIH) responded to this letter by

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27. *See, e.g.*, Rudolf Jaenisch & Beatrice Mintz, *Simian Virus 40 DNA Sequences in DNA of Healthy Adult Mice Derived from Preimplantation Blastocysts Injected with Viral DNA*, 71 PROC. NAT'L ACAD. SCI. 1250, 1250–54 (1974); Masashi Kitazawa, Rodrigo Medeiros & Frank M. LaFerla, *Transgenic Mouse Models of Alzheimer Disease: Developing a Better Model as a Tool for Therapeutic Interventions*, 18 CURRENT PHARMACEUTICAL DESIGN 1131, 1132 (2012); I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810, 810–13 (1997) (describing Dolly); Press Release, Genentech, First Successful Laboratory Production of Human Insulin Announced (Sept. 6, 1978), https://www.gene.com/media/press-releases/4160/1978-09-06/first-successful-laboratory-production-o.

28. *All About the Human Genome Project*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/10001772/all-about-the—human-genome-project-hgp/ (last updated Oct. 1, 2015). On the political setting on this effort, see VICTOR K. MCELHENY, DRAWING THE MAP OF LIFE: INSIDE THE HUMAN GENOME PROJECT (2010).

29. Berg & Mertz, *supra* note 24, at 15.

30. *Id.*

31. *Id.* at 13, 15; Paul Berg et al., Letter to the Editor, *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303, 303 (1974) [hereinafter *Potential Biohazards*]; Paul Berg et al., Letter to the Editor, *NAS Ban on Plasmid Engineering*, 250 NATURE 175 (1974); Roger B. Dworkin, *Science, Society and the Expert Town Meeting: Some Comments on Asilomar*, 51 S. CAL. L. REV. 1471, 1471–72 (1978); Glenn Davis Stone, *Both Sides Now: Fallacies in the Genetic Modification Wars, Implications for Developing Countries, and Anthropological Perspectives*, 43 CURRENT ANTHROPOLOGY 611 (2002).

32. *See* Berg et al., *Potential Biohazards*, *supra* note 31.

33. Berg & Mertz, *supra* note 24, at 16; Berg et al., *Potential Biohazards*, *supra* note 31 (requesting the NIH to create an advisory committee).

creating the Recombinant DNA Molecule Program Advisory Committee (RAC), which in turn, established an oversight process for DNA research.[34]

Over time, researchers have become more knowledgeable and comfortable with rDNA technology. To date, not a single reported public health incident has occurred despite millions of laboratory experiments with rDNA.[35] With experience and knowledge, the guidelines for working with rDNA have evolved over time.[36] During this same period of time, the potential advantages of this technology have become apparent. Application of modern molecular biology to the clinical setting is associated with major advances in the detection, prevention, and treatment of diseases, such as Herceptin and Tamoxifen for the treatment of breast cancer and anti-CD20 antibody for treatment of lymphoma.[37]

As biomedical research advanced our understanding of molecular mechanisms, plant biologists used this knowledge to develop new agricultural products through genetic modification.[38] In other words, they were able to achieve

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34. The guidelines were published in the Federal Register. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902–27,943 (1976); *see also* Berg & Mertz, *supra* note 24, at 16; INST. OF MED. OF NAT. ACADS., OVERSIGHT AND REVIEW OF CLINICAL GENE TRANSFER PROTOCOLS: ASSESSING THE ROLE OF THE RECOMBINANT DNA ADVISORY COMMITTEE 33 (2014) [hereinafter OVERSIGHT AND REVIEW], https://www.nap.edu/catalog/18577/oversight-and-review-of-clinical-gene-transfer-protocols-assessing-the.

35. Berg & Mertz, *supra* note 24, at 16 ("In the over three decades since adoption of these various regulations for conducting recombinant DNA research, many millions of experiments have been performed without reported incident. No documented hazard to public health has ever been attributable to the applications of recombinant DNA technology."); *see also* OVERSIGHT AND REVIEW, *supra* note 34, at 29.

> Many original uncertainties have been replaced by scientific clarity, and fears have been alleviated by decades of experience. Some of the early concerns about gene therapy, such as the perceived danger of creating transmissible pathogens, accidental germ-line modification, and unspecified xenogeneic dangers, have not been verified by clinical experience [citation omitted]. In general, risks that gene transfer might originally have been thought to pose to third parties and society at large have been determined to be minimal [citation omitted].

Id. (internal citations omitted).

36. *See, e.g.*, DEP'T OF HEALTH AND HUMAN SERVS., *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, NAT'L INST. OF HEALTH (Apr. 2016), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html; *see also* Henry I. Miller, *Genetic Engineering Applied to Agriculture Has a Long Row to Hoe*, 9 GM CROPS & FOOD 45, 46–47 (2017) (urging learning from the lessons of the Asilomar conference regarding creating guidelines for something that may not need guidelines).

37. *See, e.g.*, GEOFFREY M. COOPER, THE CELL: A MOLECULAR APPROACH, (2d ed. 2000), https://www.ncbi.nlm.nih.gov/books/NBK9934/ ("A major milestone in the rational development of drugs targeted against specific oncogenes was reached in 1998, when the FDA approved Herceptin for treatment of metastatic breast cancer.").

38. NAS REPORT, *supra* note 6, at 72 ("Throughout the 1980s, academic laboratories and companies set out to produce plants that could be released as commercial products.").

the same sorts of results that had previously been achieved through selective breeding, hybridization, chemical mutagenesis, or irradiation, but did so systematically, precisely, and much more rapidly. The predominant technology is the use of transgenes; that is, the transfer of genetic material from one organism to another.[39] This technology has enabled breeders to introduce genetic material into a seed that could not have been introduced by previous methods; examples include the transfer of genes from an insect-killing bacterium into corn plants (*Bt* corn)[40] and the transfer of an herbicide-tolerant gene into a variety of crops.[41] In addition, genetic engineering techniques have been able to overcome the limitations that afflicted previous breeding methods. Even if previously developed techniques introduce mutations into the seed's genome, it is difficult to create a new protein with a novel biochemical function due to the requirements that proteins must be properly folded to be active and that they must be advantageous to the organism or they will be selected out.[42] GM technology addresses this limitation.

Over the past 15 years, the arsenal of GM techniques has expanded enormously.[43] For example, the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats/Cas (CRISPR-associated)) system is a recently discovered and applied technique that allows for specific, site-directed mutagenesis.[44] By doctoring

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39. *See* Hartung & Schiemann, *supra* note 19, at 743.

40. The Cry protein(s) from an insect were isolated and inserted into crops, e.g., corn. This allows the modified corn to have an intrinsic mechanism to fend off the corn-borer pest. The Cry proteins are effective against pests but are safe for human consumption. Matthew Niederhuber, *Insecticidal Plants: The Tech and Safety of GM Bt Crops*, HARV. U.: SCI. NEWS (Aug. 10, 2015), http://sitn.hms.harvard.edu/flash/2015/insecticidal-plants/.

41. Todd Funke et al., *Molecular Basis for the Herbicide Resistance of Roundup Ready Crops*, 103 PROC. NAT'L ACAD. SCI. 13010, 13010 (2006).

> Glyphosate-based herbicides, such as Roundup, target the shikimate pathway enzyme 5-enolpyruvylshikimate 3-phosphate (EPSP) synthase, the functionality of which is absolutely required for the survival of plants. Roundup Ready plants carry the gene coding for a glyphosate-insensitive form of this enzyme, obtained from *Agrobacterium* sp. strain CP4. Once incorporated into the plant genome, the gene product, CP4 EPSP synthase, confers crop resistance to glyphosate.

Id.; *see also* Hartung & Schiemann, *supra* note 19, at 742–43.

42. *See* Weber et al., *supra* note 17, at 1847. One of the earliest examples of the development and commercialization of genetically engineered food was the FlavrSavr tomato, created by Calgene, Inc. in the 1990s. Ordinary tomatoes, if allowed to ripen on the vine, become soft by the time they are transported to market; instead, they are picked when unripe and artificially ripened, which impairs their flavor. The FlavrSavr tomato was genetically engineered to remain firm longer. Thus it could be vine ripened and transported to market without becoming soft, preserving the flavor and texture of a tomato that had been picked directly from the plant. NAS REPORT, *supra* note 6, at 72.

43. NAS REPORT, *supra* note 6, at 355–78 (describing "an array of genomic technologies").

44. Khaoula Belhaj et al., *Plant Genome Editing Made Easy: Targeted Mutagenesis in Model and Crop Plants Using the CRSIP/Cas System*, 9 PLANT METHODS 39, (2013); Tereza Sovoa et al., *Genome Editing with Engineered Nucleases in Economically Important Animals and Plants: State of the Art in the Research Pipeline*, 21 CURRENT ISSUES

the natural system, scientists can introduce site-specific DNA breaks in a plant genome and mutate the endogenous DNA.[45] Even though some non-directed, off-target mutations are possible, these can be bred out through development and commercialization processes.[46] Because of the nature of the technique, the modifications to the DNA "are indistinguishable from those introduced by conventional breeding and chemical or physical mutagenesis."[47]

B. Scientific and Public Responses to GM

At the time that scientists began creating GM crops, government regulators, independent scientists, and other private parties began to express concerns that, to some extent, paralleled the concerns expressed when the technology was first developed.[48] These included the possibilities that genetic manipulations could lead to the increased expression of endogenous toxins or allergens, or to genetic instability with large-scale insertions, deletions, or other genetic rearrangements.[49] The possibility that a novel toxin or allergen could be created by genetic instability seemed particularly threatening. Opponents to GM food issued dire warnings about "Frankenfood" that were rampant—and continue to be rampant—in the popular press and on the Internet.[50]

In 2016, after many academic studies over a period of several decades, the National Academies of Sciences, Engineering, and Medicine (NAS) issued an

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MOLECULAR BIOLOGY 41, 41 (2016). The possibilities of this technique may in fact be momentous when applied to human beings. *See* JENNIFER A. DOUDNA & SAMUEL STERNBERG, A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL EVOLUTION 66–69 (2017); JIM KOZUBEK, MODERN PROMETHEUS: EDITING THE HUMAN GENOME WITH CRISPR-CAS9, at 10–13 (2016); JOHN PARRINGTON, REDESIGNING LIFE: HOW GENOME EDITING WILL TRANSFORM THE WORLD (2006). As applied to plants, however, it is simply a further development of existing GM technology.

45. Belhaj et. al, *supra* note 44, at 39–45.

46. *Id.* at 39, 45–46.

47. *Id.*

48. *See Potential Biohazards*, *supra* note 31.

49. *See, e.g.*, JENKINS, *supra* note 2, at 55–76, 123–48; ALAN MCHUGHEN, PANDORA'S PICNIC BASKET: THE POTENTIAL HAZARDS OF GENETICALLY MODIFIED FOODS 160–81 (2000); POLLACK & SHAFFER, *supra* note 2, at 33–84; JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS 73–79 (2007); VOGEL, *supra* note 2, at 73–91. *See generally* Kieran Tuohy, Ian R. Rowland & Paul C. Rumsby, *Biosafety of Marker Genes—The Possibility of DNA Transfer from Genetically Modified Organisms to the Human Gut Microflora*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 110 (Keith T. Atherton ed., 2003).

50. *See* JEFF GILMAN & ERIC HEBERLIG, HOW GOVERNMENT GOT INTO YOUR BACKYARD: SUPERWEEDS, FRANKENFOODS, LAWN WARS AND THE (NONPARTISAN) TRUTH ABOUT ENVIRONMENTAL POLICIES (2011); *see also* MICHAEL WALD, FRANKENFOODS: GMO CONTROVERSY, LIES AND YOUR HEALTH (2014); Jim Hightower, *Frankenfood: Corporate Engineers Tinker Merrily and Dangerously with the DNA of Food* (2004), http://www.utne.com/community/frankenfood; *see also* STEVEN DRUCKER, ALTERED GENES, TWISTED TRUTH (2015); SMITH, *supra* note 49. The term was coined in a 1992 letter to the New York Times. FEDEROFF & BROWN, *supra* note 14, at 8.

extensive report summarizing the research about the safety of GM.[51] It concluded that GM crops pose no greater risk to health, safety, environment, and biodiversity than crops developed by selective breeding or previously developed means of induced variation.[52] The NAS was equivocal about whether GM crops would achieve the advantages that their proponents claimed for them, both at present and in the future,[53] but not about the safety of these crops. On that issue, there was a scientific consensus.[54]

However, it seems fair to say, that despite the scientific consensus on the safety of GM food, the public has not been convinced. According to a recent survey by the Pew Research Center, 39% of Americans believe that GM foods are "worse for health than foods with no GM ingredients."[55] Public awareness of the issue is

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51. NAS REPORT, *supra* note 6.

52. *Id.* Specific conclusions, stated in terms of genetic engineering (GE) included the following:

- "Overall, the committee found no evidence of cause-and-effect relationships between GE crops and environmental problems[.]" *Id.* at 154.
- "[T]he research that has been conducted in studies with animals on chemical composition of GE food reveals no differences that would implicate a higher risk to human health from eating GE foods than from eating their non-GE counterparts." *Id.* at 236.
- "There is some evidence that GE insect-resistant crops have had benefits to human health by reducing insecticide poisonings and decreasing exposure to fumonisins." *Id.*
- "On the basis of the research that is available, the committee concludes that existing GE crops have generally been useful to large-scale farmers of cotton, soybean, maize and canola. The same GE crops have benefited a number of smaller-scale famers, but benefits have varied widely across time and space, and are connected to the institutional context in which the crops have been deployed. Small-scale farmers were more likely to be successful with GE crops when they also had access to credit, extension services, and markets and to government assistance in ensuring an accessible seed price." *Id.* at 333.
- "To contribute to alleviation of hunger in food-insecure populations on and off farms, more GE crops and GE crop traits will need to be developed in ways that increase potential yield, protect yield from biotic and abiotic stresses, and improve nutritional quality. Even if that is accomplished, the ability of GE crops to alleviate hunger will depend on the social and economic contexts in which the technology is developed and diffused." *Id.* at 334.

53. *See, e.g.*, *id.* at 330–31; L. Val Giddings & Henry Miller, *US National Academies Report Misses the Mark*, 34 NATURE BIOTECHNOLOGY 1226, 1226 (2016).

54. NAS REPORT, *supra* note 6, at 236. For confirming views by individual scientists, see FEDEROFF & BROWN, *supra* note 14; Chelsea Snell et al., *Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: A Literature Review*, 50 FOOD & CHEMICAL TOXICOLOGY 1134, 1134–35 (2012); Weber et al., *supra* note 17, at 1849 ("Thus far, there is no evidence that a random genetic change in a crop has ever resulted in a novel safety issue, even when new alleles or genes were created.").

55. FUNK & KENNEDY, *supra* note 2, at 3–5. Notable in the Pew Report is the response that a majority of Americans think that organic food is healthier than conventional food. A similar result was found in Joanna K. Sax & Neal Doran, *Food Labeling and*

relatively high: 29% of Americans report that they have heard "a lot" about GM foods, while only 19% report that they have heard "nothing at all."[56] However, the factual content of this awareness is more limited: only half (51%) believe that some of their food has GM ingredients.[57] A large majority of Americans (69%) believe that GM foods will increase the world's food supply, and more than half (56%) think that GM foods will lead to lower prices; the same number who think they are unhealthy (39%) think that they will "create problems for the environment."[58]

A striking aspect of the Pew findings is that, in contrast to attitudes toward climate change (another leading area of science denial), attitudes toward GM food are not correlated with political ideology. While those who are worried about climate change tend to be progressive and democratic, the proportions of Democrats and Republicans who are greatly concerned or somewhat concerned about GM foods are—remarkably—almost identical. Those who are greatly concerned comprise 16% of Democrats and 16% of Republicans; those who are somewhat concerned comprise 39% of Democrats and 34% of Republicans.[59] Other possible correlations are also strikingly absent. Older Americans tend to be less concerned, but only by

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Consumer Associations with Health, Safety and Environment, 44 J.L., MED. & ETHICS 630, 633 (2016).

56. FUNK & KENNEDY, *supra* note 2, at 44.

57. *Id.* This is simply false; most foods have GM ingredients. Caroline Young, *7 Most Common Genetically Modified Foods*, HUFFINGTON POST (Dec. 3, 2013, 8:28 AM), https://www.huffingtonpost.com/builtlean/diet-and-nutrition_b_4323937.html ("[I]n reality, much of what we eat on a daily basis is a genetically modified organism (GMO).").

58. FUNK & KENNEDY, *supra* note 2, at 46–49. Perhaps one reason for a disconnect between the scientific consensus and public perception is the existence of a well-funded, anti-GMO movement that has spread misinformation and lies about agricultural biotechnology. *See, e.g.*, Michelle Miller, *Who Funds the Grassroots Anti-GMO Movement?*, GENETIC LITERACY PROJECT (Sept. 15, 2016), https://geneticliteracyproject.org/2016/09/15/funds-grassroots-anti-gmo-movement/; *see also* William Saletan, *Unhealthy Fixation*, SLATE, (Jul. 15, 2015, 5:45 AM), http://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html.

59. FUNK & KENNEDY, *supra* note 2, at 50. The Pew Study of attitudes toward climate change found that "[a] substantial majority of Democrats (79%) say there is solid evidence that the average temperature on earth has been increasing over the past few decades, and 53% think the earth is warming mostly because of human activity. Among Republicans, only 38% agree the earth is warming and just 16% say warming is caused by humans." PEW RES. CTR., LITTLE CHANGE IN OPINIONS ABOUT GLOBAL WARMING: INCREASING PARTISAN DIVIDE ON ENERGY POLICIES 3 (2010), http://www.people-press.org/2010/10/27/little-change-in-opinions-about-global-warming/.

very slight margins.[60] There is no difference on the basis of race.[61] Differences on the basis of family income are slight and seemingly random.[62] Those in the lowest category of educational attainment show the lowest level of concern, but here again, the differences are slight.[63] The one demographic variable that does seem to make a difference is gender, but even here, the difference appears only among those who are greatly concerned (20% of women, 12% of men) and not among those who are somewhat concerned (39% of women, 34% of men).[64]

Perhaps equally surprising, people's level of scientific knowledge did not produce a clearer pattern regarding the perceived dangers of GM food than did the demographic variables. Pew ranked science knowledge as high, medium, or low based on a nine-item test.[65] While higher levels of knowledge were associated with a more sanguine view of GM foods' potential advantages, they did not lead to any significant difference in views regarding the potential dangers.[66] The Pew Study

60. FUNK & KENNEDY, *supra* note 2, at 53. For the four identified age groups, the numbers of those who were greatly concerned and those who were somewhat concerned, respectively, were as follows: 18–29: 18%, 37%; 30–49: 18%, 39%; 50–65: 16%, 40%; and over 65: 13%, 29%. *Id.* The variation of any group from the general population, for which the numbers are 16% and 37%, is clearly slight. *Id.*

61. For the three identified racial groups, the number of those who were greatly concerned and those who were somewhat concerned, respectively, were as follows: White: 16%, 38%; Black: 17%, 31%; Hispanic: 17%, 38%. *Id.*

62. *Id.* For the five identified income categories, the number of those who were greatly concerned and those who were somewhat concerned, respectively, were as follows: above $100,000: 17%, 37%; $75,000–$99,999: 16%, 38%; $50,000–$74,999: 23%, 35%; $30,000–$49,999: 17%, 41%; and under $30,000: 14%, 34%. *Id.* The one notable outlier is the 23% greatly concerned for the middle category, but the figure is difficult to interpret because the categories both above and below it show the typical distribution. The variation might be significant for a category that was salient to its members, such as race or political party, but it is hard to imagine that people in this middle-income category are aware of any difference between them and those who are immediately above and below them in family income. Moreover, the variation from the mean is quite small when compared to the variation on climate change on the basis of political affiliation. PEW RES. CTR. *supra* note 59, at 3–4.

63. FUNK & KENNEDY, *supra* note 2, at 53. For the four identified education levels, the number of those who were greatly concerned and those who were somewhat concerned, respectively, were as follows: postgraduate degree: 17%, 40%; college degree: 22%, 38%; some college: 17%, 39%; high school or less: 12%, 34%. *Id.* A future survey study may seek to understand whether religious beliefs also play a role in public perception.

64. *Id.* The reason for this one disparity is far from obvious, although, as the Report points out, it is consistent with other Pew studies that reveal higher levels of skepticism about technological advances among women than among men.

65. For the test questions, see FUNK & KENNEDY, *supra* note 2, at 96–99. Two examples: "Which of the following conditions can be treated effectively by antibiotic medications?" (choices were viral, fungal, bacterial, or allergic; 44% of the people surveyed gave the correct answer); "Which gas makes up most of the Earth's atmosphere?" (only 27% of the people surveyed gave the correct answer). *Id.* at 97, 99.

66. *Id.* at 61–62. Of those whose science knowledge ranked high, 41% thought that GM would increase the world's food supply, as opposed to just 11% for those whose science knowledge ranked low, and 35% of those with high knowledge thought that GM would lead to more affordably priced food, as opposed to 13% of those with low knowledge.

found that Americans generally express confidence in the information provided by scientists about GM foods: 35% reported that they trusted scientists "a lot," which was somewhat more than the number who trusted information provided by small farm owners (29%), and much more than the number who trusted information provided by food industry leaders (10%), the news media (9%), or elected officials (an amazingly low 4%).[67] When those who trusted the information "some" (as opposed to "not too much" or "not at all") are added, scientists scored 78%, which seems notably high.[68] Small farmers caught up to them,[69] but other groups lagged well behind: 42% for food industry leaders, 45% for the news media, and a sorry 25% for elected officials.[70] Oddly, however, this trust in scientists did not lead to an understanding of their conclusions. While 63% of Americans surveyed thought that scientists understood the health effects of GM foods "very well" or "fairly well,"[71] only 14% of the respondents knew that "almost all" scientists believe that GM foods are safe to eat.[72] Another 28% thought that more than half, but not most of the scientists, came to this conclusion, while 54% thought that fewer than half the scientists thought GMs were safe, with 23% believing that "almost none" of the scientists thought these foods were safe.[73]

Id. at 57. But the proportions of those who thought that GM foods would create problems for the environment were considerably closer and went in the opposite direction—19% of high-knowledge people thought that GM food would create problems for the environment, as opposed to 13% of those with low knowledge. *Id.* And the proportions of those who thought the GM foods would cause health problems in the general population was virtually the same—11% as opposed to 12%. *Id.*

67. *Id.* at 61–62. As might be expected, those with higher levels of science knowledge trusted scientists more than those with lower levels. *Id.* at 17–18.

68. *Id.* at 60–61.

69. *Id.* (showing 78% for Americans who trust small farm owners about GM foods a lot or some).

70. *Id.* at 61–62. Somewhat remarkably, given the apparently high levels of trust in scientifically generated information, Americans view scientists who study food as being subject to a wide variety of motivations, not all of them associated with reliability. While 81% said that scientists base their findings on the best-available evidence, and 67% said that scientists had the public's best interests in mind, 80% thought that scientists were motivated by the desire to help "their industries," 78% thought scientists were motivated by the desire to advance their careers, and 69% thought scientists were motivated by their political preferences. *Id.* at 63. It may be that each of these questions conjured up a plausible image in the interviewees' minds, or that the questions led the interviewees to picture two different kinds of scientists: independent university researchers in response to questions about evidence and public interest, versus company scientists for questions about industry. *See id.* at 61–65.

71. *Id.* at 60. Only 19%, however, thought that scientists understood the issue "very well." *Id.* This may reflect the sense of uncertainty that accompanies a new technology. Most scientists would probably agree that the consequences of genetic modification are not certain. *See* DOUDNA & STERNBERG, *supra* note 44, at 116.

72. FUNK & KENNEDY, *supra* note 2, at 58–59.

73. *Id.* at 59. The authors add, "those who view GM foods as worse for health are especially inclined to say that there is little agreement among scientists about the safety of GM foods." *Id.* They also add, "[p]ast Pew Research Center studies have found a similar

Consistent with the expressed levels of confidence, most people thought that scientists should play a major role in public policymaking about GM foods, and most thought that the general public should play a major role as well.[74] Of those who expressed "a great deal" of concern about GM foods, 78% thought the general public should play a major role, followed by small farmers (73%), scientists (66%), food-industry leaders (41%), and in last place again, elected officials (39%).[75] Of those who identified as having some concern about the issue, scientists came in first at 64%, the general public and small farmers were close behind at 61% each, food-industry leaders scored 43%, and elected officials were again at the bottom, this time with only 26% believing they should play a major role in policymaking.[76] Among those who were concerned "not too much" or "not at all," the proportions were lower, as might be expected. Scientists were again in the lead with 55%, followed closely by small farm owners with 54%, and the general public with 47%, while elected officials scored an abysmal 17%.[77]

To summarize, people trust scientists a great deal both to provide accurate information and formulate good public policy about the safety of GM food. But many do not agree with the conclusions that scientists have reached, nor do they understand that these conclusions represent a consensus in the scientific community. A significant number of people continue to express strong or fairly strong concerns about the issue. However, the source of this concern is unclear because it is not correlated with political views, age, race, income, or scientific knowledge, and only moderately correlated with gender, which standing alone, does not have much explanatory force.[78] People also want the general public to play a major role in making policy, but they do not trust elected officials to either provide accurate information or to make good policy decisions.

II. THE REGULATORY RESPONSE TO GENETICALLY MODIFIED FOOD

In response to the concerns raised by scientists, informed observers, and the general public about the safety of GM food, federal regulators turned their attention to the subject in the early 1980s.[79] They faced at least two complexities in doing so. The first was the intrinsic complexity that GM food represented the advancing edge of technological development, so regulators did not possess, and could not possess, the level of knowledge that is desirable when deploying government authority to achieve particular results. The second complexity, extrinsic

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pattern when it comes to perceptions of scientific consensus and beliefs about climate change as well as beliefs about evolution." *Id.*

74. *Id.* at 66.

75. *Id.* at 67.

76. *Id.*

77. *Id.*

78. For a discussion of the complexity of decision-making and how it might relate to this area, see Joanna K. Sax, *Biotechnology and Consumer Decision-Making*, 47 SETON HALL L. REV. 433, 448–454 (2017).

79. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

to the substantive issue but nonetheless quite real, was that questions regarding the safety of GM foods fell within the purview of at least three different federal agencies: the United States Department of Agriculture (USDA), a cabinet-level executive agency that regulates the production and marketing of products grown on farms; the Environmental Protection Agency (EPA), a non-cabinet executive agency that regulates actual and potential threats to human health resulting from disruption of the environment; and the FDA, a unit of another cabinet agency—the Department of Health and Human Services—that regulates the safety of all food and cosmetic products sold for human use.[80]

The response to these complexities, quite reasonably, was to convene representatives of the three agencies, and other agencies whose mission might be relevant, to develop a "Coordinated Framework" for addressing the safety issue regarding GM foods. This Part describes and discusses the Coordinated Framework. It begins with an overview, then addresses the role of each of the three agencies involved, and ends with an account of the FDA guidance that functions within the Coordinated Framework but serves as the decisive set of rules for GM foods. Because this Article focuses on the role of the FDA, the actions of the other agencies, although not irrelevant to the discussion, will be dealt with summarily and largely for the purpose of providing the context for the FDA decision.

A. The Coordinated Framework

Once the Coordinated Framework was developed, it was published in the Federal Register in preliminary form and opened to public comment for a 60-day period.[81] The document declared the intention that "the policies contained herein be effective immediately."[82] It then stated, "[i]n consideration of comments, modifications, if any, may be published either in a separate notice or as part of proposed rulemaking by the involved agencies."[83] After the notice and comment period, the Framework went through at least two iterations, with the most recent (and currently applicable) policy promulgated in 1992.

The procedure adopted by the Office of Science and Technology Policy (OSTP) was the functional equivalent of rulemaking subject to the notice and comment requirements of the APA, as will be described in further detail below.[84] It

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80. For a description of each agency's role in the Coordinated Framework, see *How the Federal Government Regulates Biotech Plants*, U.S. DEP'T AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles (last visited May 29, 2018).

81. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

82. *Id.*

83. *Id.*

84. In 1976, Congress established the White House Office of Science and Technology Policy (OSTP) to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technical aspects of the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources, among other topics.

was not itself a rule, however, but a sort of meta-rule that represented a commitment by the OSTP that it would exercise its discretionary authority in particular ways, and that the agencies with regulatory authority would exercise that authority by adopting further rules. Its declared purpose was

> [T]o guide the exercise of agencies' oversight, within the scope of the authority afforded by statute, to ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions. This approach therefore focuses on the characteristics and risk posed by the introduction, rather than on the process by which a product is created.[85]

The OSTP went on to say that "nothing in this document displaces agencies' duties under applicable statutes, nor does this document provide the basis for additional authority not available to agencies under applicable law. Rather, this document guides the exercise of discretion within the range of authority left to agencies under their statutes."[86] As the Coordinated Framework recognized, the principal agencies responsible for implementing its policies—that is, the EPA, USDA, and FDA—were operating under the authority of their authorizing statutes that existed at the time.[87] No new legislation was enacted to regulate GM food, and no such legislation has been enacted since then.[88] It was understood that the three agencies would proceed to exercise their existing authority in accordance with the APA, which both empowers agencies to make rules and adjudicate cases, and imposes procedural requirements on the way in which they carry out these basic functions. Each agency was charged with addressing a different aspect of the issue,[89] and each interpreted its statutory authority, its procedural requirements under the APA, and the terms of the Coordinated Framework in a different way.[90] There is thus some doubt whether the Coordinated Framework represented true coordination, where the individual agencies worked together to solve problems through cooperative efforts, or whether it was simply a means of defining the separate jurisdictions of the agencies,

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Office of Science and Technology Policy, WHITE HOUSE, https://www.whitehouse.gov/ostp/about (last visited Dec. 4, 2017).

85. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753-01, 6755. (Feb. 27, 1992). The OSTP acknowledged that "[j]ust as with traditional breeding techniques, the production of organisms using new molecular techniques of genetic manipulation may or may not pose risk, depending on the characteristics of the organism, the target environment, and the type of application." *Id.*

86. *Id.* at 6757.

87. These statutes were as follows: the Plant Protection Act (PPA), 7 U.S.C. §§ 7701–7786 (2012); the Federal Fungicide, Insecticide and Rodenticide Act (FIRA), 7 U.S.C. §§ 136–136y (2012); and the Federal Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. §§ 301–399i (2012).

88. Conko et al., *supra* note 20, at 495.

89. *Id.* at 495–96.

90. *Id.*

functioning as a sort of treaty that would allow each agency to maintain its regulatory preserve.

B. The Role of the EPA and USDA

The EPA is responsible, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), for the safety of all pesticides used on agricultural products.[91] The FIFRA establishes a registration procedure by which anyone who wants to make use of a pesticide must file an application with the EPA documenting the nature of the product and demonstrating its safety.[92] The EPA then evaluates each application on an individualized basis.[93] If it finds the product safe, either initially or after the applicant has made requested modifications, it issues the registration.[94] The registration is defined as an "order" by the APA, which means that the EPA's process for issuing it is considered an "adjudication." The EPA has the authority to issue rules providing generalized standards for pesticide approvals, but thus far it has not done so.

In applying the FIFRA to GM foods, the role recognized by the Coordinated Framework, the EPA treats GM plants to resist disease as pesticides.[95] One of the most important uses of GM is to produce plants that are intrinsically resistant to pests, which decreases the need for external application of a chemical pesticide.[96] Such modifications, called Plant Incorporated Protectants (PIPs), achieve their effects by enhancing the natural processes by which plants resist pests—a technique that is generally regarded by scientists as creating no additional risk.[97] The EPA's decision to treat PIPs as pesticides means that they are required to undergo extensive pre-market regulatory review followed by extensive post-market regulatory compliance, just like the chemical pesticides they are designed to replace.[98]

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91. 7 U.S.C. §§ 136(u), 136a(a).
92. 7 U.S.C. § 136a(c)(1)(C)–(D).
93. 7 U.S.C. §136a(c)(3)(A).
94. *Id.*
95. Conko et al., *supra* note 20, at 495–96.
96. Brian A. Federici, *Case Study: Bt Crops, a Novel Mode of Insect Control*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 164, 164 (Keith T. Atherton ed., 2002); Ivan E. Gard, Michael F. Treacy & John J. Wrubel, *Case Study: Recombinant Baculoviruses as Microbial Pest Agents*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 201, 201–02 (Keith T. Atherton ed., 2002); Hector Quemada, *Case Study: Virus-Resistant Crops*, *in* GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 219, 222 (Keith T. Atherton ed., 2002).
97. The EPA treats a PIP as a pesticide by invoking the "active ingredient" definition in the FIFRA, which reads, in part: "[I]n the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest[.]" 7 U.S.C. § 136(a)(1). Eleven scientific societies with expertise in plant breeding provided comments to the EPA that the PIP rule was scientifically incorrect, stigmatizing, and unwise policy. ROGER N. BEACHY ET AL., APPROPRIATE OVERSIGHT FOR PLANTS WITH INHERITED TRAITS FOR RESISTANCE TO PESTS 2–3 (1996). The EPA could have used its discretion sensibly to not treat these plants as pesticides.
98. In addition to the regulatory requirements that result from the characterization of plants that have been genetically modified to resist disease as pesticides, the product must

The USDA is authorized by the Plant Protection Act (PPA) to regulate plant pests.[99] It carries out this responsibility through the Animal and Plant Health Inspection Service (APHIS), a component agency.[100] Unlike the EPA, APHIS does not rely on the statutory provisions alone to make determinations regarding the status of plant pests, but rather it has issued several regulations, or rules, to ramify the statutory language and direct its individualized determinations.[101] The principal regulation defines a "regulated article," that is, something subject to APHIS's full prior approval requirements, as:

> [a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in §340.2 and meets the definition of plant pest.[102]

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be labeled as such. 7 U.S.C. § 136(p). The label itself can create confusion for consumers; most members of the public are unlikely to understand what it means to label a piece of fruit as a pesticide. *See, e.g.*, Conko et al., *supra* note 20, at 495 fig.1 (using Honey Sweet Plum as an example of how the current framework leads to pesticide labeling of a pest-resistant GM fruit).

99. 7 U.S.C. § 7711. The Act defines a "plant pest" as:

> any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

7 U.S.C. § 7702(14).

100. 7 U.S.C. § 7701.

101. Regulations to Improve Management and Oversight of Certain Regulated Articles, Pub. L. No. 110–234, tit. X, § 10204, 122 Stat. 1343 (2008); Pub. L. No. 110–246, tit. X, §10204, 122 Stat. 1664, 2105 (2008).

> (a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act [June 18, 2008], the Secretary [of Agriculture] shall— ''(1) take action on each issue identified in the document entitled 'Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework', dated October 4, 2007; and ''(2) as the Secretary considers appropriate, promulgate regulations to improve the management and oversight of articles regulated under the Plant Protection Act.

7 U.S.C. § 7701 (2012).

102. 7 CFR § 340.1 (2018). The remainder of the definition goes on to say:

> or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.

Id.

This definition turns out to be both over- and underinclusive. Many genetically engineered plants that have been field tested over the past 30 years have promoters that contain parts of the genetic sequence of *Agrobacterium tumefaciens*, the cause of crown gall disease in plants, or of the cauliflower mosaic virus.[103] Because the organisms from which these snippets of transgenes are derived are considered plant pests, the crop, simply by having a promoter sequence, becomes subject to review by APHIS. On the other hand, some GM plants are now produced without any DNA sequences from a known plant pest, and can thus avoid review by APHIS (although they may be regulated by the EPA and the FDA) even though they do not include a full-length DNA sequence encoding a protein for that plant pest.[104] It is possible that the genetically engineered crop could actually function as a plant pest, but the APHIS regulations would not apply to it because none of its gene sequences originated in an organism that would fit into this category.[105]

In place of a new rule to address the specifics of GM food, APHIS has issued a series of guidance documents to assist developers and manufacturers to petition for deregulated status.[106] Depending on the intended introduction of the genetically engineered organism, a developer or manufacturer will have to apply for notification or permit,[107] with notification status being much more limited than the permit status.[108] However, APHIS has an extension process available whereby a manufacturer can qualify for notification status by essentially piggybacking off of the data known about a previously deregulated article.[109]

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103. Conko et al., *supra* note 20, at 496. A promoter is a noncoding sequence; in other words, it does not translate to a protein.

104. *Id.*

105. In 2008, APHIS issued a proposed rule to amend the regulations for genetically engineered organisms that attempted to solve the overinclusiveness problem by aligning the regulations with the developments in GM technology. Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60008, 60008 (Oct. 9, 2008) (to be codified at 7 C.F.R. § 340). According to APHIS, 88,300 commenters provided comments on the 2008 proposed rule. Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms, 80 Fed. Reg. 11598, 11598 (Mar. 4, 2015). In 2015, APHIS withdrew this rule. *Id.*

106. *Guidance Documents*, U.S. DEP'T AGRIC., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_guidance_documents (last modified July 13, 2017).

107. BIOTECHNOLOGY REGULATORY SERVS., NOTIFICATION (2011), https://www.aphis.usda.gov/biotechnology/downloads/notification_guidance_0311.pdf.

108. However, neither is simple. The guidance for notification is 30 pages long (53 with the appendix), and the guidance to apply for a permit is 44 pages long (93 with the appendix). *See id.*; BIOTECHNOLOGY REGULATORY SERVICES, PERMIT USER'S GUIDE WITH SPECIAL GUIDANCE FOR EPERMITS (2017), https://www.aphis.usda.gov/biotechnology/downloads/permit_guidance.pdf.

109. U.S. DEP'T AGRIC., REQUEST TO EXTEND NONREGULATED STATUS FROM A PREVIOUS DETERMINATION: EXTENSION GUIDANCE FOR DEVELOPERS (2016), https://www.aphis.usda.gov/brs/aphisdocs/guidance_ext_nonreg.pdf; *see also Petitions for Determination of Nonregulated Status*, U.S. DEP'T AGRIC.,

Congress has now assigned the USDA responsibility for labeling of any product containing GM food. In July 2016, Congress enacted the National Bioengineered Food Disclosure Standard,[110] amending the Agricultural Marketing Act of 1946[111] to assign the USDA responsibility for labeling GM food and preempt any state or local law that prescribes labels on food indicating that it was produced with GM technology. The legislation was controversial: opponents, including a wide range of environmental and proconsumer groups, nicknamed it the DARK Act, standing for "Deny Americans the Right to Know."[112] In fact, the primary sponsor of the legislation, Representative Mike Pompeo (R-Kansas), received large campaign contributions from Koch Industries.[113] On the other hand, the legislation was signed by President Barack Obama, and uniform federal legislation that preempts the welter of state laws has generally been favored by progressives and good-government advocates. Ultimately, the test of this statute's advisability will be determined by the quality of the legislation that the federal government enacts, and that determination will be based on matters that remain controversial.[114]

C. The Role of the FDA

While the EPA and the USDA regulate important aspects of the food industry and play a major role in determining the extent and manner that GM foods are produced and distributed, the FDA, under the authority of the Food, Drugs and Cosmetics Act (FDCA), determines what can be sold as food in the United States and what cannot.[115] In other words, the EPA regulates pesticides used on food plants,

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https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status (last visited Aug. 3, 2017) (showing extension petitions).

110. Pub. L. No. 114-216, 130 Stat. 834 (July 29, 2016) (codified at 7 U.S.C. § 293(a)(1)) (directing the Secretary of the USDA to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered . . . ." within two years of the date of enactment of this law). This law allows the USDA to determine the amount of substance within a food product that would tip the balance in favor of it needing a label. *Id.* It means, for example, that a cereal product that only contains a small amount of bioengineered wheat may not be considered as a bioengineered food product. The law also provides that the label may be a "text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer." *Id.* In other words, manufacturers could provide some sort of picture that can be scanned by a smart phone by the consumer, if the consumer wants to find out if the product contains the requisite level of bioengineered ingredient.

111. Agricultural Marketing Act of 1946, 7 U.S.C. §§ 1621–1638 (2012).

112. *See* JENKINS, *supra* note 2, at 43.

113. *Id.* The Koch Brothers have interests within and around the food industry and are large supporters of Mike Pompeo. *See* John Nichols, *The Koch Brothers' Favorite Congressman will be in Charge of the CIA*, NATION (Nov. 18, 2016), https://www.thenation.com/article/the-koch-brothers-favorite-congressman-will-be-in-charge-of-the-cia/.

114. The USDA sought comments on its proposed labeling rule. *USDA Seeks Comments on Proposed Rule for National Bioengineered Disclosure Standard*, U.S. DEP'T AGRIC., https://www.usda.gov/media/press-releases/2018/05/03/usda-seeks-comments-proposed-rule-national-bioengineered-food (last visited May 29, 2018).

115. Food Drug and Cosmetic Act of 1938, 21 U.S.C. § 321 (2016).

and the USDA regulates plant pests that afflict these plants, but the FDA regulates food itself. In this role, the FDA necessarily determines whether, and under what conditions, GM foods can be marketed. This role is, of course, recognized by the Coordinated Framework in its attempt to delineate the overlapping responsibilities of the three regulatory agencies, various other agencies, and research units of the federal government.

For GM food, the FDA relies on two provisions of the FDCA: the adulteration provision (section 402(a)(1)) and the food additives provision (section 409),[116] both of which differentiate between a new substance intentionally added to the food supply and a substance that is generally recognized as safe (GRAS).[117]

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116. For a description of how these provisions apply, see U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 1, 15–16 (2017) [hereinafter COORDINATED FRAMEWORK 2017 UPDATE], https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537315.pdf. The Act was amended in 1958 to require that all food additives should undergo extensive pre-market safety testing, including longitudinal animal studies. Food Additive Amendments of 1958, Pub. L. No. 85-929, § 2, 72 Stat. 1784, 1784 (Sept. 6, 1958). The Act defined "food additives" as follows:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—
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> (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
> (2) a pesticide chemical; or
> (3) a color additive; or
> (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
> (5) a new animal drug; or
> (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

Id.

117. COORDINATED FRAMEWORK 2017 UPDATE, *supra* note 116, at 16. Presumably, the FDA considers changes to a genetic sequence using biotechnology to create a new substance. This designation is questioned by many steeped in the field because mutagenesis

While manipulating DNA is not technically a food additive, the FDA seems to make use of these provisions to address the issue.[118] In determining whether a food additive, as thus defined, can be marketed, the FDA—like the EPA, and in contrast to the USDA—has chosen to rely on the language of its authorizing statute rather than issue supplementary regulations.[119] This means that it evaluates each application for approval of a food additive on an individual basis, applying the statutory provisions to the information that appears in the application.[120] As might be imagined, given the age and generality of the statutory language, the FDA's procedure grants it a good deal of discretion, and it creates a good deal of uncertainty when applied to the enormously varied and rapidly developing field of GM foods.

In 1992, the FDA attempted to ameliorate this situation by issuing a guidance document that includes a mechanism for a "voluntary consultation process" prior to a GM product entering the food supply.[121] The consultation process is not actually voluntary because every GM product goes through it.[122] It requires extensive studies demonstrating that the genetically engineered version is as safe and nutritious as its conventional counterpart. In particular, section VII of the FDA's guidance document provides an extensive list of "scientific considerations for evaluating the safety and nutritional aspects of foods from new plant varieties," including the following: questions and endpoints for determining whether the genetic modification alters known toxicants of the host and donor species; its potential for transfer of food allergens; a safety evaluation of donor DNA; its concentration of important nutrients; the safety and nutritional value of newly introduced proteins; and the identity, composition, and nutritional value of any modified oils, fats, or carbohydrates.[123]

As might be imagined, completing this pre-market review is expensive and time-consuming.[124] Most scientists with experience in GM regard it as

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by conventional methods also introduces genetic modifications, but the resulting food may be considered GRAS. In other words, this interpretation may be scientifically indefensible.

118. 21 U.S.C. § 348 (2012).

119. *Id.*; Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992) ("The new methods of genetic modification have focused attention, however, on the possibility that intended changes in the composition of food resulting from genetic modification might be of a nature sufficient as a legal and public health matter to trigger regulation of a component of the food under section 409 of the act."); *see also* LISA HEINZERLING, FOOD LAW CASES AND MATERIALS 296–334 (2017).

120. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

121. FDA 1992 Guidance Document, *supra* note 1, at 22,985.

122. Conko et al., *supra* note 20, at 496 ("The FDA 'requests' developers of GE crops to discuss with the agency whether foods derived from those crops are 'substantially equivalent' to foods from the same unmodified crops. . . . With the knowledge that the FDA has the authority to remove from commerce any foods it deems unsafe, developers of GE crops have in every case consulted with the FDA, producing extensive documentation of each new product's safety and nutritional equivalency to a non-engineered reference food." (internal citation omitted)).

123. FDA 1992 Guidance Document, *supra* note 1, at 22,991.

124. Conko et al., *supra* note 20, at 496 ("[E]ven for products of negligible risk, some of these reviews have been unnecessarily prolonged: for example, 34 months in the case

unnecessary.[125] It is important to remember that non-GM manufacturers may be using large-scale mutagenic techniques, such as irradiation or chemical mutagenesis, to obtain a particular trait, which means that the resulting crop almost certainly has many unknown and uncharacterized mutations.[126] The FDA could, under its authority, require these manufacturers to undergo the same extensive pre-market testing, but in practice, it does not. The elaborate procedure established by the FDA guidance, voluntary in name but virtually compelled in fact, applies only to GM products.

In 2006, the FDA released a lengthy guidance document expressing its current thinking on the procedures that developers of GM food should contemplate following.[127] This addressed the possibility that new varieties of bioengineered plants may be inadvertently introduced into the environment and thus the food supply, a circumstance known as adventitious presence (AP).[128] As noted above, APHIS regulates anything deemed to be a plant pest; but some forms of bioengineered crops will not be engineered to be plant pests; thus, the FDA issued a guidance document to scoop up those crops that do not need to undergo review by APHIS. The concern, expressed by the FDA, is that uncharacterized traits may be introduced into the environment, incorporated by non-GM crops, and then inadvertently introduced into the food supply.[129] Notably, this early evaluation is in addition to the FDA's recommendation that developers participate in the FDA's 1992 biotechnology consultation process.[130] In practice, it takes about ten years and $136 million to move a GM product through the FDA's regulatory process.[131] This is in stark contrast to foods created through conventional breeding techniques, which usually enter the marketplace as GRAS and, thus, without significant FDA review.

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of non-browning Artic apples. . . ."); *see also* J.R. Prado et al., *Genetically Engineered Crops: From Idea to Product*, 65 ANN. REV. PLANT BIOLOGY 769, 770 (2014) (costing an average of $136 million and ten years for an entire regulatory review, not just by the FDA).

125. Conko et al., *supra* note 20, at 493–97; Steven H. Strauss & Joanna K. Sax, *Ending Event-Based Regulation of GMO Crops*, 34 NATURE BIOTECHNOLOGY 474, 475–76.

126. Noteworthy is that the FDA has never considered these large-scale mutagenic techniques to be "additives."

127. *Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm (last updated July 1, 2016) [hereinafter *FDA 2006 Guidance Document*].

128. *Id.*; *see also* Strauss & Sax, *supra* note 125, at 476 (discussing AP).

129. *FDA 2006 Guidance Document*, *supra* note 127; *see also* Strauss & Sax, *supra* note 125, at 476 (discussing the FDA's 2006 guidance document).

130. *FDA 2006 Guidance Document*, *supra* note 127. ("Yes, we recommend that if you decide to commercialize your new plant variety that you participate in FDA's biotechnology consultation process even if you have submitted to us and completed the early food safety evaluation of the new protein in your bioengineered plant.").

131. Prado et al., *supra* note 124, at 769–90.

The FDA has also issued guidance on its use of guidance.[132] This unique document, a "meta-guidance" as Professor Richard Epstein calls it,[133] offers a definition of guidance, explains how the agency will use it, and outlines procedures for public participation. The definition is that guidance documents "describe the agency's interpretation of or policy on a regulatory issue."[134] The document goes on to declare that "[g]uidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA."[135] The document distinguishes between "level 1" guidance, which includes "initial interpretations of statutory or regulatory requirements . . . complex scientific issues . . . [and] highly controversial issues,"[136] and "level 2" guidance, which are, in the FDA's view, "minor changes in interpretation or policy."[137] For level 1 guidance, but not for level 2 guidance, the FDA states that it will publish a notice of the proposed guidance in the Federal Register and the proposed guidance itself on the Internet, invite comments, review the comments, and then publish a notice of the final guidance in the Federal Register and the final guidance itself on the Internet.[138] It will not do so, however, if it "determines that prior public participation is not feasible or appropriate."[139]

D. Reevaluation of the Coordinated Framework

In July 2015, after decades of research on GM foods and many calls by scientists to reevaluate the regulatory process, the White House issued a memorandum asking for a review of the regulatory regime for GM foods to "ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment."[140] This much-needed call for review sparked commentary reiterating the vast amount of research over many decades showing the utility and safety of genetic engineering techniques.[141]

As part of the process to reevaluate the Coordinated Framework, the White House released an update to the regulation of biotechnology products on January 4, 2017.[142] One main criticism by many engaged in the field was that it was necessary

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132. 21 C.F.R. § 10.115 (2015). The Office of Management and Budget (OMB) relied heavily on this document to produce its own meta-guidance, a bulletin on "Good Guidance Practices." Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).

133. Epstein, *supra* note 5, at 70; *see also* Rakoff, *supra* note 5, at 160 (discussing the FDA guidance in the context of the general interplay between legislative rules and guidance).

134. 21 C.F.R. § 10.115(b)(1).

135. § 10.115(d)(1).

136. § 10.115(c)(1).

137. § 10.115(c)(2).

138. § 10.115(g)(1)(ii).

139. § 10.115(g)(2).

140. Holdron et al., *supra* note 3, at 1.

141. *See, e.g.*, Strauss & Sax, *supra* note 125; Conko et al., *supra* note 20.

142. COORDINATED FRAMEWORK 2017 UPDATE, *supra* note 116.

to clarify the role that each agency plays in the regulation of new products, especially when a product may fall within the jurisdiction of multiple agencies.[143] The 2017 update memorandum attempted to do so,[144] but this is bureaucratic housekeeping; it does not address the substance of the issue, i.e., which products *should* or *should not* be regulated, and to what extent. To accomplish the update to the Coordinated Framework, a series of documents containing case studies of different types of products and the regulatory pathway to commercialization were prepared for public comment.[145] The OSTP, EPA, FDA, and USDA held a series of public meetings to discuss the case studies, and the verbal comments became part of the official transcript.[146] In addition, the National Science and Technology Council (NSTC) issued a request for information in the Federal Register to solicit information and comments that could be used to update the Coordinated Framework.[147] The FDA also noticed a public meeting in the Federal Register.[148] In short, the situation today is somewhat fluid. Clearly, the status of the FDA guidance is under review, and there has been some effort to obtain public participation in this process. But the FDA guidance, rather than a rule subject to notice and comment procedure, remains the basic means by which GM food is regulated at the present time.

III. GUIDANCE AS A MEANS OF REGULATION

Under the Coordinated Framework, the EPA is responsible for the effect of GM food on the general environment, and the USDA is responsible for the process by which GM food is produced.[149] But the FDA plays a crucial role, and the one that has been the major source of controversy; it determines whether GM foods can be marketed to American consumers. The guidance document by which it has chosen to carry out this role is, in effect, the driving force behind the entire regulatory system described in the previous Part. If GM foods could not be marketed to

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143. *Id.* at 2; *see* Michael P. Vandenberg, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529, 1550–64 (1986).

144. COORDINATED FRAMEWORK 2017 UPDATE, *supra* note 116, at 8.

145. *Id.* at 39.

146. *Id.* at 52.

147. *Id.*

148. Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology, Public Meeting, 80 Fed. Reg. 62538-01, 62538. (Oct. 16, 2015). In addition, the Advisory Committee on Biotechnology & 21st Century Agriculture (AC21) is a working group that is currently gathering information in response to the growing complexity of agriculture. *Advisory Committee on Biotechnology & 21st Century Agriculture (AC21)*, U.S. DEP'T AGRIC., https://www.usda.gov/topics/biotechnology/advisory-committee-biotechnology-21st-century-agriculture-ac21 (last visited July 28, 2018); ADVISORY COMMITTEE ON BIOTECHNOLOGY & 21ST CENTURY AGRICULTURE (AC21), A FRAMEWORK FOR LOCAL COEXISTENCE DISCUSSIONS 4 (2016), https://www.usda.gov/sites/default/files/documents/ac21-report-final-local-coexistence.pdf.

149. *See id.* at 15–17; Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753-01, 6754 (Feb. 27, 1992); *see also* Conko et al., *supra* note 20, at 495–97 (discussing the Coordinated Framework).

consumers, farmers would not produce them, and they would have no effect on the environment.

As will be described below, American administrative law defines two standard categories of agency action: rules and orders. Rules are, in effect, supplemental legislation enacted by agencies. Adjudications are individualized decisions that determine the rights or obligations of a private party, and thus resemble civil trials. The FDA could have used either of these defined techniques; that is, it could have issued a rule that determined the circumstances under which GM foods could be marketed, or it could have adjudicated the marketability of each proposed GM product on an individualized basis. Instead, it used a different approach—one that occupies an intermediate position between these two techniques and that is not defined by law. This Part addresses the legal validity of this approach. Its conclusions will then be applied, in the following Part, to the FDA's responsibility within the Coordinated Framework.

A. Guidance in Administrative Law

Administrative law is a field beset by fiendishly complicated terminology, and "administrative guidance" is one of the prime examples. As used in current law, it is not an English word, but rather a translation of the Japanese term *Gyōsei shidō*.[150] Originally, it was an informal strategy by which Japanese agencies requested voluntary compliance from regulated parties,[151] but Japan's Administrative Procedure Act of 1993 subjected it to legal standards.[152] The Act defines "Administrative Guidance" as "guidance, recommendations, advice, or other acts by which an Administrative Organ may seek, within the scope of its duties or affairs under its jurisdiction, certain action or inaction on the part of specified persons in order to realize administrative aims, where such acts are not

150. Paul A. Davis, *Administrative Guidance,* SOPHIA U. SOCIO-ECONOMIC INST. BULL. No. 41, 21 (1972); Jeffrey M. Lepon, *Administrative Guidance in Japan*, 2 FLETCHER F. WORLD AFF. 139, 139–40 (1978). Its non-English origin is indicated by its use as a concrete noun that can take an indefinite article ("the FDA issued a guidance"). In English, "guidance" is an abstract noun that is not introduced by an article ("we need guidance on this issue"), or only by the definite article when a specific instance is involved ("the guidance provided by the Bible"). It is thus similar to words such as wisdom or shyness; we speak of the need for wisdom, or the affliction of shyness, and we can refer to the wisdom of Solomon or the shyness of a child, but there is no such thing as "a wisdom" or "a shyness." Similarly, abstract nouns such as guidance, wisdom, and shyness cannot be pluralized in English; we say "the guidance many experts offer" or "the wisdom of the ages." The word "guidances," which makes sense when referring to more than one agency pronouncement, is not acceptable English usage, and the Word program underlines it in red.

151. Yoriaki Narita, *Administrative Guidance*, 2 L. JAPAN 45, 45–46 (James L. Anderson trans., 1968); Michael K. Young, *Judicial Review of Administrative Guidance: Governmentally Encouraged Consensual Dispute Resolution in Japan,* 84 COLUM. L. REV. 923, 926–41 (1984).

152. [Administrative Procedure Act], Act No. 88 of 1993 (Japan), http://www.cas.go.jp/jp/seisaku/hourei/data/APA.pdf.

Dispositions."[153] While this language is not a model of clarity, two elements seem clear enough. First, Japanese guidance is designed to induce specific actions by regulated parties, and second, it is supposed to do so without the use of the government's coercive force.[154]

In our system, the specific technique to which the term "guidance" has generally been attached is a type of rule under the APA.[155] Section 553 of the APA prescribes procedures for two types of rulemaking: formal rulemaking, which must follow the same trial-type procedures as adjudications under sections 556 and 557 of the statute, and informal rulemaking, which must follow only the much less demanding notice and comment procedure specified in section 553 itself. These are often described as "legislative rules" because they are equivalent to statutes; to violate their commands is to violate federal law.[156] Section 553 also provides for several different exceptions from both its formal and informal requirements. In particular, "interpretative [*sic*] rules, general statements of policy, or rules of agency organization" are excluded from the section's notice and comment requirements.[157] To the extent that such actions can be considered rules they are, in effect "informal informal rules;" that is, rules that are subject to fewer "formal" or procedural requirements than the "informal rules" to which notice and comment requirements apply. Administrative agencies rely on these exceptions when issuing the kinds of statements that have come to be characterized by the translated term "guidance."[158] As the courts have increased the scrutiny devoted to informal or notice and comment rulemaking, originally through the "hard look" doctrine and now through the framework of a leading case, *Motor Vehicle Manufacturers Association v. State*

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153. *Id.* at Ch. 1, Art. 2(vi). "Dispositions" are defined as "the exercise of public authority by administrative agencies." *Id.* at Ch. 1, Art. 2(ii).

154. Chapter 4 of the Act goes on to describe various features that guidance must possess. An agency issuing a guidance must remain strictly within its own jurisdictional limits; it must "make clear to the subject party the purpose and the content of, and the persons responsible for" the guidance; it must issue the guidance in written form or reduce it to written form on request; and, in essence, it may not use threats of action or inaction to compel a regulated party to comply with the guidance. *Id.* at Ch. 4. These elements of the definition codify basic features of Japanese guidance as they developed prior to the Act. *See* Young, *supra* note 151, at 932–43.

155. Administrative Procedure Act, 5 U.S.C. § 551–596 (2012).

156. § 551(4). *See., e.g.*, Robert A. Anthony, *"Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog*, 8 ADMIN. L.J. 1, 2 (1994); Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1709 (2007); Richard J. Pierce, *Distinguishing Legislative Rules from Interpretative Rules*, 52 ADMIN. L.J. 547, 552 (2000).

157. § 553(b)(3)(A).

158. Exec. Order No. 13,422, 3 C.F.R. § 191 (2007). The Bush II Administration order that subjected guidance documents to the requirements of Executive Order No. 12,866 (cost-benefit review of executive-agency rules), defines the term "guidance document" as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue." *Id.* at 192. In other words, the term "guidance," as used by federal agencies, refers to any statement that can be characterized as a rule that falls within the APA exceptions to the notice and comment requirement.

Farm Mutual Auto Insurance Company,[159] agencies have increasingly relied on these exceptions, as well as others, to effectuate regulation.[160] Because none of the exceptions are defined in the APA, debate about their meaning and their proper scope has become intense.[161]

Administrative-law scholars have tended to identify an agency's use of techniques described by the translated term "guidance" as falling within the exception of "interpretative rules."[162] The reason, presumably, is that this verbal barbarism, which has generally been assumed to mean "interpretive" rather than being a coinage of some sort, refers to rule-like actions that are not subject to notice and comment requirements. Thus, it resembles the Japanese practice now defined by Japanese law. Attaching a new term, with a certain amount of comparative-law cachet, to the category of interpretive rules may have encouraged their use, or perhaps it merely intensified the debate about their proper range.

B. The Guidance Conundrum

The statutory home that has been found for the translated term "guidance" has not turned out to be a happy one. Courts and scholars have experienced great difficulty in determining the contours of the interpretive-rules exception to section 553 informal rulemaking. Redefining this exception as "guidance," or as including guidance, has only made the problem worse. This Section will consider three efforts to resolve this conundrum, relying in turn on the idea of interpretation, the idea of legal bindingness, and *ex post* judicial review. It concludes that the distinction between interpretive and informal or legislative rules is not simply difficult, but impossible. This means that fitting guidance within the interpretive-rules exception

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159. 463 U.S. 29 (1983); *see* William Funk, *Legislating for Nonlegislative Rules*, 56 ADMIN. L. REV. 1023 (2004); Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1410–14 (1992); Richard J. Pierce, *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 84 (1995).

160. One of the other exceptions is the "good cause" exception. 5 U.S.C. § 553(b)(3)(B) (2012). *See also infra* notes 233–86 and accompanying text.

161. This does not necessarily mean that the agencies are circumventing the APA; that is, substituting guidance when the law requires them to use notice and comment rulemaking. It might only mean that they are opting to replace definitive requirements with recommendations, in the expectation that those will be sufficient to obtain an acceptable level of compliance. *See* Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 820–23 (2010) (concluding, on the basis of a survey and analysis of guidance documents, that agencies do not rely on guidance to circumvent their notice and comment obligations).

162. *See, e.g.*, Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like: Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1321–27 (1992); Michael Asimow, *Guidance Documents in the States: Toward a Safe Harbor*, 54 ADMIN. L. REV. 631, 639–40 (2002); Kristen E. Hickman, *Unpacking the Force of Law*, 66 VAND. L. REV. 465, 491 (2013); Sam Kalen, *The Transformation of Modern Administrative Law: Changing Administrations and Environmental Guidance Documents*, 35 ECOLOGY L.Q. 657, 658 (2008); Rakoff, *supra* note 5. Guidance documents can also be characterized as "general statements of policy," one of the other operative terms in the § 553(b)(3)(A) exception. *See infra* notes 163–172 and accompanying text.

will be to no avail, and that another way of reconciling the practice (always extensive and now explicit as well) with the requirements of the controlling statute must be found.

1. The Problem with Relying on Interpretation

Relying on the idea of interpretation would seem to be a promising way to delineate the boundaries of the interpretive-rules exception, and thus the boundaries of guidance. The problem is that the term "interpretive," or "interpretative," does not correspond to the distinction to which it refers; that is, the distinction between actions that should be subject to notice and comment rulemaking and actions for which this informal, but nonetheless demanding, procedure is unnecessary. In some sense, every rule, including every legislative rule, is an interpretation of the statute, no matter how many policy decisions it embodies. Any agency rule that cannot be derived from a reasonable interpretation of the statute's authorization should be struck down by the judiciary as *ultra vires*, no matter what procedure was used to adopt it.[163] Moreover, as Jerry Mashaw, Kevin Stack, Peter Strauss, and others have pointed out, the agency's task always begins by reading, and thus interpreting, the statute.[164] Barring the rare event of a constitutional challenge to the statute on its face, the agency is generally the first non-congressional interpreter of the statute and will often be the only one. The APA seems to acknowledge this reality. It defines the term "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, *interpret* or prescribe law or policy . . . ."[165]

Unless we want to assert that "interpretate" is different from "interpret" (but what would it mean?), we are left with the problem that the statute uses the same term to define a rule and specify the exceptions from that definition.[166] Perhaps, however, the ambiguity arises from an overly broad concept of interpretation. One might be inclined to regard the term that appears in the exception as referring to the process of explaining the verbal meaning of a specific word or phrase in the authorizing statute, while treating the word that appears in the initial definition as referring to the process of using an understanding of the statute as the

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163. That is, in fact, part of the standard of review specified in the APA. 5 U.S.C. § 706(2)(C) (2012). Every regulation issued by a federal agency begins with a recitation of the statutory authority for the action being taken.

164. Jerry L. Mashaw, *Norms, Practices and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation*, 57 ADMIN. L. REV. 501, 502–03 (2005); Kevin M. Stack, *Purposivism in the Executive Branch: How Agencies Interpret Statutes,* 109 NW. U. L. REV. 871, 895 (2015); Peter L. Strauss, *When the Judge is Not the Primary Official With Responsibility to Read: Agency Interpretation and the Problem of Legislative History*, 66 CHI.-KENT L. REV. 321, 351 (1990).

165. 5 U.S.C. § 551(4) (2012) (emphasis added).

166. This is similar to the APA's better-known drafting enigma involving the word "discretion." Administrative Procedure Act, 5 U.S.C. §§ 701, 706 (2012). Section 701(a)(2) excludes actions "committed to agency discretion by law," but § 706(2)(A) instructs courts to hold unlawful agency actions that constitute "an abuse of discretion." How can courts strike down actions abusing discretion when discretionary actions are excluded from review?

basis for action.[167] But limiting the meaning of the word "interpret" as used in the exception to an explication of the statute's verbal meaning is much too restrictive. It would subject many agency pronouncements to the notice and comment requirement that virtually everyone agrees should be excluded.[168]

As soon as one broadens the term "interpret" in the exception to include the process that agencies actually employ in creating interpretive rules or guidance, the term loses its ability to distinguish between those actions and legislative rules. To use a variant of the fact situation in *Hoctor v. U.S. Department of Agriculture*, a leading guidance case decided by Judge Richard Posner,[169] suppose a statute provided that any person keeping "big cats" on private property must file a report that included specified information.[170] Consider two actions: first, the agency issues a statement that it will consider the term "big cats" to include cheetahs but not ocelots; second, the agency produces a brochure that lists the locations or websites where the report can be filed, offers a sample form that the big-cat owners can use, provides a bibliography of sources about animal behavior and husbandry that the owners might find relevant in obtaining the information required for the report, and then summarizes a number of federal-court cases that determined the adequacy of required disclosures under other statutes.

The agency's first decision, placing cheetahs within the statute's requirements, would appear to be a legislative rule; that is, a definitive imposition of legal requirements on a group of people who might otherwise be exempt from

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167. This would correspond to the differing approaches to interpretation that have been explored in literary criticism. Explaining the verbal meaning of a specific word or phrase would be an effort to resolve the inevitable ambiguities of a text. *See, e.g.*, CLEANTH BROOKS, THE WELL WROUGHT URN 124–50, 151–66, 167–77 (1942) (examining Wordsworth's *Intimations*, Keats' *Ode to a Grecian Urn*, and Tennyson's *Tears, Idle Tears*); WILLIAM EMPSON, SEVEN TYPES OF AMBIGUITY 1 (1966); NORTHROP FRYE, ANATOMY OF CRITICISM 270–93 (1971). An understanding of the statute as a basis for action might correspond to the hermeneutic approach that relates the meaning of a particular language to the entire text in which the passage appears. *See, e.g.*, HANS-GEORG GADAMER, TRUTH AND METHOD 157–71 (2011); ANTHONY C. THISELTON, HERMENEUTICS: AN INTRODUCTION 13–16, 24–34 (2009).

168. *See* Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 850 (2001) (describing the range of agency actions that should be subject only to the requirement of publication).

169. 82 F.3d 165 (7th Cir. 1996). The decision has been ensconced in academic discourse—possibly Judge Posner's motivation for writing it the way he did. For example, it is the centerpiece of Jacob Gersen's article proposing the shortcut. *See* Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1705–08 (2007). And it is the introductory example for Peter Strauss's comprehensive discussion of rules governed by the procedural requirement of publication. *See* Strauss, *supra* note 168, at 812–17.

170. The actual situation in *Hoctor* was that the agency, having promulgated a rule (whose validity was unquestioned) that animal enclosures must be of the material and strength appropriate for the animal being enclosed, then issued an interpretation of the rule requiring that dangerous animals must be enclosed by a perimeter fence at least eight-feet high. 82 F.2d at 167–68. The Court declared the interpretation invalid, holding that it constituted a change in legal obligations that would require notice and comment procedure under the APA. *Id.* at 171.

such requirements. Yet this decision is necessarily interpretive, in the sense that it relies on the verbal meaning of a statutory term. The agency is only authorized to issue it if it is a reasonable reading of the term "big cats." An agency rule that extended the statute to bears, on the grounds that they are equally dangerous, would be struck down as *ultra vires* based on a reading of the word "cats;" an agency rule that extended the statute to house cats would be struck down based on a reading of the word "big." If the cheetah rule were challenged, the agency would justify it in primarily interpretive terms. It might point out that cheetahs belong to same genus (*Panthera*) that includes lions and tigers, whereas ocelots do not; that people using ordinary language would describe cheetahs as big because they are nearly the size of an adult human, whereas ocelots are much smaller; and that zookeepers place cheetahs in the same size enclosures as leopards, whereas they place ocelots in smaller ones. These are the types of interpretive tropes that common-law courts used in answering category-related questions such as "what is chicken" or "what is a tomato."[171]

In contrast, none of the provisions in the hypothesized brochure can reasonably be regarded as interpretations, nor can they be justified in interpretive terms. The list of addresses or websites cannot be derived from any language in the statute; promulgating such a list is certainly authorized by the statute (if only by implication), but the particular websites in the brochure are entirely arbitrary from a statutory perspective. The same is true of the sample form: its content may be statutorily required, but its visual features—the whole point of providing a sample, after all—are equally arbitrary. The list of references clearly does not emerge from any language in the statute; the summaries of cases are interpretations, but not of the statute that is being implemented. Thus, it is the cheetah rule that is interpretive, not the various parts of the brochure.

This example suggests that excluding an agency action from notice and comment requirements on grounds that it is interpretive produces exactly the opposite result from the intuitive or desirable one. The declaration that cheetahs should be treated as "big cats" is a definitive expansion of the statutory requirements beyond what may be called, in *Chevron* terms, the statute's unambiguous meaning, which would include lions and tigers but exclude housecats and bears.[172] Although it is properly described as interpretive, it is a legislative rule and might well be seen as requiring notice and comment procedures. The various elements of the brochure, in contrast, consist of non-obligatory information whose purpose is to facilitate compliance with the statute. In ordinary language, we would tend to call them "advice," or perhaps "guidance." They supplement or add to the statute rather than

171. *See* Nix v. Hedden, 149 U.S. 304, 306 (1893) (although the fact that tomatoes are biologically fruits is relevant, the decisive fact is that they are described as vegetables in ordinary discourse); Frigaliment Importing Co. v. B.N.S. Int'l Sales Corp., 190 F. Supp. 116, 118 (S.D.N.Y. 1960) (meaning of the term "chicken" in a contract can be determined by referring to "one of the dictionary meanings, . . . the definition in the Department of Agriculture Regulations . . . at least some usage in the trade [and] the realities of the market").

172. *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984). The rule that this case announced is that a reviewing court will determine de novo if the statute has an unambiguous meaning, and if so, it will apply that meaning, but it will defer to a reasonable-agency interpretation if the statutory language is ambiguous. *Id.* at 866.

interpret it, but they do so only in a way that makes compliance easier and is unlikely to be viewed as an expansion of the statutory obligations. It thus seems difficult, if not impossible, to distinguish them from the enormous range of other ways in which agencies communicate with regulated parties. To require notice and comment procedures for all of these communications would bring the regulatory process to a halt.

2. The Problem with Relying on Bindingness

Considerations such as these have induced both judges and scholars to seek a different way to distinguish between guidance and legislative rules. The one that has become most prevalent is based on the "bindingness" of the agency's action.[173] The cheetah declaration would be deemed a legislative rule according to this distinction because it imposes a definitive obligation on a group of private persons. The elements of the brochure would be regarded as nonlegislative, and thus exempt from notice and comment, because they merely offer suggestions that a regulated party can ignore without incurring any sanction.

This distinction seems to rest upon and implement important values. At the doctrinal level, it maintains the integrity of the APA, precluding agencies from using an exception to circumvent a legal obligation that the statute imposes on them.[174] At the normative level, it maintains the rule of law by ensuring that legal requirements that are announced in advance, when there is no opportunity for the private party to contest particularized applications through the adversary process, are subject to public participation and reviewed by judicial authorities.[175] But the bindingness criterion is problematic because it does not address the central concerns that underlie the APA's notice and comment requirement. To return to the hypothetical brochure, the website list might be seen as nothing more than friendly advice to the regulated entity; if that entity knew of another way to submit the information, it would generally be safe in doing so. But would any regulated party feel comfortable using anything other than the suggested form? It might be confident that it had read the statute accurately and provided the required information, thus avoiding liability for noncompliance. But the possibility that it might incur inconvenience and expense if the agency mistakenly rejected disclosures that looked unfamiliar would probably be sufficient to make it feel compelled to use the form.[176] In legal doctrine or a

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173. The leading articulation of this standard is probably *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993). For a ringing endorsement of the decision, see Pierce, *supra* note 156, at 554. *See generally Chevron*, 467 U.S. 837 (1984).

174. *See* Hamilton & Schroeder, *supra* note 5, at 127 (sources asserting that agencies use guidance to avoid the obligations that the APA imposes on them).

175. *See* Epstein, *supra* note 5, at 48 (agency use of guidance often violates the rule of law); Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 ADMIN. L. REV. 343, 366–68 (2009) (use of guidance represents a preference for administrative expertise over public participation).

176. This is, in effect, the objection that critics of the shortcut proposal have raised. *See* Epstein, *supra* note 5, at 75–92; David Franklin, *Legislative Rules, Non-Legislative Rules, and the Perils of the Shortcut*, 120 YALE L.J. 276, 303–24 (2010); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents,* 90 TEX. L. REV. 331, 357–64 (2011). It is all very well to give private parties a good chance of prevailing

law-school classroom, there may be a great difference between disobeying and annoying a government agency, but in the real, regulated world, that difference is not as evident.[177]

The "bindingness" standard confronts an additional and deeper difficulty when the interaction between rules and adjudications—whether subject to the APA's formal adjudication procedures or not—is considered. Suppose the hypothetical brochure not only gave a list of helpful cases decided under other statutes, but also announced that those cases serve as a framework for the agency's own decisions.[178] Selfreferential statements often generate conundrums, and they do so here as well.[179] The agency's statement about its decisions might be the sort of observation that an external entity would suggest: "We notice that when we adjudicate the adequacy of disclosures, we tend to follow disclosure decisions made by other agencies."[180] On the other hand, it might be a declaration of the agency's own intentions: "We intend to follow decisions made by other agencies."

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against the agency when the agency charges them with violation of a statute or regulation, but lawsuits are expensive, time consuming, uncertain in their outcome, and sometimes disruptive of ongoing business operations. Thus, regulated parties may well choose to comply with agency guidance documents, even if they plausibly believe the document is invalid, rather than disobeying the guidance, having a sanction imposed by the agency, and then challenging the agency in court.

177. This emphasizes the oddity of Judge Edwards's statement, in *Ctr. for Auto Safety v. National Highway Traffic Safety Admin.*, 452 F.3d 798, 811 (D.C. Cir. 2006), that the "flaw" in the argument that the party challenging the guidance raised is that "the 'consequences' to which they allude are practical, not legal." One would think that the practical consequences of agency action should have a bearing on the action's legality, rather than treating the agency's action as an exercise in jurisprudence.

178. See Pacific Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33 (D.C. Cir. 1974), which is generally considered one of the seminal cases on guidance. Pipeline companies that expected to curtail delivery of natural gas during periods of shortage were required to file documents specifying their curtailment plans that would be subject to review by the Commission. *Id.* at 35. The Commission promulgated an order, characterized as a policy statement (and thus not subjected to the notice and comment requirements), stating that it preferred curtailment to be based on end use, rather than existing contractual commitments. *Id.* The Court held that the order was valid under the policy-statement exception because its purpose was not "to provide an inflexible, binding rule but to give advance notice of the general policy with respect to curtailment priorities that the Commissions prefers." *Id.* at 40.

179. The most famous, perhaps, being Russell's Paradox, a contradiction in set theory that he described as follows:

> normally a class is not a member of itself. Mankind, for example, is not a man. Form now the assemblage of all classes which are not members of themselves. This is a class: is it a member of itself or not? If it is, it is one of those classes that are not members of themselves, i.e., it is not a member of itself. If it is not, it is not one of those classes that are not members of themselves, i.e. it is a member of itself.

BERTRAND RUSSELL, INTRODUCTION TO MATHEMATICAL PHILOSOPHY 136 (1919).

180. This is not fanciful; it is, in essence, the holding of one of the leading guidance cases, *Ctr. for Auto Safety v. NHTSA*, 452 F.3d at 808, where the court said (per Judge

These two declarations clearly carry different implications for those subject to the agency's authority. In a regulatory program where sanctions are imposed after an adjudication of some sort, the first is helpful advice that has no effect on the decisions that are actually made, while the second is virtually equivalent to a rule that affects, or perhaps even determines, the outcome of the adjudication. In most cases, however, it will not be possible for outsiders to determine, from the discourse of a statement that the agency presents as an interpretive rule or guidance document, which of these declarations are intended. Perhaps a compliance officer or administrative lawyer familiar with the agency may be able to make the distinction based on inside knowledge of the agency's decision-making process. But it is also possible that even the agency itself may not be able to make the distinction. At bottom, the question is whether the decision-maker is open minded about changing its previous pattern of decisions on the basis of new arguments or information, and this is an extremely difficult matter for anyone, including the decision-maker, to know.

Several administrative-law scholars, including Richard Epstein and Mark Seidenfeld, suggest that this problem could be solved by subjecting guidance documents to immediate judicial review to determine their validity.[181] In other words, courts should abandon the existing requirements of standing and finality when asked to adjudicate the validity of a rule that the agency claims comes under one of the exceptions specified in section 553, such as the one for interpretive rules.[182] These scholars argue, quite correctly, that a regulated party may feel compelled to comply with an agency command if it cannot obtain a determination of the command's validity before designing its compliance strategy.[183] But the ambiguity of the translated term "guidance" would open the agency to challenges against a much wider range of its communications than would seem desirable. More

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Edwards) that the agency's guidance stating that it may allow vehicle manufacturers to limit their recall of defective vehicles to those states where weather conditions make the defect less likely to cause injury was "nothing more than a privileged viewpoint in the legal debate" about geographically limited recalls.

181. Epstein, *supra* note 5, at 63; Seidenfeld, *supra* note 176, at 386.

182. In general, federal courts impose a variety of rules limiting access to judicial review of administrative actions. These include standing limitations based on the identity of the plaintiff or the nature of the claim, and timing limitations based on failure to exhaust administrative remedies or the fact that the agency has not taken final action on the claim. *See* Lujan v. Defenders of Wildlife, 504 U.S. 555, 583–84 (1992) (suit could not go forward because plaintiff lacked a sufficient personal stake in the outcome, and relief sought was purely procedural); Simon v. E. Kentucky Welfare Rights Org., 426 U.S. 26, 42 (1976) (lack of causal connection between injury claimed and relief sought); McGee v. United States, 402 U.S. 479, 490 (1971) (applicant for conscientious-objector status must present his claim to draft board before being granted a judicial hearing); FTC v. Standard Oil Co., 449 U.S. 232, 245 (1980) (plaintiff cannot obtain judicial relief when claim is part of a larger proceeding that remains under agency consideration).

183. *See* Epstein, *supra* note 5, at 75–92; Franklin, *supra* note 176, at 303–24; Seidenfeld, *supra* note 176, at 357–64. Similar considerations led the Supreme Court to grant review in *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), the leading case on the availability of pre-enforcement judicial review of agency regulations.

generally, this ambiguity creates the danger that any effort to restrain or regulate agency guidance, in the translated or technical sense, could spill over into the broader category of actions to which the ordinary language terms apply.[184] This would enable private parties to impede and frustrate regulatory law in its entirety, much as they were able to do in the few cases where formal rulemaking was required.

Underlying these pragmatic difficulties with an expansion of judicial review lies a deeper and still more intractable problem. Our legal tradition provides us with no theory or experience for imposing substantive rules on executive authority.[185] The development of democratic government in Britain was achieved by progressively limiting the power of the monarch, transferring his authority to Parliament and, to a lesser but significant extent, independent courts.[186] Thus, we know how to limit executive authority, but our political tradition does not provide us with established methods to constrain its exercise or evaluate its performance. Therefore, when the APA was drafted, it is not surprising that Congress was able to articulate procedural requirements that would constrain the legislative and adjudicatory functions of an agency,[187] but not its executive function. The legislative function was subjected to section 553's notice and comment process, while the adjudicatory function was subjected to the more elaborate, court-like requirements of sections 556 and 557. The executive function went unregulated and virtually unnoticed.[188] That is the scholars' residual category of informal adjudication, a term the APA does not use for an issue that the APA does not address.[189]

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184. *See* Steven M. Johnson, *In Defense of the Short Cut*, 60 U. KAN. L. REV. 495, 532 (2012); Rakoff, *supra* note 5, at 168; Strauss, *supra* note 168, at 838–43.

185. Substantive limits on governmental power in general are, of course, available from the political-rights tradition. *See, e.g.*, GERTRUDE HIMMELFARB, THE ROAD TO MODERNITY: THE BRITISH, FRENCH AND AMERICAN ENLIGHTENMENTS (2005); LYNN HUNT, INVENTING HUMAN RIGHTS (2007). These have been applied to the executive through the mechanism of judicial review. But substantive limits that are specifically directed to the executive are absent. It is notable, for example, that none are stated in the Constitution or the Bill of Rights, as opposed to the explicit limits on the legislature and the implicit but widely understood limits on judicial authority. *See* U.S. CONST. art I, § 9 (prohibiting bills of attainder, direct taxes, taxes on state exports, expenditures without state authorization, and title of nobility); *id.* art. III, § 2, cl. 3 (prohibiting punishment of persons for treason by a family member); *id.* art. III, § 2, cl. 1 (limiting federal judicial power to specified cases); *id.* art. III, § 2, cl. 2 (limiting Supreme Court authority to appellate jurisdiction except in specified cases).

186. For more extensive discussion of this point, see Edward L. Rubin, *Executive Action: Its History, Its Dilemmas and Its Potential Remedies*, 8 J. LEGAL ANALYSIS 1 (2016).

187. *See* Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1263–68 (1986) (describing compromise between New Dealers and their opponents regarding the level of procedural requirements imposed on rulemaking and adjudication); Martin Shapiro, *APA: Past, Present and Future*, 72 VA. L. REV. 447, 452–62 (1986).

188. *See* Rubin, *supra* note 186, at 9–15.

189. *See The Federal Administrative Procedure Act: Codification or Reform*, 56 YALE L.J. 670, 703–04 (1947) (observing that the APA's two dichotomies of rulemaking vs.

The upshot is that it is impossible to distinguish legislative from nonlegislative action for the purpose of defining or constraining guidance. There is no set of principles or standards for executive action on which the distinction can be based. Any substantive principle that is proposed will necessarily rest on shifting sand and will be undermined by the fluidity and subterranean dynamics of a system we do not know how to control or even describe. Interpretation will merge into command; communications will exhibit kaleidoscopic shifts from friendly advice to veiled threats to adversarial demands; crucial decisions will disappear from stated rules to appear in directives to adjudicators, or never appear in either and hide out in employee manuals or training documents. It is always possible to formulate some verbal test to characterize the concept of guidance, but it will never be possible to apply that test in any realistic way.

3. The Problem with Relying on Ex Post *Review*

Several scholars have suggested a different way of resolving the difficulty of determining whether a guidance document is acceptable as an interpretive rule or illegal because it is, in fact, a legislative rule. Sometimes labeled the "short cut," it is described by Jacob Gersen as follows:

> Rather than asking whether a rule is legislative to answer whether notice and comment procedures should have been used, courts should simply ask whether notice and comment procedures were used. If they were, the rule should be deemed legislative and binding if otherwise lawful. If they were not, the rule is nonlegislative. If the rule is nonlegislative, a party may challenge the validity of the rule in any subsequent enforcement proceeding; if the rule is legislative, the agency may rely on the rule in a subsequent enforcement proceeding without defending it.[190]

If guidance is associated with interpretive rules, this proposal then becomes a way to resolve questions about the propriety of this device.[191] An agency could issue whatever guidance documents it chose, but because they were not subjected to

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adjudication and formal vs. informal produced a category of action that the statute neither described nor controlled). This category includes a vast range of administrative action, including planning, negotiation, threats, inspections, no-action letters, etc. *See* PETER L. STRAUSS, ADMINISTRATIVE JUSTICE IN THE UNITED STATES 210 (2d ed. 2002); Marshall J. Breger, *The APA: An Administrative Conference Perspective*, 72 VA. L. REV. 337, 355–56 (1986); Edward Rubin, *It's Time to Make the Administrative Procedure Act Administrative*, 89 CORNELL L. REV. 95, 107–08, 173–81 (2003).

190. Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1719 (2007); *see* John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 932 (2004) (advancing a similar approach to "nonlegislative" rules); Matthew C. Stephenson & Miri Pogoriler, *Seminole Rock's Domain*, 79 GEO. WASH. L. REV. 1449, 1460–65 (2011) (short-cut solution to problem of non-legislative rules may be undermined by doctrine that courts defer to agency interpretations of their own regulations); E. Donald Elliott, *Re-inventing Rulemaking*, 41 DUKE L.J. 1490, 1490–91 (1992) (courts should respect agency's declaration about whether a rule is binding, and only reverse the agency if it then treats the rule as binding in a particular case).

191. Seidenfeld, *supra* note 176, at 352–56.

informal rulemaking procedures (this being, in effect, the definition of guidance), the agency could not rely on the provisions of the document in an enforcement proceeding but rather would be required to defend them as proper interpretations of enacted statutory or regulatory rules.

The short cut appears to be an elegant solution, but a number of administrative-law scholars, including Mark Seidenfeld, Richard Epstein, and David Franklin, have voiced objections to it.[192] They point out that giving the agency free reign to adopt rules without subjecting it to notice and comment procedures, and only declaring those rules invalid in subsequent enforcement actions, grants the agency too much discretion. As noted above, many regulated parties may not want to disobey their regulatory agency and then challenge the agency's enforcement action in court. It may be less costly for the party to comply, and certainly less likely to inflict reputational damage.[193] In addition, many agencies have the authority or pragmatic ability to impose significant sanctions on a party that violates a rule that the agency regards as valid.[194] Those sanctions would be maintained until the matter is resolved by litigation, a process that can take many years.[195]

A further criticism of the shortcut proposal is that it is too lenient because agencies receive extensive deference under the *Chevron* doctrine.[196] That doctrine, which applies specifically to agency interpretation of its authorizing law, provides that any ambiguity in the statutory language should be resolved in favor of the

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192. Epstein, *supra* note 5, at 62–68; Franklin, *supra* note 176, at 303–24 (2010); Seidenfeld, *supra* note 176, at 357–64; *see also* Anthony, *supra* note 162, at 1318 (raising similar concerns about guidance documents in a more general context).

193. *See supra* notes 175–177 and accompanying text.

194. *See, e.g.*, 15 U.S.C. § 57b(b) (2012) (Federal Trade Commission may issue a cease-and-desist order, enforced by its authority to initiate a civil action where relief may include "rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation or the unfair or deceptive act or practice"); 15 U.S.C. § 2615(a)(1) (2012) (Securities Exchange Commission may, after an administrative hearing, impose penalties of up to $37,500 per day for violation of statutory rules or agency regulations); 42 U.S.C. § 7413(b) (2012) (EPA may, if it finds that a state has failed to enforce a Clean Air Act State Implementation Plan, impose an administrative penalty of up to $25,000 per day, in addition to bringing a civil action).

195. In response to this concern, Professor Stephen Johnson suggests that the shortcut proposal can be modified by requiring the agency to publish (on the Internet) significant rules that it regards as guidance, receive comments on those rules, and then subject that decision to judicial review. Stephen M. Johnson, *In Defense of the Short Cut*, 60 U. KAN. L. REV. 495, 498 (2012). There is certainly no harm in requiring electronic publication, and it would be hard to stop people from commenting if they chose to do so, but opening the process to judicial review would once again "formalize" and encumber agency communication, particularly if comments were, in fact, received. The suggestion here is that the court should evaluate a challenge to a guidance document on the basis of whether comments would be likely; if so, then full notice and comment process should be required.

196. Epstein, *supra* note 5, at 60–61; Franklin, *supra* note 176, at 321–23; Seidenfeld, *supra* note 176, at 354–57; *see* Hickman, *supra* note 162, at 484–91, 510–15 (2013) (analyzing the various contentions in the debate regarding the shortcut proposal).

agency's interpretation.[197] Defenders of the shortcut proposal have responded that the force of this objection has been much reduced by the Court's subsequent decision in *United States v. Mead Corp.*[198] In *Mead*, the Court denied *Chevron* deference to agency action that does not represent a law-making effort by the agency itself.[199] Guidance, the defenders suggest, would generally fail to meet this test and thus be denied the deference that *Chevron* grants to more definitive action, such as informal rulemaking and formal adjudication.[200] It would, therefore, be subject to more intensive scrutiny, possibly by being reviewed de novo, but more likely by being granted the lesser level of deference that the *Mead* decision applied.[201] In other words, the defenders of the shortcut are suggesting that the crucial distinction between agency action that should be regarded as a legislative rule and action that should be regarded as merely interpretive is the level at which the agency action is taken, or perhaps the agency's own commitment to the policy that the action implements.

Once again, however, the distinction in question does not correspond to the one we want to make; that is, the one that seems both intuitive and desirable.[202] It is true that informal rules and formal adjudications constitute definitive and fully authorized action by the agency and are, according to the rationale of the *Chevron* decision, entitled to deference. It is also true that certain actions that we identify as guidance, such as advice to a regulated party from a subordinate official, might not necessarily reflect the agency's position, so courts might want to scrutinize them more carefully on that basis. But a guidance document might be adopted at the highest levels of the agency; that is, by its presidentially appointed decision-makers, whether a single director or a multi-member board. Returning to the big-cat scenario, for example, if this regulation was regarded as central to the agency's mission, it seems plausible that the hypothesized brochure would be submitted to the secretary or the board for approval. This is certainly true of the Federal Communications Commission's (FCC) "Policy Statement" regarding the broadcasting of "indecent"

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197. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 (1984) ("[I]f the statute is silent or ambiguous with respect to the specific issue. . . [a reviewing court should not] simply impose its own construction of the statute. . . the question for the court is whether the agency's answer is based on a permissible construction of the statute.").

198. 533 U.S. 218 (2001). *Mead* holds that product-specific decisions about tariff status by low-level agency officials are not entitled to *Chevron* deference, but only to the lower level of deference provided in the earlier case of *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *Id.* at 235.

199. *Mead Corp.*, 533 U.S. at 231–34.

200. Gersen, *supra* note 190, at 1720–21; Manning, *supra* note 190, at 937–40.

201. *See Mead Corp.*, 533 U.S. at 234–39 (holding that the agency's decision is entitled to the lower level of deference established in *Skidmore*, 323 U.S. 134 (1944)).

202. For other responses to the preservation of the shortcut solution through *Mead*, *see* Franklin, *supra* note 176, at 276; Manning, *supra* note 190, at 940–44; Seidenfeld, *supra* note 176, at 354–57.

language,[203] subsequently at issue in *FCC v. Fox Television Stations, Inc*.[204] In fact, the document begins: "The Commission issues this Policy Statement to provide guidance to the broadcast industry . . . ." It is equally true of the FDA guidance document that this Article discusses.[205]

There are, moreover, a variety of documents or pronouncements that are even less formal than an interpretive rule or guidance document but nonetheless represent a decision of the agency at its highest level. Perhaps the clearest example is the employee manual. This might well be the document that the staff members who carry out the agency's functions regularly consult to determine their proper courses of action, and the staff members' supervisor might treat their failure to obey the manual's rules as grounds for discipline or dismissal.[206] Significant changes in the employee manual are likely to be matters that are considered by the secretary or the board. Nor is this internal document the most "informal" means that an agency's directors can use to control the behavior of their subordinates. Training sessions can serve the same function as a manual, in some cases more effectively, because they induce the staff members to internalize the desired behaviors.[207] Thus, the protocols or curriculum of the training sessions, again something that might be designed or

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203. In the Matter of Industry Guidance on the Commission's Case Law Interpreting 18 U.S.C. § 1464 and Enforcement Policies Regarding Broadcast Indecency, 16 FCC Rcd. 7999 (March 14, 2001).

204. 556 U.S. 502, 515 (2009) (holding that the FCC could validly alter the policy described in the guidance by subsequent adjudicatory decisions without offering an explanation beyond that which would be required to justify the decisions in the absence of the guidance document).

205. FDA 1992 Guidance Document, *supra* note 1, at 22,984 ("The Food and Drug Administration (FDA) is issuing a policy statement on foods derived from new plant varieties, including plants developed by recombinant deoxyribonucleic acid (DNA) techniques. This policy statement is a clarification of FDA's interpretation of the Federal Food, Drug, and Cosmetic Act.")

206. Employee manuals have been virtually invisible in the decided cases in the administrative-law area. A rare exception is *Morton v. Ruiz*, where the Court confronted the issue because the relevant statute placed no geographic limitation on the availability of the benefits it provided to Native Americans, but the agency, through a provision in its employee manual, did not provide benefits to Native Americans living on reservations. 415 U.S. 199, 209 (1974). The Court treated the question as one of statutory interpretation and, after extensive quotations from congressional hearings regarding both passage of the Act and subsequent reconsiderations of it, concluded that Congress had not intended the limitation. *Id.* at 199. The Court seemed to sense that it would create potential disruption for administrative agencies to grant no legal force to an employee manual, because that is actually what determines the behavior of agency staff and, therefore, acknowledged that its provisions were entitled to some level of deference. *Id.* at 237 (citing *Skidmore*, 323 U.S. 134). The Court's solution was to say, adumbrating *Chevron*, that such deference would only be granted if the provision was "consistent with the congressional purpose." *Id.* That, of course, leaves the crucial question—consistent to what extent?—open, and *Mead* does not resolve that question in the crucial case of employee manuals. *See Mead*, 533 U.S. at 220.

207. *See* Edward L. Rubin, *Discretion and Its Discontents*, 72 CHI.-KENT L. REV. 1299, 1324–36 (1997) (discretion of bank examiners in Germany is tightly controlled by a three-year training program, not by any printed document that is provided to them).

approved at the highest level of the agency, might embody the most crucial decisions. Yet these documents must be regarded as guidance or its equivalent. To hold that the provisions of an employee manual or the protocols for an employee training course should be subject to notice and comment rulemaking would not be viable. It would either lead to massive circumvention of the holding or be equivalent to the dissolution of the agency.

Conversely, there are some agency decisions made by low-level employees that we would not regard as guidance, but rather as definitive actions by the agency. The reason is that some of the decisions reached by administrative judges (AJs), hearing officers (the former term for AJs), or other agency officials are functionally equivalent to the decisions reached by administrative-law judges (ALJs). AJs preside over deportation (removal) hearings that determine the status of the persons subject to them.[208] An automobile-recall hearing that can be presided over by any designee of the Secretary, such as an automotive engineer, can produce equally definitive consequences and possess as much precedential value for future decisions as a hearing by an ALJ.[209] If the crucial question is the level at which the decision is made, however, these decisions would be considered guidance; that is, they would be reviewed without *Chevron* deference. But calling a definitive adjudicatory decision "guidance" seems conceptually wrong, whatever the consequences of the nomenclature might be. The idea that guidance can be defined in terms of the level of the agency at which it is adopted seems no better than the idea that guidance can be defined in terms of its interpretive character or its bindingness for regulated parties.

C. An Alternative Approach to Governing Guidance

One strategy for solving enigmatic puzzles is to begin with the desired result and reason backwards.[210] This strategy possesses a distinguished equivalent

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208. *See* 8 U.S.C. § 1227 (2012) (establishing grounds for deportation of aliens who, among other things, have violated the immigration laws, engaged in marriage fraud, committed crimes, or carried out terrorist activity); 8 C.F.R. § 1003.10(a) (establishing procedures that shall be presided over by "attorneys whom the Attorney General appoints as administrative judges"). This does not require appointment according to the provisions of 5 U.S.C. § 3105, which defines the status of an administrative-law judge. Shortly after the APA was enacted, the Supreme Court held that deportation hearings were subject to the formal adjudication provisions of the Act, which means that an ALJ would need to preside. Wong Yang Sung v. McGrath, 339 U.S. 33, 50 (1950); *see* 5 U.S.C. § 556(b)(3). This decision was almost immediately overruled by Congress in the Supplemental Appropriations Act of 1951, 64 Stat. 1044, 1048 (1950), and the Court upheld the constitutionality of the congressional revision in *Marcello v. Bonds*, 349 U.S. 302, 306–07 (1955).

209. *See* National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, § 111, 80 Stat. 718, 724 (requiring manufacturer of a motor vehicle that violates the safety standards of the statute in its implementing regulations to repurchase or repair the vehicle); § 113(e), 80 Stat. at 726 (providing for hearings to determine whether such violation has occurred, but not requiring that these hearings be subject to the APA adjudication procedures).

210. The classic example is the question of how many one-on-one matches must be played among 100 players in a tournament before the winner of the tournament is determined.

in law. According to Kelsen's *General Theory*, law should be defined by its result; thus, anything that is properly described as a law should be in the form that if the private person engages in activity X, the state will impose consequence Y upon the actor.[211] Many legal theorists regard this as reductionist,[212] but in a technical field such as administrative law, where the norms of civil society are attenuated and the demands of pragmatism strong, it seems like a promising approach.

When a private party challenges an agency guidance document on the grounds that it should have been adopted as an informal rule under section 553, the remedy that it is asking for is that the document be subject to notice and comment rulemaking.[213] That is the only thing the plaintiff could be asking for, and the only thing that the court can require the agency to provide. Of course, the plaintiff might be hoping that the agency would decide to withdraw the guidance document rather than subject it to the section 553 procedures, but that decision is entirely within the discretion of the agency.[214]

If notice and comment rulemaking is the only possible result that the plaintiff can expect, then that result might be used to solve the guidance enigma. The question that the reviewing court might ask when a document that the agency promulgates as guidance is challenged for failure to comply with section 553, is whether notice and comment rulemaking would serve a useful purpose in the promulgation of the document in question. A finding that it would serve such a purpose would then lead to the conclusion that the document should have been adopted as an informal rule. A finding to the contrary would lead to the conclusion that it was validly promulgated as guidance.

It is possible to obtain the answer by beginning with 50 matches, then 25 and so on, but the easier approach is to begin with the result that 99 of the players need to be eliminated; that is the number of necessary matches.

211. HANS KELSEN, GENERAL THEORY OF LAW AND THE STATE (2007).

212. Most notably H.L.A Hart. *See generally* H.L.A. HART, THE CONCEPT OF LAW (1961).

213. This is not simply a matter of choosing one remedy over another, as in the case of the Federal Tort Claims Act (FTCA), 60 Stat. 812, 842 (1946) (codified as reenacted and amended at 28 U.S.C. §§ 2671–2680 (2012)), which was enacted in the same year as the APA. Congress might have chosen to allow punitive-damage claims under the FTCA, but declined to do so. The remedy of notice and comment rulemaking, in contrast, is implicit in the structure of the entire APA. *See* 5 U.S.C. § 553 (2012).

214. *See* Vermont Yankee Nuclear Power Corp. v. Nat'l Res. Def. Council, Inc., 435 U.S. 519, 524 (1978) (reviewing courts may not impose additional procedural requirements on agencies); Nat. Labor Relations Bd. v. Bell Aerospace Co., 416 U.S. 267, 294 (1974) (reviewing court should not interfere with agency's choice of decision-making procedures); Elizabeth Magill, *Agency Choice of Policy Making Form*, 71 U. CHI. L. REV. 1383, 1398–1403 (2004) (discussing reasons why agencies are granted this discretion). The plaintiff could not expect that the court would hold the guidance document unconstitutional, *ultra vires*, or arbitrary and capricious, these being the standards for judicial review under the APA. *See* 5 U.S.C. § 706(2) (2012). If the plaintiff thought such challenges possible, it would be filing a different suit; namely, one to preclude the agency's action in its entirety.

While some scholars view notice and comment rulemaking as a great innovation, others question its effectiveness.[215] For present purposes, however, the statute must be taken as a given, and the statutory purpose of its informal rulemaking procedures is generally agreed upon. First, there is the instrumental purpose of supplementing the information that the agency possesses or acquires through its own expertise with information from private parties that is relevant to the issue that the proposed rule is addressing. Second, there is the normative purpose of providing private parties with the sense that they have been able to participate in the rulemaking process, particularly in light of the fact that it is carried out by non-elected officials.[216] Thus, a reviewing court could reasonably hold that a guidance document should have been promulgated as an informal rule because these statutory purposes were necessary or important in the formulation of the action that the document embodies.

But the APA balances this policy with a somewhat countervailing policy of administrative discretion and flexibility in the rulemaking process.[217] This is based on an underlying belief that agencies possess expertise and that they will be primarily controlled by the political branches; that is, presidential nomination, and Senate confirmation of the leadership, presidential supervision of agency action and legislative oversight of such action.[218] Perhaps the drafters felt that the relatively lenient requirements for informal rulemaking, in contrast to the formal standards for both rulemaking and adjudication, fully implemented that intended policy. Over time, however, judicial review of informal rulemaking has proved to be demanding, and it has often been criticized as running counter to that basic policy decision and

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215. *See* 1 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE 448 (2d ed. 1978). ("[A]dministrative rulemaking is one of the greatest inventions of modern government . . . ."); James V. DeLong, *Informal Rulemaking and the Integration of Law and Policy*, 65 VA. L. REV. 257, 257–58 (1979) (rulemaking widely used as basic tool of regulation); Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CAL. L. REV. 1276, 1314 (1972) (notice and comment rulemaking suffers from a range of procedural defects); Alan Morrision, *The Administrative Procedure Act: A Living and Responsive Law*, 72 VA. L. REV. 253 (1986) (rulemaking procedure leads to rational and efficient results); Rubin, *supra* note 189, at 155 (rulemaking procedure is modeled on adjudication and does not produce rational policy).

216. *See* Mendelson, *supra* note 5, at 441 (describing the value of notice and comment procedures for beneficiaries of the regulation in question).

217. It is generally agreed that the APA embodies a decision to place fairly strict procedural constraints on agency adjudication but to grant agencies broad discretion in the quasi-legislative task of rulemaking. This reflects a compromise between the Democrats, who wanted to preserve the authority and discretion of the New Deal agencies, and the Republicans, who wanted to decrease the regulatory burdens on private enterprises. *See* McNollgast, *The Political Origins of the Administrative Procedure Act*, 15 J. L., ECON & ORG. 180, 191 (1999); Shapiro, *supra* note 187, at 452–55; George B. Shepherd, *Fierce Compromise: The Administrative Procedure Act Emerges from New Deal Politics*, 90 NW. U. L. REV. 1557, 1649–53 (1996).

218. *See* KENNETH C. DAVIS, ADMINISTRATIVE LAW TEXT 127 (3d ed. 1972); RICHARD J. PIERCE, JR., SIDNEY A. SHAPIRO & PAUL R. VERKUIL, ADMINISTRATIVE LAW AND PROCESS 41, 82 (6th ed. 2013).

"ossifying" the rulemaking process.[219] If a court decides that a pronouncement that the agency describes as guidance—and thus falls within an exception to the rulemaking requirements—is in fact subject to those requirements, it will be expanding the scope of this ossification process and further frustrating the intention of the APA. This suggests that the remedy of notice and comment rulemaking should be imposed with caution.[220]

A remedially oriented approach to the review of guidance documents would satisfy both the instrumental and normative goals of notice and comment procedure and the countervailing goal of rulemaking flexibility. To begin with, this approach suggests that notice and comment rulemaking should only be imposed on agency pronouncements to the general public. Instructions to staff members of the agency, even if they are instructions regarding the direction that formal or informal adjudications are expected to take, should be exempt from notice and comment. This result can probably be reached under a separate statutory exemption in the same clause as the interpretive exemption; namely, "rules of agency organization, procedure, or practice." As indicated above, however, staff directives of various kinds, such as those found in employee manuals or training documents, can exercise significant impacts on the public. Whether a particular instruction is truly a rule of agency procedure, rather than a decision rule, may be unclear. The preferable principle is that subjecting internal rules to notice and comment rulemaking procedures would impair the flexibility of the regulatory process to an unacceptable degree.[221] There is simply no way to distinguish among non-promulgated directives,

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219. McGarity, *supra* note 159, at 1387–97; Pierce, *supra* note 159, at 66; Paul R. Verkuil, *Rulemaking Ossification: A Modest Proposal*, 47 ADMIN. L. REV. 453, 453–57 (1995). The ossification claim, however, has been subject to substantial criticism. *See, e.g.*, William S. Jordan III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 395–96 (2000); Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 490–92 (1997). Several empirical studies conclude that there is little evidence to support the ossification theory. *See* Cary Coglianese, *Empirical Analysis and Administrative Law*, U. ILL. L. REV. 1111, 1127–31 (2002); Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950-1990*, 80 GEO. WASH. L. REV. 1414, 1436–40 (2012).

220. *See* Johnson, *supra* note 184, at 495–96; Mantel, *supra* note 175, at 398; Strauss, *supra* note 168, at 804–08. Considering the relative values of democratic accountability and agency expertise, Professor Mantel reaches the conclusion that agency expertise should be favored, on social-contract grounds, and thus concludes that notice and comment rulemaking should be restricted and agency guidance should be favored. Mantel *supra* note 175, at 398–405. The suggestion here is somewhat similar but does not necessarily grant guidance a broader scope. Rather, it suggests that guidance should be used when additional participation, which can be regarded as somewhat similar to democratic accountability, would serve a purpose and avoided where it would only impose a further procedural hurdle on the agency.

221. Whether or not judicial review "ossifies" the process of informal rulemaking, it seems likely that extending judicial review beyond that process to the many truly informal

given the lack of substantive standards for executive action. Any suggestion that such directives could be challenged for their failure to use notice and comment rulemaking procedures would give regulated parties the power to bring the entire regulatory process to a halt. In other words, a remedy of that sort would destroy the underlying action.

Once a document is promulgated, its eligibility for the interpretive-rule exception should be assessed in terms of both its instrumental and normative value. The instrumental question is whether ordering the remedy of notice and comment rulemaking will provide the agency with information that might otherwise be unavailable to the agency, or be ignored by the agency because of a pre-existing mindset. We do not want an agency to take action when there is evidence available that the action is likely to be ineffective or counterproductive, nor do we want an agency to take action that will have unintended consequences, such as inadvertently damaging someone's business with a regulation designed for a different purpose.

Notice and comment rulemaking is a remedy for mistakes such as these, but that remedy should only be imposed on agency action when it is likely to produce the desired information. In many cases, an agency issuing a guidance document will have been in longstanding and continuous contact with the firms that it is regulating, and it will already possess all the information that it needs or is likely to get.[222] Similarly, the agency may have already held hearings or carried out research. With respect to a rule that might be viewed as either interpretive or legislative, a court should only require informal rulemaking procedures when it can identify some potential body of information that the agency has ignored because it did not make use of those procedures.[223] It is not enough to demonstrate that the procedures will produce additional communications because these communications may be of no informational value. Prior judicial decisions have identified the types of communications that an agency can validly ignore, and this experience should be used in determining whether the remedy of notice and comment rulemaking is likely to produce anything of greater value.[224]

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decisions that agencies make in the course of administering a regulatory program would be truly disruptive. *See* Jordan, *supra* note 219.

222. *See, e.g.*, FDA 1992 Guidance Document, *supra* note 1, at 22,984 ("Representatives of the food biotechnology industry have expressed to FDA the need for strong by appropriate oversight by Federal agencies to ensure public confidence in foods produced by the new techniques."). The heavy regulation at the time may have led to an unintended consequence, which is that the public perceives that GM food is dangerous because it is heavily regulated. Wiedemann & Schutz, *supra* note 11, at 402–05.

223. Professor Elliott argues that notice and comment rulemaking has ceased to serve any informative purpose because agencies get the information they need through "informal meetings with trade associations and other constituency groups." Elliott, *supra* note 190, at 1492. The argument here is that such familiar channels of communication will be sufficient if it seems unlikely that anyone outside those channels would want to comment or have anything to add. When that is not the case, however, notice and comment rulemaking becomes valuable and important.

224. *See, e.g.*, Rybachek v. EPA, 904 F.2d 1276, 1286 (9th Cir. 1990) (agency was not required to give "Rosalie A. Rybachek, North Pole, Alaska, pro se" an additional

The normative question is whether the proposed rule activates people's desire for participation. Many agency pronouncements involve technical matters with an extremely low political profile.[225] They may be controversial within the affected industry, but they are of limited interest to those outside it. When notice of such rules is given under section 553, it generates only a small number of comments, and those comments come from industry insiders who have already been in contact with the agency about the issue. There seems to be no normative value in expanding the scope of notice and comment procedure to include more agency actions of this sort. To conclude that an agency document that is promulgated as guidance should be subject to notice and comment procedures on participatory grounds, a court should be convinced that there are people who would want to participate. In fact, Judge Posner offered this criterion, in dictum, to justify his conclusion in *Hoctor*. He wrote: "The Department's lawyer speculated that if the notice and comment route had been followed in this case the Department would have received thousands of comments. The greater the public interest in a rule, the greater reason to allow the public to participate in its formation."[226]

This interpretation of the legislative-rule exception to section 553's requirements tracks the prevailing interpretation of the "good cause" exception that the agencies themselves have developed.[227] Several agencies—most notably the EPA, various units within the Department of Agriculture, and the Department of

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opportunity to comment on the record). The scheme of relevance is determined by the Supreme Court's formula for arbitrary and capricious review in Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983); essentially a codification of the previous "hard look" doctrine. That formula is that the reviewing court should overturn a regulation "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem," or made an error of judgment in assessing relevant evidence. *Id.* Thus, a comment related to an issue that was not within the scope of the congressional legislation, or the problem as identified by the agency and evaluated by the court, can be safely ignored.

225. *See, e.g.*, Fuel Economy Regulations for Automobiles: Technical Amendments and Corrections, 74 Fed. Reg. 61537-01, 61537–555 (Nov. 25, 2009) (codified at 45 C.F.R. §§ 86, 600) (making minor corrections and amendments to final rule for fuel-economy labeling requirements for cars and light trucks, including a slight revision to the minivan definition; changing corporate average fuel economy (CAFE) standards for 2008–2011 model-year passenger automobiles and light trucks to add reporting requirements for manufacturers to report to the EPA their applicable reformed CAFE fuel-economy standards and adding provisions to clarify that special test procedures, calculation methods, and label formats may be used for advanced-technology vehicles for fuel-economy labeling and CAFE purposes); Launch Safety: Lightning Criteria for Expendable Launch Vehicles, 76 Fed. Reg. 33,139, 33,139–152 (June 8, 2011) (codified at 14 C.F.R. § 417) (amending lightning commit criteria to account for new information regarding the risks of natural and triggered lightning).

226. Hoctor v. U.S. Dept. of Agric., 82 F.3d 165, 171 (7th Cir. 1996).

227. 5 U.S.C. § 553(b)(3)(B) (1966) (holding that the requirement of notice and comment does not apply "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest").

Transportation[228]—in conjunction with recommendations by the Administrative Conference of the United States,[229] have instituted a practice referred to as "direct final rulemaking": publishing a rule in the Federal Register that the agency declares will be final as long as there is no objection to it. This resembles the familiar management technique of a consent calendar, where items are placed on the meeting agenda of a board or deliberative chamber and then accepted without discussion unless one member of the body objects.[230] As with that technique, a single objection is sufficient to stop the direct final rule from going into effect and require the agency to revert to notice and comment procedure.[231]

The rationale behind direct final rulemaking is that there is no point engaging in the time and expense of notice and comment procedure if the proposed rule is uncontroversial, such as conforming a regulation to a statutory revision or simplifying a form without changing its content.[232] Of course, questions will arise about whether a particular proposal truly fits within the term "good cause" as used by the APA, whether a comment to the final rule should count as adverse, whether the agency needs to publish a confirmation that the rule has not received any adverse comments before it goes into effect, and what the timing of the initial publication or the confirmation should be.[233] The EPA has chosen to proceed without resolving

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228. *See* Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1, 4 (1995) (describing the way the three named agencies have employed this device).

229. Adoption of Recommendations, 60 Fed. Reg. 43108-02, 43111-112 (Aug. 18, 1995).

230. For an example of this technique used by the Department of Health and Human Services, see Consent Calendar and Appendices Procedures, 45 C.F.R. § 2102.14 (2018).

231. *See, e.g.*, How Does the FAA Process Direct Final Rules?, 14 C.F.R. § 11.31(a) (2018)("A direct final rule will take effect on a specified date unless the [Federal Aviation Administration] FAA receives an adverse comment or notice of intent to file an adverse comment within the comment period."); *Direct Final Rule Procedures*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm (last updated Mar. 21, 2018) ("FDA ordinarily will allow at least 75 days for comment on the direct final rule after it is published in the Federal Register. If the agency receives any significant adverse comment, the agency will publish a notice of significant adverse comment and withdraw the direct final rule."); *see also* Levin, *supra* note 228, at 1.

232. *See* Levin, *supra* note 228, at 12 (quoting examples of actions for which notice and comment would fit into the definition of "unnecessary" according to the House and Senate Reports accompanying the APA).

233. *See* Michael Kolber, *Rulemaking Without Rules: An Empirical Study of Direct Final Rulemaking*, 72 ALB. L. REV. 79, 80 (2009); Levin, *supra* note 228, at 26–28; Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner-Cutting*, 51 ADMIN. L. REV. 757, 760–63 (1999); Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401 (1999). Most of these issues are not directly relevant to the analogy between direct final rulemaking and guidance that is being used here. One overlap involves the question of what constitutes an adverse comment. Clearly, a response that compliments the agency should not be regarded as adverse, nor should a comment, whether friendly or hostile, that is completely irrelevant. But what about an inquiry or a friendly suggestion? *See* Levin, *supra* note 228, at 26–28; Levin, *supra* note 233, at 759–61; Noah, *supra*, at 420–22. The question for the agency is when such comments should lead to withdrawal of the rule; the

any of these questions on a general level, but the FDA has chosen to promulgate a general explanation of the way it will use direct final rulemaking.[234] Intriguingly, it has done so in the form of a guidance, thereby raising the issue of self-referential statements that was discussed above; namely, whether it predicts or announces the agency's future position.[235]

For present purposes, the important point is that the same insight that has led agencies to base their interpretations of the good-cause exception on the likelihood of opposition can be used by courts to evaluate an agency's use of the interpretative-rules exception. This insight is that the purpose of notice and comment procedure is to achieve the instrumental and normative values of participation. Therefore, when participation will not be forthcoming, the cost of this more elaborate rulemaking procedure need not be incurred. Admittedly, the settings of these two applications of the insight are somewhat different. When an agency uses direct final rulemaking, it is predicting that there will be no participation and stands ready to withdraw the rule and institute notice and comment if its prediction proves wrong. If a court were to follow the recommendation regarding guidance that this Article proposes, it would be observing a rule that has been promulgated sometime in the past and concluding that no significant participation has occurred or is likely to occur. It would have the advantage of experience, but it would be conclusively exempting the agency from the need to use notice and comment procedure. Nonetheless, the two approaches are based on the same idea that the exceptions to the notice and comment requirements should be understood in terms of the purposes that those requirements are intended to achieve.

To be sure, a court's assessment of the likelihood and value of participation is bound to be somewhat speculative and must rely on judgment. But the existing standards, such as the interpretive or binding nature of the guidance, share these same features. The difference is that the remedy-oriented approach provides a meaningful framework for the exercise of judgment. Any effort to make conceptual distinctions between guidance and informal rules dissolves into conundrums because we have no coherent set of legal concepts in the realm that these two modes of administrative action inhabit. It seems preferable to rely on the one part of the governing statutory scheme that possesses a definitive contour—the distinction between actions that are governed by notice and comment rulemaking procedures and those that can be permissibly taken without resort to those procedures.

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question for a court is when such comments indicate that the agency and the public would benefit from full notice and comment procedure.

234. *Direct Final Rule Procedures*, *supra* note 231. Much of the document discusses the timing of the rule. On the issue discussed in note 233, the FDA Guidance states, "significant adverse comment is defined as one where the comment explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change." *Id.* The Guidance goes to explain that "comments that are frivolous, insubstantial, or outside the scope of the rule would not be considered adverse under this procedure." *Id.* This seems to provide the FDA with a fair amount of leeway in ignoring comments and proceeding with the rule.

235. *See supra* note 181and accompanying text.

IV. EVALUATING THE USE OF GUIDANCE TO REGULATE GENETICALLY MODIFIED FOOD

As discussed in Part II, administrative guidance has been the principal mode that federal administrators have employed to regulate GM food. While the Coordinated Framework was opened to public comment, it was not a regulation—in the sense of determining any private party's status—but simply a planning document. As such, there was no basis for a legal challenge and thus no judicial review. Of the three agencies that were seen by the Framework as having statutory authority to regulate GM food, the USDA in fact issued regulations, but only in the delimited area to which its authority over GM food extended. The EPA exercised its authority through guidance. Most significantly, the FDA—with the primary authority in the area of food safety—also acted by guidance and, in fact, has never issued regulations on the subject.

This Part evaluates the use of guidance, and specifically the guidance issued by the FDA, to regulate GM food. Its first Section considers the legality of the decision in light of the discussion in Part III about the proper role of administrative guidance. It concludes that GM food is an issue that should have been addressed by regulation, not guidance, and thus through the APA mechanism of notice and comment rulemaking. The second Section of this Part then considers whether the use of legislative rules, as opposed to guidance, would have led to better or worse policy consequences in light of the scientific and public opinion data presented in Part I. The discussion is necessarily speculative, but our best judgment is that the use of the notice and comment process would lead to at least two beneficial results. First, it would serve as a means of educating the general public about the true risks of GM food;[236] second, it would give other industry participants a voice and possibly lead to more even-handed and effective regulation in this area.

A. The Legality of Guidance on GM Food Regulation

As suggested in the previous Part, neither the interpretation nor the bindingness tests are meaningful ways to assess the legality of guidance as a regulatory mechanism, and the *ex post* review short cut, with its reliance on the level of agency decision-making, is no better. Applying the general discussion in that Part to the issue of GM foods, it seems apparent that the FDA approach cannot be challenged or even evaluated on interpretive or bindingness grounds. The FDA has authority to require any food that fits into the statutory definition of adulteration or additives to be subject to its evaluation process.[237] That evaluation process determines the rights of the food's producer; that is, whether the producer can market the product in question.[238] As such, it is an adjudication within the meaning

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236. One consequence of the current regulatory milieu in this area is that it contributes to consumer misperceptions of the safety in GM food; that is, the heavy regulation leads consumers to perceive that this must be an unsafe area. *See* Wiedemann & Schutz, *supra* note 11, at 402–05.

237. *See* 21 U.S.C. §§ 321, 348 (2012).

238. *See* 21 U.S.C. § 348(b)(1).

of the APA. By definition, it is legally binding, and it is only valid if it reaches a conclusion that represents an acceptable interpretation of the authorizing statute.

The FDA's guidance document declares that the Agency will evaluate GM foods according to this process, rather than allow them to be marketed without testing on grounds that they are GRAS.[239] In addition, it outlines the basis on which it will conduct its evaluation.[240] Whether this document is a proper interpretation of the statute, and whether it is binding on private parties, raises exactly the sort of quandaries that were discussed above. Much of the FDA's guidance document cannot be derived from the statutory language, but it is the sort of information that is undoubtedly useful to anyone who wants to submit a GM food to the FDA for evaluation. Requiring notice and comment rulemaking for these sorts of housekeeping decisions would serve no purpose and would unnecessarily encumber the regulatory process. The likely result would be that the Agency would communicate this necessary information to the few large companies with which it regularly deals in a truly informal manner, such as verbal advice, that would make the entire process more opaque and run entirely counter to the purposes of the APA.

A bindingness test also suffers from the problems that were outlined above. When the FDA announces the policies regarding the evaluation of GM foods, is it actually establishing the policies that will govern its evaluators, or is it simply informing people of the policies that its evaluators have tended to follow on their own? How can a court possibly make such a determination? It is conceivable that there exists some "smoking gun" memo in the Agency's files that would resolve this question, but that seems more likely to be found in a Hollywood movie, or on a conspiracy theory website, than in the real world.

The crucial question—the policy issue that the science of GM food suggests—is whether these foods should be automatically subjected to the evaluation process, as opposed to being treated the same way that foods produced by selective breeding and other GM techniques are treated. That is the most important consequence of the FDA's guidance document, but it does not seem to be an interpretive decision at all. The FDCA of 1938, like most federal regulatory statutes, authorizes the Agency to take specified actions in a specified range of situations but does not guide the Agency's decisions regarding which action will apply to which situations. Those decisions are generally analogized to prosecutorial discretion, the highest level of discretion that can be granted to an executive agent, and thus are decisions in which courts decline to intervene.[241] Nor can the FDA's

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239. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (1992); *see also* HEINZERLING, *supra* note 119, at 304–21.

240. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,986; *see also* Conko et al., *supra* note 20, at 495–98.

241. *See, e.g.*, Lincoln v. Vigil, 508 U.S. 182, 192–94 (1993) (refusing to review agency decision to phase out a program providing service to handicapped Native American children on grounds that allocation of funds lies within the discretion of the agency); Heckler v. Chaney, 470 U.S. 821, 831–34 (1985) (refusing to require the FDA to regulate drugs used in executions, and noting the "general unsuitability for judicial review of agency decisions to refuse enforcement"); Ctr. for Auto Safety v. Dole, 846 F.2d 1532, 1533–35 (D.C. Cir. 1988)

decision be regarded as binding. It does not bind anyone; it only announces that it might make binding decisions in certain cases by adjudication.

Academic proposals for alternative approaches to the guidance issue also seem to be of little assistance in this case. The short cut proposed by Professor Gersen and others would deprive the FDA of the ability to rely on the guidance document in a subsequent court challenge.[242] But the FDA does not rely on it. If it forbids a particular food product from being marketed, or allows it to be marketed, it will necessarily rely on the evaluation itself, not on its decision to evaluate. The suspension of the administrative-law finality rule suggested by Professors Epstein and Seidenfeld would not be of much assistance either;[243] if the FDA's guidance document were challenged in court, the court would still need to decide, according to current doctrine, on interpretive or bindingness grounds. This would again involve the difficulties just described with these two standards.

In contrast, the test proposed in the preceding Part—the remedy-oriented approach—can be used as a supplementary principle, or even the determinative one. It would address the problem with the FDA's guidance document directly, asking whether notice and comment rulemaking should be imposed on the agency; that is, whether the public participation that this procedure provides is demanded by the nature of the action that the guidance document embodies. This is not to assert that such participation will necessarily produce the best result; that issue will be addressed in the next Section. Rather, the point is that public participation is the basic procedural requirement that the APA imposes on administrative action. Determining the proper scope of that participation is therefore the basic task that courts must undertake in interpreting and applying the prevailing statute.

Both the instrumental and the normative values of notice and comment rulemaking can be assessed by considering three groups of possible participants: first, the general public, including public interest organizations; second, large firms that dominate the market; and third, small firms that are either current or potential market entrants.[244] With respect to the general public, the answer in this case is clear. The issue of GM foods is of enormous concern. As the Pew Study, summarized in Part I, indicates, 29% of those surveyed report that they have heard "a lot" about GM foods, and only 19% report that they have heard "nothing at all."[245] Fully 39% of those surveyed believe that GM food will cause health problems, and an equal

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(refusing to review denial of petition to reopen enforcement investigation); Nat'l Res. Def. Council v. Envtl. Prot. Agency, 606 F.2d 1031, 1046 (D.C. Cir. 1979) (refusing to require SEC to force regulated firms to disclose environmental and equal employment policies on ground that agency is in the best position to decide when and how to regulate).

242. Funk, *supra* note 159, at 1037; Gersen, *supra* note 156, at 1719; *see* Manning, *supra* note 190, at 945.

243. Epstein, *supra* note 5, at 48; Seidenfeld, *supra* note 219, at 490.

244. The assumption of this categorization is that there is no separate group of large firms that want to enter a market. Although there may be a number of such firms that are studying the possibility, any large firm that decides to enter a market will do so. This might not be true for markets with extraordinary barriers to entry, such as automobile manufacturing, but food production is not a market of that sort.

245. FUNK & KENNEDY, *supra* note 2, at 44.

number believe that it will cause problems for the environment.[246] A variety of measures have been proposed or enacted at the state or local level to ban GM food or to require its disclosure;[247] these measures are now preempted by federal law,[248] but the fact that GM food producers devoted lobbying resources to passage of this law indicates that the measures were regarded as a serious threat.[249] In other words, there seems little doubt that regulation of GM food is a highly salient public issue, about which many Americans have strong opinions. The APA's notice and comment requirement is designed to expose agencies to these sorts of concerns. It is thus preferable to interpret the APA to impose that requirement on the FDA, rather than allow it to avoid the requirement by issuing a guidance document.[250]

Large firms that are extensively engaged in crop production include, according to the Fortune 500 rankings, Archer Daniels Midland (27), Dow Chemical (48), CHS (62), Dupont (86), and Monsanto (189).[251] Companies of this size can be expected to possess extensive resources for monitoring and lobbying their regulators. According to the FDA itself, these firms seem comfortable with its regulations.[252] Anecdotal evidence, often from critics of the FDA, confirms this impression.[253] With respect to the issue discussed here, it is these firms that regularly

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246. *Id.* at 55; *see also* Sax & Doran, *supra* note 55, at 633–36 (finding that survey respondents associate food labeled "GMO" to be less healthy, safe, or environmentally friendly compared to other labels, including the labels "Organic" and "Natural").

247. *See* JENKINS, *supra* note 2, at 138–48 (passage of local GM disclosure law in Kauai, Hawaii); Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN. ST. L. REV. 789, 790–91 (2014) (reporting that 110 bills in 32 different states were enacted in the year 2013 alone).

248. National Bioengineered Food Disclosure Standard, Pub. Law 114-216, 130 Stat. 834 (July 29, 2016) (codified at 7 U.S.C. § 293(e)).

249. *See, e.g.*, *Why we Support Mandatory National GMO Labeling*, CAMPBELL'S (Jan. 7, 2016), https://www.campbellsoupcompany.com/newsroom/news/2016/01/07/labeling/.

> We've worked with GMA, legislators and regulators to forge a national voluntary solution. We've engaged a variety of stakeholders, from lawmakers to activists. I've personally made multiple trips to Capitol Hill to meet with elected officials. Despite these efforts, Congress has not been able to resolve this issue. We now believe that proposing a mandatory national solution is necessary. Printing a clear and simple statement on the label is the best solution for consumers and for Campbell.

Id.

250. Members of the public would certainly qualify as beneficiaries of the FDA's regulatory system for approving food according to Professor Mendelson's analysis. *See* Mendelson, *supra* note 5, at 414. Thus, their concern should trigger the notice and comment requirement.

251. FORTUNE 500, http://fortune.com/fortune500/2016/ (last visited Jul. 18, 2018).

252. *See, e.g.*, FDA 1992 Guidance Document, *supra* note 1, at 22,984 ("Representatives of the food biotechnology industry have expressed to FDA the need for strong but appropriate oversight by Federal agencies to ensure public confidence in foods produced by the new techniques.").

253. DRUCKER, *supra* note 50, at 9–35, 127–66 (relationship between agribusiness and government regarding approval of GM food); JENKINS, *supra* note 2, at 47–105

apply to register GM foods or request exceptions from regulation.[254] Thus, a court might reasonably conclude that notice and comment rulemaking serves relatively little value for these firms. The instrumental value of commentary will be satisfied through regular channels of communication on any given issue, and the normative value is satisfied by the firms' ongoing relationship with the Agency. Clearly this would not be sufficient to satisfy the APA when the FDA is issuing a definitive rule of major significance. But a rule that is plausibly described as an interpretation of the statute might well appear to be technical if only large firms are involved, because it will reflect earlier communications and agreements between the agency and the firms.

The third group of possible participants are small firms attempting to develop GM foods or alternatives to GM foods; that is, new agricultural products that use other breeding techniques to achieve similar or superior effects.[255] As in other fields characterized by new and rapid technological development, there appears to be a significant number of such firms.[256] In contrast to the large, established firms, these smaller firms are often excluded from channels of communication with the agency, sometimes because they are seen as potential competitors to large firms that the Agency seems to favor, sometimes because they are regarded as untrustworthy, and sometimes because they are simply unfamiliar. In addition, the expense of obtaining approval through the FDA registration process weighs more heavily on these smaller firms because they are more thinly capitalized,

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(describing the connections between regulators and agribusiness research and product-development programs); *id.* at 123–76 (describing cooperation between federal officials and agribusiness firms in opposing anti-GM legislation in Hawaii); MARIE-MONIQUE ROBIN, THE WORLD ACCORDING TO MONSANTO: POLLUTION, CORRUPTION, AND THE CONTROL OF OUR FOOD SUPPLY: AN INVESTIGATION INTO THE WORLD'S MOST CONTROVERSIAL COMPANY 20–22, 71–73 (2012) (Monsanto's relationship with the federal government in securing approvals for pesticides); *Id.* at 131–225 (Monsanto's relationship with the federal government in securing approvals for GM products).

254. *Biotechnology Consultations on Food from GE Plant Varieties*, *supra* note 12 (showing 153 submissions with FDA responses, including 10 submissions from Dow (all for insect resistant or herbicide tolerant); 73 submissions from Monsanto (the majority for herbicide tolerant and insect or virus resistant); 4 submissions from DuPont (3 for herbicide tolerant and/or insect resistance); 10 submissions from Syngenta (9 of which for herbicide tolerance and/or insect resistance); and 2 from Okanagan Specialty Fruits (both for the non-browning apple)); s*ee also Petitions for Determination of Nonregulated Status*, *supra* note 109 (showing petitions for deregulated status from many firms). Most firms are larger companies, such as Monsanto, Dow, and Bayer. Other mid and small firms are on the list as well, such as Syngenta and Okanagan Specialty Fruits.

255. *E.g.*, ARROWHEAD MILLS, http://www.arrowheadmills.com/ (last visited July 29, 2018) (alternative flour products, such as coconut flour); CLIF BAR & CO., http://www.clifbar.com/ (last visited July 29, 2018) (energy bars); LAND INST., https://landinstitute.org/ (last visited July 29, 2018) (perennial crops, sustainable agricultural products); SPECTRUM ORGANICS, http://www.spectrumorganics.com/ (last visited July 29, 2018) (cooking oils and dietary supplements).

256. *See, e.g.*, ARCTIC APPLES, https://www.arcticapples.com/ (last visited July 29, 2018).

and their ability to market their products is more speculative.[257] As with the exclusion of the general public, this issue can be framed in terms of regulatory capture—the ability of large firms to use their market power and political influence to distort the regulatory process so that it serves their private interest. The APA's notice and comment procedure might then be viewed as designed to combat this situation. But the procedure also rests on a much more general rationale. Even a public-oriented, conscientious agency may rely on large firms for its information or simply overlook alternative sources. If there are other firms that are likely to have information or opinions about the subject at issue, they should be able to communicate with the Agency before it reaches its decision.

The FDA's decision about its regulatory strategy for GM food can be contrasted with other regulatory decisions that might be embodied in a guidance document. Consider again the hypothetical brochure in connection with *Hoctor* that lists the locations where the report can be filed, offers a sample form that the big-cat owners can use, provides a bibliography of sources about animal behavior and husbandry that the owners might find relevant in obtaining the information required for the report, and then summarizes a number of federal-court cases that determined the adequacy of required disclosures under other statutes.[258] As an instrumental matter, these are not issues that are likely to benefit from public participation. They involve the Agency's own procedures and research, and are thus matters on which the agency itself is likely to have sufficient expertise.

Use of guidance in this situation might be equally acceptable in terms of the normative value of participation. To be sure, more participation always seems better than less from this perspective, but participation has costs that most regulated parties may not want to incur on a technical issue. If those parties are relatively uniform, consisting for example of individual owners and small zoos, the Agency's communications with a sampling of each might satisfy any felt need for participation. A court might well conclude that regulated parties would feel that they had been adequately represented by the Agency's existing contacts, and that no further channels of participation would be necessary.

But the FDA's decision to employ a guidance document to determine its policy on GM food does not fit within either the instrumental or the normative rationale that would exempt a rule from notice and comment procedure. In instrumental terms, GM food is one of the most controversial issues facing this controversial agency. The FDA's guidance defines the basic regulatory structure for a technology of vast and ever increasing proportions. Most of the largest food-producing companies in the nation have enormous economic stakes in this

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257. *Biotechnology Consultations on Food from GE Plant Varieties*, *supra* note 12 (compare 73 submissions to the FDA from Monsanto with 2 submissions from Okanagan Specialty Fruits); *see also Petitions for Determination of Nonregulated Status*, *supra* note 109 (compare 55 petitions submitted by Monsanto with 2 petitions submitted by Okanagan Specialty Fruits); Strauss & Sax, *supra* note 125, at 475.

258. *See supra* Section I.B.1.

technology,[259] and many smaller companies may thrive or fail as a result of the FDA's decisions in this area.[260] Academic scientists who conduct research in this field, but are unaffiliated with any of these companies, would also be motivated to comment.[261] GM food is possibly of greater concern to the general public than any other science-based issue, aside from the colossal one of climate change. Evidence from the Pew Study, a survey of books published on the subject, a survey of media coverage, or any other rigorous or anecdotal test of public opinion suggests that GM food cannot be regarded as a technical issue.[262] There seems little doubt that any significant proposal from the FDA that was promulgated through notice and comment rulemaking would elicit an enormous number of comments. It is difficult to believe that none of these comments would provide useful information for the Agency; in any case, to reach that conclusion in advance is a violation of the APA.

With respect to the normative aspect of participation, the FDA's use of guidance is equally questionable. Large firms seem relatively satisfied with the FDA's reliance on a guidance document to regulate the field, at least on the basis of the "dog-that-didn't-bark" principle. These firms are politically influential, and certainly capable of making their voices heard in Congress; if they were unhappy with the current regime, it seems likely that those concerns would have appeared in legislative proposals, perhaps even in enacted statutes.[263] But the group of potential participants in any notice and comment rulemaking regarding GM food is hardly uniform. Small firms that are already in the field and trying to gain market share in the field, and those that want to enter the field, have directly adverse interests to the currently dominant firms.[264] They are unlikely to be satisfied with the FDA's current sources of information.

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259. *See, e.g.*, *Biotechnology Consultations on Food from GE Plant Varieties*, *supra* note 12 (showing 73 submissions from Monsanto and 2 from Okanagan Specialty Fruits, suggesting large agricultural giants dominate the field).

260. *See id.*

261. *See, e.g.*, Conko et al., *supra* note 20.

262. *See, e.g.*, FUNK & KENNEDY, *supra* note 2, at 70–71.

263. *See* National Bioengineered Food Disclosure Standard, Pub. Law 114-216, § 293(a), 130 Stat. 834, 835 (July 29, 2016) (codified at 7 U.S.C. § 293(e)) (directing the Secretary of the USDA to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered . . . ." within two years of the date of enactment of this law). As discussed above, see *supra* note 24 and accompanying text, this law resulted from the concerns of large food-producing companies that state government would enact separate and sometimes demanding disclosure laws. The belief, borne out by subsequent events, was that the federal government would not impose equivalent requirements, which is why opponents dubbed the law "the DARK Act," standing for "Deny Americans the Right to Know." *See supra* note 112 and accompanying text.

264. The long and expensive regulatory process keeps small players out of the field because they may not have the resources to complete the process. A heavy regulatory process favors large companies that have the resources to invest in an expensive regulatory process. *See, e.g.*, *supra* note 259 and accompanying text.

Members of the public are equally unlikely to regard large agricultural firms as representing their interests. According to the Pew Study,[265] 78% of those who expressed "a great deal" of concern about GM foods thought the public itself should play a major role in policymaking on the subject, followed by small farm owners (73%) and scientists (66%).[266] The food industry leaders who are likely to have provided the only input to the FDA on its guidance document were seen as desirable participants by a much smaller proportion (41%).[267] Of those who identified as having some concern about the issue, scientists came in first at 64%, the general public and small farm owners were close behind at 61%, while food industry leaders lagged behind once again at 43%.[268] In other words, people want to participate directly, and if there are any groups who they see as reflecting their interests, it is scientists and small farm owners, not big agricultural firms.

A recent study of the FDA's direct final rulemaking practice provides additional evidence of the Agency's misjudgment regarding the response to its policies. As discussed above, direct final rulemaking is not the same as guidance, but the two are related, both being techniques that use one of the exceptions to section 553 as a means of avoiding notice and comment procedure. The study by Professor Michael Kolber found that the FDA was required to fully withdraw 40% of its direct final rules because those rules had elicited objections.[269] In contrast, the EPA, an agency that has been the object of at least as much controversy, was required to withdraw fewer than 5% of its proposed rules regarding state implementation plans, and no agency's withdrawal rate was more than 20%—half the FDA's.[270] The FDA's decision to rely on guidance to set policy regarding GM food, rather than using notice and comment rulemaking, seems to be a similar misjudgment.

B. The Effectiveness of Guidance for GM Food Regulation

The legal requirements for regulating GM foods are established by statute; that is, the substantive statutes authorizing the FDA and other agencies to act, and the APA that governs the procedures for all federal agencies. It is not irrelevant, however, to ask whether the interpretation of these statutes proposed above would produce good public policy. The answer to the question can be taken as one particular test, in an unarguably important case, of the desirability of the proposed approach to guidance documents.[271]

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265. FUNK & KENNEDY, *supra* note 2.

266. *Id.* at 67.

267. *Id.*

268. *Id.*

269. Kolber, *supra* note 233, at 82.

270. It should also be noted that the FDA guidance that governs its use of this technique uses a fairly restrictive definition of the comments that require withdrawal of the rule. *See Direct Final Rule Procedures*, *supra* note 231.

271. *Cf.* All. for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000) (arguing for use of notice and comment for GM foods, but for different reasons and concerns than expressed within this Article).

As noted in Part I, there is a fairly dramatic disconnect between the scientific consensus regarding GM food and the prevailing views among the public. Scientists generally agree that GM food is as safe as non-GM food and that there is nothing about gene splicing and transfer that is inherently dangerous.[272] The American public, however, disagrees; according to the Pew Study, 39% of the people surveyed believe that GM food is likely to cause health problems, and an equal number believe that it poses dangers for the environment.[273] This disconnect between scientific and public opinion resembles the one that prevails in another controversial area, namely climate change.[274] The difference is that the GM food issue lacks an obvious explanation. Daniel Kahan's study disproved one explanation for climate-change denial—that rejection of the scientific consensus results from lack of knowledge about science—but offered another in its place: that the rejection is based on political orientation.[275] But the results of the Pew Study contradict both explanations. Those who disbelieve the scientific consensus about GM food are not only equally educated about science, but also have no particular political orientation; the proportion of disbelievers among Democrats and Republicans is virtually

272. *See supra* note 239 and accompanying text. Commentator(s) on this Article suggest that the result of the informal rulemaking process on this topic would lead to the classification of GM food as GRAS.

273. FUNK & KENNEDY, *supra* note 2, at 3–5. Also noted in this report is that "[y]ounger adults, ages 18 to 49, are more inclined than older adults to consider organic produce better for one's health." *Id.* at 39. This demonstrates the disconnect between science and consumer perception because in some circumstances organic may even be more risky. *See, e.g.*, Avik Mukherjee et al., *Preharvest Evaluation of Coliforms, Escherichia Coli, Salmonella, and Escherichia Coli O157:H7 in Organic and Conventional Produce Grown by Minnesota Farmers*, 67 J. FOOD PROTECTION 894, 894–900 (2004).

274. *See* ANTHONY GIDDENS, THE POLITICS OF CLIMATE CHANGE 89–90 (2d ed. 2011) (climate-change denial motivated by lobbying groups and political polarization); ANDREW J. HOFFMAN, HOW CULTURE SHAPES THE CLIMATE CHANGE DEBATE 1–47 (2015) (climate-change denial is supported by organized interests but is largely motivated by forms of cultural cognition); GEORGE MARSHALL, DON'T EVEN THINK ABOUT IT: WHY OUR BRAINS ARE WIRED TO IGNORE CLIMATE CHANGE 226–28 (2014) (climate-change denial results from cognitive errors and a general inability to evaluate complex, long-term situations); GERNOT WAGNER & MARTIN L. WEITZMAN, CLIMATE SHOCK: THE ECONOMIC CONSEQUENCES OF A HOTTER PLANET 80–91 (2016) (climate-change denial is based on people's inability to evaluate the scope of risk); Daniel Kahan et al., *The Polarizing Impact of Science Literacy and Numeracy on Perceived Climate Change Risks*, 2 NATURE CLIMATE CHANGE 732, 733 (2012) (climate-change denial motivated by political orientation, not level of science literacy); Edward L. Rubin, *Rejecting Climate Change: Not Science Denial, but Regulation Phobia*, 32 J. LAND USE & ENVTL. L. 103, 106 (2016) (climate-change denial is motivated by adverse reaction to regulatory consequences of addressing the crisis). Wagner and Weitzman compare climate change with GM foods, pointing out that people react as strongly to the minimal risk of environmental contamination by these foods as they do to the oncoming catastrophe of climate change. In other words, concern, as well as denial, is not realistically adjusted to actual risk. WAGNER & WEITZMAN, *supra*, at 90.

275. Kahan et al., *supra* note 274, at 733.

identical.[276] There is also no correlation on the basis of age, race, or income.[277] There is a significant, but delimited, one on the basis of gender, but that itself demands an explanation rather than offering one.[278]

An even greater oddity, perhaps, is that 78% of those surveyed by Pew trusted scientists "a lot" or "some."[279] Small farmers scored equally well, but the media scored considerably lower (45%), and elected officials scored much lower (25%).[280] Moreover, 63% of those surveyed thought that scientists understood the health effects of GM foods "very well" or "fairly well."[281] But only 14% of those surveyed knew that "almost all" scientists believe that GM foods are safe to eat.[282] In other words, fully 86% of those surveyed were unaware of the scientific consensus regarding GM foods, even though most people trusted scientists and believed that they understood the issues.[283] This suggests that there is real value in open debate about GM foods. The majority of Americans, it appears, are ready to listen to scientists on this issue and seem willing to be educated about the subject. Factors that often impede people's willingness to think rationally about an issue in substantive terms, such as race, religion, income level, and political orientation, do not seem to have much influence in this case.[284]

The notice and comment process for federal regulations, to be sure, is unlikely to be a major factor in shaping public opinion. Elected officials, the news media, and even entertainment products will almost certainly affect people's views more profoundly. But the debate about the actions of federal regulators, and most importantly about the FDA's general regulatory approach, could well produce incremental effects, either directly or through media coverage. Given the scientific consensus, it would seem that any public debate, in whatever arena, could only have beneficial effects in moving the public to a better understanding of the issue, and thus toward more rational attitudes.

The policy effect involving small, innovative companies that are seeking to enter the GM market would likely be more definitive. The FDA's current regulatory stance creates serious barriers of entry into the GM food industry.[285] Depending on how many agencies a firm may need to petition or voluntarily consult,

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276. FUNK & KENNEDY, *supra* note 2, at 50, 57. Most dramatically, the percentage of self-identified Democrats and self-identified Republicans who expressed great concern about GM food was identical, at 16%, and the percentage who expressed some concern, virtually identical, at 39% and 34% respectively. *Id.* at 8, 53.

277. *Id.* at 53.

278. *Id.* The explanation offered by the authors of the study is that women are more skeptical of technological innovation, but this is based only on the results of other studies. *Id.* at 56.

279. *Id.* at 61.

280. *Id.*

281. *Id.* at 60.

282. *Id.* at 59.

283. *Id.*

284. *Id.* at 53.

285. Strauss & Sax, *supra* note 125, at 475.

the process currently requires ten years to bring a new GM product to market.[286] This may be an annoying burden for companies such as Monsanto or Dow, but it functions as a preclusion for small firms with limited access to capital. Experience in other high-tech industries suggests that many of the real innovations originate with small firms, even if these innovations are ultimately marketed by larger ones. The notice and comment process would give these firms a voice; their participation is a certainty, and might well alert the Agency to the benefits of allowing greater access to the market. Perhaps the FDA is already alert to this issue but has been captured by the giant agribusiness firms.[287] If so, notice and comment would help alert the public and the courts to this situation and might ultimately lead to the same advantages for smaller firms.[288]

CONCLUSION

The public reaction to GM food is anomalous in several ways. In a society that generally relies on science at the policy level and readily accepts its innovations at the personal one, people continue to reject the consensus among scientists that GM food is safe and express serious doubts about its effects on both personal health and the general environment. Moreover, this rejection of scientific conclusions does not resemble other examples of science rejection in our society—most notably with respect to climate change and evolution—which are correlated with a set of political or ideological views. In fact, people generally express confidence in scientists' conclusions about GM food; survey data suggests that people simply do not know what those conclusions are. Over the past two decades, an enormous amount of money has supported an anti-GM food movement, the impact of which may not necessarily be quantified but cannot be ignored. A future investigation might also inquire as to how much the anti-GM movement has impacted regulation in this area.

The regulatory response to GM food seems to follow a more familiar pattern, at least if one is inclined to be critical of regulation from either a conservative or liberal perspective.[289] The FDA has established a regulatory regime that generally allows GM food to be marketed only after a time consuming and expensive regulatory process. To conservatives, this represents an excessive burden of both expense and delay on legitimate and beneficial commerce. To liberals, it is a familiar story of regulatory capture, where the agency is in regular contact with

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286. *See* Prado et al., *supra* note 124, at 770.

287. Another concern is whether regulators are captured by the strong anti-GM groups. But the Agency should have expertise to separate comments based on science versus comments based on anti-science.

288. While this Article focuses on crops, a similar controversy is occurring in the regulation of genetically engineered animals. In January 2017, the FDA issued a draft guidance on the regulation of genetically engineered animals. FOOD & DRUG ADMIN., REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS, No. 187 (2017), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf. This draft guidance also faced opposition by scientists well-steeped in this field. *See* Amy Maxmen, *Gene-Edited Animals Face US Regulatory Crackdown*, NATURE (Jan. 19, 2017), https://www.nature.com/news/gene-edited-animals-face-us-regulatory-crackdown-1.21331.

289. "Liberal" in the sense of political progressive of course. Philosophical liberalism is allied with political conservatism.

the large companies that dominate the field and designs its policies to favor the interests of those companies over those of less powerful competitors or the general public.

Clearly, the public and regulatory responses elicit deep questions about our governmental system—both its democratic reliance on public opinion and its technocratic reliance on administrative expertise. The particular practices of the regulatory agencies assigned to address this issue are unlikely to overcome or resolve such general concerns. But to the extent that its particularized decisions can produce at least marginal or incremental effects, the FDA's decision to regulate GM foods through the controversial mechanism of guidance seems to be a poor one.

Guidance is an important regulatory tool. Giving it a name, partly mistranslated from Japanese, underemphasizes the generality and value of informal, flexible communication by agencies in the regulatory process. Courts and commentators, however, have struggled to determine when its use is permitted by the Administrative Procedure Act (APA), which governs the federal regulatory process. Two tests have been proposed thus far: whether the communication or guidance is only an interpretation of an existing statutory or regulatory rule rather than a new rule in itself, and whether the communication exercises a binding effect on private parties. If a court finds that the communication is not interpretive or creates a binding effect, it generally does not conclude that the communication itself is impermissible, but rather that it can only be effectuated through the APA's "informal" rulemaking process, its standard—i.e., formal—means of establishing new rules that bind the public. This means that the Agency must act through the APA's notice and comment procedure.

This Article argues that neither the interpretation test nor the bindingness test is a useful way to determine whether the APA requires that an agency communication or guidance should be subject to the informal rulemaking process; neither test captures the real concerns about an agency's use of informal communication. The preferable test is derived from the remedy that would be imposed; namely, whether the notice and comment process should be required in the particular case. Notice and comment is designed to enable a wide range of participants, from both the general public and specially interested individuals or entities, to make their views known to an agency before an agency reaches a decision. This Article argues that notice and comment should be required when these participants—i.e. anyone with whom the agency is not in regular contact—might have useful information or merely be interested in participating.

According to this test, the FDA's reliance on guidance to regulate GM foods is inadvisable because the issue is a highly controversial one. While the FDA is exposed to the view of large agribusiness firms through regular contact and their requests for exceptions from the Agency's requirements, it has failed to receive sufficient input from members of the general public and from small firms developing GM foods. There can be little question that both these groups are highly motivated to participate. GM is one of the most controversial issues in contemporary society, and it is a fluid, rapidly developing area of technological innovation that attracts many small-scale entrepreneurs. That should be sufficient for purposes of reaching a decision under the APA.

This Article also argues that participation by the public and smaller GM developers might have a beneficial impact on the quality of regulation; that is, the social results that it produces. It might produce somewhat-greater public understanding of the scientific consensus regarding GM food, thereby reducing irrational fears about its safety. It might make the FDA more aware of the needs of smaller firms and the benefits that they might offer, or at least compel the Agency to defend the burdens it imposes on these firms. This is not to say that notice and comment procedure is a panacea or even a major influence on public policy. But it is the device that administrative agencies have available to them at present, and it should be used when it is appropriate to do so.